

National Competition Policy Review of Pharmacy

PART A

FINAL REPORT OF THE REVIEW

OVERVIEW AND RECOMMENDATIONS

INTRODUCTION

Pharmacy is an important element of Australia's health care system. Whether operating in hospitals and other acute care facilities, or in the familiar chemist shops of Australian cities and towns, pharmacists and pharmacies are an integral part of the day to day life of our nation. Pharmacists are highly-regarded and highly-trusted professionals, consistently rated in opinion surveys as one of the best-regarded occupational groups¹.

The shopfront community pharmacy is something most people take for granted. Beyond this social acceptance, pharmacy has developed its own professional culture. The profession itself is remarkable for its superb ability to organise itself, develop an *esprit de corps* and common outlook among its members, and convert that professional discipline into community influence.

This unique pharmacy culture has developed amid, and partly as a result of, the relatively high level of industry regulation. Government controls are apparent in almost every aspect of community pharmacy – from who may practise as a pharmacist, the location of the shop, to the prices it charges for subsidised prescription goods, to who can actually own and run the pharmacy.

BACKGROUND TO THE REVIEW AND THE REGULATION OF PHARMACY

The National Competition Policy (NCP) Review of Pharmacy Regulation was announced in June 1999. It was asked by the Council of Australian Governments (COAG), to examine specified Acts and regulations relating to pharmacy. It was also asked to determine whether these impose restrictions on competition and, if so, whether any such restrictions are of net public benefit and, if not, whether they should be removed.

This has been the first single national review of a profession commissioned under the NCP systematic legislative review process.

What is being reviewed?

The Review's Terms of Reference asked it to look at State and Territory *Pharmacy and Pharmacists Acts*, and relevant parts of the Commonwealth *National Health Act 1953*.

The Terms of Reference asked the Review specifically to examine the restrictions that legislation may impose on three specific areas of pharmacy practice and the commercial operation of the pharmacy industry:

- Ownership of pharmacies;
- Location of pharmacies to dispense benefits under the Commonwealth Pharmaceutical Benefits Scheme (PBS); and
- The registration of pharmacists.

¹ The 1999 Morgan occupational trust survey gave pharmacists an 86 per cent "approval" rating, and placed them as an occupation as the most trustworthy occupational group in terms of respondent answers: *The Bulletin*, 29 June 1999.

Each State or Territory has a *Pharmacy* or *Pharmacists Act*², consistent with their responsibility for regulating the professions. While each Act covers relatively common ground on such matters as pharmacist registration, the professional and commercial practice of pharmacy, and the constitution and powers of regulatory authorities, they reflect local needs and conditions in each State and Territory.

The Commonwealth also has a regulatory interest through its *National Health Act 1953*. The Act sets out statutory requirements for the administration of the Pharmaceutical Benefits Scheme (PBS), including the power to determine which pharmacies may “supply” pharmaceutical benefits to the public, and where these may be located.

Progress of the Review

After it was announced by COAG on 19 June 1999, the Review released a discussion paper posing a number of questions based on its Terms of Reference. It also advertised for submissions.

The Review received over 100 submissions from governments, industry and stakeholder groups, practising pharmacists, allied health practitioners and members of the general public. It also held face-to-face consultations with interested parties in all States and the Australian Capital Territory.

A *Preliminary Report* was submitted to COAG, with the Review’s indicative findings and recommendations, in November 1999. The *Preliminary Report* generated a great deal of interest, particularly from pharmacy professional and industry bodies. The public comment, detailed responses and other feedback from the *Preliminary Report* have been invaluable to the Review, challenged some of that Report’s assumptions and reinforced others, and generally have helped to sharpen the analysis, findings and recommendations contained in this *Final Report*.

THE REVIEW AND THE PHARMACY PROFESSION

The NCP process is not a universally popular one. It generates more than a measure of apprehension and concern from both the regulators and the regulated, as it seeks to test assumptions and practices in areas of commercial and professional activity that many consider have served Australia well and see no reason to change. But even the most trusted ways of doing things benefit from being evaluated critically, from being validated if they do continue to serve a good purpose, and from being removed if they do not.

Pharmacy is no exception.

Both pharmacy as a profession and community pharmacy as an industry have long enjoyed shelter from the full force of market competition. There is competition between pharmacies and pharmacists, but it is competition within a relatively homogenous, conservative and stable professional market. Pharmacists have not had truly to compete against non-pharmacist competitors for generations.

The regulatory framework of pharmacy has been relatively static for many years, indeed many decades. Professionals in general are comfortable with traditions of self-regulation and

² These Acts are listed in Attachment A to the Review's Terms of Reference, which are set out at Appendix A. They are henceforth referred to collectively as *Pharmacy Acts*.

control, and many pharmacists have felt uneasy, even hostile, to the prospect of change arising from an external process of review.

In addition, the industry's operating and regulatory environment is relatively static and benign and does not in itself foster competition. The greater part of community pharmacies' income (about two dollars in every three in turnover) is underpinned by government-funded remuneration and the fixed retail prices of subsidised medicines dispensed on the PBS. Related to the PBS are restrictions on where dispensing pharmacies may locate for PBS purposes, which themselves influence the shape and operation of the community pharmacy market.

Such stable income and regulatory bases, coupled with the increasing demand for costly drugs and medicines as the Australian population ages, help to ensure that pharmacies are seen by those who own and finance them as low risk businesses, when the overall chances of a small and medium business failing are high.

Against this background, the Review examined the relative costs and benefits of the legislative restrictions on pharmacy referred to it by the Terms of Reference, and formed the findings, conclusions and recommendations contained in this Report.

OWNERSHIP OF PHARMACIES

Under each State Act, with the specified exceptions of friendly societies and some "grandparented" proprietors (that is, for-profit non-pharmacist proprietors whose holdings predate existing restrictions), by and large only registered pharmacists may own pharmacies.

The Australian Capital Territory and Northern Territory *Pharmacy Acts*, however, only require conclusively that a pharmacy be managed by a pharmacist – their provisions actually are ambiguous as to whether this extends to requiring pharmacist ownership of pharmacies.

The Review interpreted its ownership reference as examining not only the core question of who can own pharmacies, but also as considering issues related to the commercial operation of pharmacies as this may be affected by professional regulation in State and Territory Acts. Such factors include how many pharmacies a proprietor may own, ownership structures for pharmacy businesses, third party pecuniary interests in pharmacy businesses, and regulatory authorities registering both pharmacy premises and businesses. All of these factors relate to the central question of who may lawfully own or have a proprietary interest in a pharmacy.

While they are serious restrictions on competition, the current limitations on who may own and operate a pharmacy are seen as a net benefit to the Australian community as a whole. Pharmacist proprietorship of pharmacies adds reasonable value to the professional quality and performance of that network, over and above any questions of how integral the ownership of pharmacies by pharmacists is to the long-term future of the community pharmacy industry as Australians are accustomed to it.

The Review also recommends that existing exceptions to the general pharmacist ownership principle, friendly societies and grandparented non-pharmacist owned pharmacies, be retained. The close regulation of friendly society pharmacies could also be simplified if those eligible to operate them are limited to existing groups, those groups derive no undue competitive advantage from their status, and the overall pharmacist proprietorship principle of the community pharmacy industry is not called into question.

Beyond this point, however, *Pharmacy Acts* and regulatory machinery have become involved in all aspects of a pharmacy business, ranging from the goods and services sold in a pharmacy shop with whom a pharmacist may enter commercial relations, and the nature of those relations.

The Review believes that *Pharmacy Acts* and regulatory authorities should focus their regulatory attention exclusively on the safe and competent practice of pharmacy. Pharmacists are, after all, professionals whose high training enables them to trust their personal judgment and make all manner of decisions carefully and analytically. Beyond this is a range of other commercial mechanisms safeguarding the public interest, from the *Trade Practices Act* to sale of goods legislation, that support fair and responsible trading and business practices.

With this in mind, the Review has concluded that regulations of the commercial aspects of pharmacy practices should be wound back, or removed, wherever possible to ensure that pharmacy businesses can make their own commercial judgments without undue interference from professional regulatory authorities. The only criterion for pharmacy legislation's intervention in commercial matters should be ensuring that pharmacy services are practised by professionals safely and competently, and that these professionals act always in the best interests of their patients and clients without undue, inappropriate or unethical interference from any third party.

The Review believes that this is the spirit of existing pharmacy legislation, but that over time its coverage has been extended too far by convention and precedent.

The Review has also given some thought to whether the range of workable pharmacy ownership structures can be extended to give a greater semblance of genuine commercial thinking and competition among community pharmacy businesses and practices. It has outlined a model of corporate governance that could be considered in this regard, consistent with the assumptions of its recommendations.

OWNERSHIP OF PHARMACIES - RECOMMENDATIONS

Recommendation 1

The Review recommends 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.

Recommendation 2

The Review recommends 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.

Recommendation 3

The Review recommends 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 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.

Recommendation 4

The Review recommends 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 the 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.

Recommendation 5

The Review recommends that:

- (a) Friendly societies may continue to operate pharmacies, but that:
 - (1) Regulations specific to the establishment and operation of pharmacies by friendly societies pharmacies, 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 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 grandparenting 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 these 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.

Recommendation 6

The Review recommends that:

- (a) Any statutory prohibition on natural persons or bodies corporate, not being a registered pharmacist, or other permitted entity, having a direct proprietary interest in community pharmacies are retained;
- (b) "Proprietary interest" be defined clearly in *Pharmacy Acts* as relating to the direct ownership of, or a partnership, shareholding or directorship in a pharmacy operating entity;
- (c) Subject to the proprietor of a pharmacy remaining responsible and accountable for the safe and competent practice of professional services in that pharmacy, provisions in *Pharmacy Acts* relating to:

- (1) Preventing parties other than a registered pharmacist to have a lawfully permitted association with a pharmacy business, but not including a proprietary interest as defined in Recommendation 6(b);
 - (2) Inserting specific terms in commercial documents relating to those businesses;
 - (3) Preventing considerations for third parties based on of a pharmacy's turnover or profit;
 - (4) Preventing pharmacies having preferred wholesale suppliers of medicines;
 - (5) Otherwise preventing pharmacy proprietors from developing lawful business associations with other parties; and
 - (6) Allowing regulatory authorities to intervene inappropriately in matters of this nature; are removed; and
- (d) Removed provisions of the types described in Recommendation 6(c) are replaced in each *Pharmacy Act* with a statutory offence, with appropriate and substantial penalties for individuals and corporations, of improper and inappropriate interference with the professional conduct of a pharmacist in the course of his or her practice.

Recommendation 7

The Review recommends that:

- (a) Legislative 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 or Territory, and that business registration is not connected to the safe and competent practice of pharmacy.

Recommendation 8

The Review recommends 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:

- (a) An acceptable range of services to be provided; and
- (b) Appropriate quality assurance and professional practice standards to be adopted by community pharmacies covered by the agreements.

LOCATION OF PHARMACIES

The Commonwealth approves a pharmacy to supply medicines subsidised by the PBS. Under a ministerial determination made under section 99L of the *National Health Act 1953*, the Commonwealth imposes strict controls on approving a new pharmacy, and on relocating existing pharmacies, for PBS purposes. These location-based controls help to give effect to the Australian Community Pharmacy Agreement between the Commonwealth and the Pharmacy Guild of Australia.

In themselves, and however willingly they may be accepted by the community pharmacy industry, these location controls are an anti-competitive layer of regulation and government intrusion on the community pharmacy industry and market.

The restrictions assist a rational distribution of PBS-funded services, and help the Commonwealth to manage the costs of the PBS as a demand-driven programme. Given that PBS sales and dispensing remuneration form the greater parts of a pharmacy's overall turnover, the PBS location criteria are central to operating a financially viable pharmacy, and they also help to insulate pharmacies from new competitors in their catchment areas.

These regulations restrict free and effective competition in the community pharmacy industry. The Review concludes that it cannot be shown definitively that the current restrictions are entirely in the public interest. It also suggests that there may be more "competition-friendly" mechanisms, particularly in terms of an efficiency-linked PBS remuneration structure for pharmacies, that could also substitute for the existing new pharmacy approval measures to keep the overall number of pharmacies to a level consistent with community need.

The Commonwealth's regulatory restrictions on pharmacy relocation have, however, served little justifiable purpose since a major rationalisation of pharmacy outlets was completed in the early 1990s, and should be removed as soon as practicable.

In theory, the current restrictions could be dispensed with, or replaced, when the current Australian Community Pharmacy Agreement ends in mid 2000. In practice, and given the considerable investment in pharmacy infrastructure and pharmacy businesses based on present arrangements, there is merit of achieving change through a phased transition of several years, perhaps commencing on 1 July 2001. The Review suggests some practical features of a transitional framework in Appendix 5 to this Report.

In making these comments, however, the Review is aware that the parties to the Australian Community Pharmacy Agreement – the Commonwealth and the Pharmacy Guild of Australia – effectively have the last word by determining what is incorporated in any forthcoming Agreement and subsequently given legislative force.

It is up to these two parties to agree on arrangements that benefit the Australian community as a whole in terms of greater competition in the community pharmacy industry, as expressed in terms of fair access to better quality professional services at a reasonable cost.

LOCATION OF PHARMACIES – RECOMMENDATIONS

Recommendation 9

The Review recommends 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 approval to supply pharmaceutical benefits could be retained but, if so, any "definite community need" criteria for those approvals should be made more relevant to the needs of underserved communities, particularly in rural and remote areas.

Recommendation 10

The Review recommends that Pharmaceutical Benefits Scheme (PBS) related restrictions on the relocation of pharmacies from one site to another are phased out.

Recommendation 11

The Review recommends 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.

Recommendation 12

The Review recommends that:

- (a) Legislation to support specific programmes 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.

Recommendation 13

The Review recommends 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.

REGISTRATION OF PHARMACISTS

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.

Consistent with this assumption, the Review sees the relevant legislative provisions it has to examine as being not only pharmacist registration and registration requirements. It also sees as directly relevant the constitution, functions and powers of the regulatory authorities that administer *Pharmacy Acts* and regulations, and the accountability of pharmacists to the community through complaints, investigative and disciplinary processes.

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 the professional activities of its practitioners. The qualification is that such regulation should only be to the minimum level needed to ensure the safe and competent practising of pharmacy.

Consistent with its other recommendations, the Review also concludes that regulating pharmacists and pharmacy practice should not intrude unduly on the commercial and “non-pharmacy” aspects of running a pharmacy. It also concludes that, as far as possible, standards for safe and competent pharmacists and pharmacy services should be set or adopted

by governments on behalf of the community at large, and administered and implemented by regulatory authorities such as Pharmacy Boards.

The Review is also concerned to ensure that regulatory authorities are demonstrably open, transparent, and effective, so that they are always seen as being directly accountable to the community and not just to their profession. For this reason, it is important to ensure that authorities are composed of appointed rather than elected, members. Appointees could be expected predominantly to be pharmacists, but should also include lay members of the community capable of articulating a consumer point of view. Ideally, authorities should also include a lawyer member who can assist and advise on legislative interpretation and procedural matters.

As a matter of particular interest, the Review has some views about the minimal requirements in State and Territory *Pharmacy Acts* relating to pharmacists renewing their registration.

Generally, registration renewal occurs with the payment of a prescribed annual fee, and without any active mechanisms to assure regulatory authorities, and through them the community, of the ongoing competence of the pharmacist. While these mechanisms are acceptable in themselves, when they are viewed in conjunction with complaints and disciplinary processes against incompetent and dangerous practitioners. The time may have come, however, to consider appropriate and defensible competency assurance benchmarks as part of re-registration processes.

REGISTRATION OF PHARMACISTS - RECOMMENDATIONS

Recommendation 14

The Review recommends 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.

Recommendation 15

The Review recommends 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.

Recommendation 16

The Review recommends 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 that membership of a professional association or society is 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.

Recommendation 17

The Review recommends 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 practise, are retained.

Recommendation 18

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

Recommendation 19

The Review recommends 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.

Recommendation 20

The Review recommends 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.

CONCLUSION

The Review commends its findings and conclusions to Commonwealth, State and Territory governments.

It believes that it has sought to address its Terms of Reference independently, impartially and comprehensively. It also believes that it has developed constructive advice that would help to reduce the encrusted layers of regulation enveloping the pharmacy profession and the community pharmacy industry, while maintaining the Australian community’s interest in ensuring that pharmacy services are safe, competent and readily accessible.

Just as importantly the Review's findings and recommendations, if implemented, have the potential to make pharmacy practice and the community pharmacy industry more competitive and more responsive to the needs of both urban and rural communities.

CHAPTER 1: PRELIMINARY ISSUES

Before addressing the specific regulatory areas of pharmacy ownership, location of pharmacies for Pharmaceutical Benefits Scheme (PBS) purposes, and the registration of pharmacists, it is important to consider what it is that jurisdictions are seeking to regulate, and why. It is thus helpful to ask:

- What is the current nature of pharmacy practice and the pharmacy profession in Australia, and how is this likely to evolve in the foreseeable future?
- What other environmental factors are relevant to the Review's areas of inquiry?
- What should be regulated, and for what purpose?

Besides helping to define the scope and coverage of what is acceptable regulation, consideration of these questions also assists in identifying whether the elements of the Public Benefit Test of the Competition Principles Agreement³ may apply to the regulatory provisions of primary concern to this Review.

CURRENT NATURE OF PHARMACY PRACTICE IN AUSTRALIA

STREAMS OF PROFESSIONAL PRACTICE

In looking at pharmacy as both a profession and an industry, there is little distinction between pharmacists in terms of their professional knowledge and training. In practice, however, most pharmacists work in two distinct areas of practice: clinical (or hospital) pharmacy, and community pharmacy.

Clinical pharmacy

Clinical pharmacy is the provision of pharmacy and dispensary services in public and private hospitals, laboratories, and other clinical and research facilities. Hospital pharmacists in particular are usually attached to a pharmacy department in their institution, and prepare or supervise the preparation of compounds and solutions as well as dispense ready-prepared pharmaceutical medicines.

Sometimes, however, hospital pharmacists work as external providers contracted to provide pharmacy and dispensary services. This is more common for smaller private hospitals and aged care facilities.

Clinical pharmacists are often assisted by technician-level staff who perform a range of administrative, preparation and related tasks under a pharmacist's direction. A recent Australian Institute of Health and Welfare study indicates that about 15 per cent of Australia's 14,000 practising registered pharmacists work in the clinical sector and another 6 per cent work in industry (mainly with pharmaceutical manufacturers), administration and research⁴.

³ See attachment B to the Review's Terms of Reference, Appendix 2 of this Report.

⁴ Australian Institute of Health and Welfare, *Pharmacy Labour Force 1994*, December 1996, page 3.

Community pharmacy

The second area of practice is community pharmacy. This consists of shopfront pharmacies that provide a network for the delivery of pharmacy services to the Australian community. Most are found in local shopping strips, shopping centres and malls, and in some medical centres. They employ almost 80 per cent of employed pharmacists⁵ as well as many non-professional pharmacy assistants and sales staff.

Community pharmacies are the principal distribution points for prescription medicines and for scheduled over-the-counter medicines. Unscheduled medicines, such as aspirin and paracetamol products, are shared with general retailers.

THE FUNCTIONS OF CONTEMPORARY PHARMACY

The main functions of pharmacy in contemporary Australian health care are to:

- Distribute prescription medicines, including the minimisation of the risk of adverse consequences for the patient;
- Supervise the proper sale and distribution of “pharmacy only” (Schedule 2) and “pharmacist only” (Schedule 3) medicines;
- Provide, upon a client’s request or where required by professional duty, specific advice and counselling on the best medication for their needs, and the best and proper use of the medications dispensed to them;
- Provide advice as necessary to other health professionals (eg medical practitioners and hospital and community nurses) on the medicinal needs of their patients, including situations where a prescription medicine may be contraindicated for the patient; and
- Participate, as part of an increasingly multi-disciplinary primary health care team, in community health, preventive health and other public health services and programmes.

DUAL NATURE OF COMMUNITY PHARMACY

Community pharmacies are somewhat unique in that they almost invariably combine the functions of professional and retail services within the same premises. Unlike most other professional groups, community pharmacists in particular do not have a private professional-client relationship based on a fee for service. Instead, the client may simply walk off the street and seek “free”⁶ advice without an appointment. Rather than charge for this advice directly, the pharmacist derives his or her income from the medicines dispensed (including related fees and mark-up remuneration) and the other products sold in the pharmacy.

In many pharmacies, too, the situation is further blurred by the fact that the pharmacy offers numerous lines of non-pharmacy business including general merchandising, cosmetic sales, agency arrangements for banks, health insurers, photographic services and so on. Indeed, many larger pharmacies have evolved to look very similar to niche and sometimes even general retailers.

This unusual dual nature of community pharmacy, as a combination of shopfront-based small business and professional practice, complicates any evaluation of the professional regulation of the professional services offered by pharmacies. This relates particularly to matters

⁵ Australian Institute of Health and Welfare, *Pharmacy Labour Force 1994*, page 3.

⁶ The advice is free to the inquirer, but is usually linked to a transaction for a given drug or medicine, and the cost to the business of the professional and staff time in providing such advice is effectively part of a pharmacy’s real operating costs.

concerning who owns community pharmacies and where these can be located for PBS-related purposes. Certainly, most small businesses are not regulated to the extent that community pharmacies and the pharmacists who operate them are regulated.

OTHER ENVIRONMENTAL FACTORS SHAPING PHARMACY PRACTICE IN AUSTRALIA

Like other health care professions, pharmacy in Australia is practised in a highly regulated environment. State, Territory 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 medicines, the cost at which they can be sold to consumers.

The Terms of Reference for the Review set three specific areas of inquiry – ownership of pharmacies, location of pharmacies and registration of pharmacists. However, these have to be seen in the broader context of the regulatory, professional and commercial environments in which they operate, and with which they are interdependent. Relevant factors include:

- State and Territory drugs and poisons legislation;
- The Commonwealth's Pharmaceutical Benefits Scheme;
- The Australian Community Pharmacy Agreement; and
- The high level of interdependence between retail pharmacies and pharmaceutical wholesalers.

Drugs and poisons legislation

Australia has obligations under international conventions to protect the public from the uncontrolled availability of potentially dangerous drugs and poisons.

The added complexity and costs associated with these provisions, particularly in relation to accountability, handling, storage and transport, have a significant effect on the practice of pharmacy. These special requirements need to be taken into account when assessing and considering changes in the pharmacy industry. This is especially the case given that pharmacists are one of the key classes of persons whose have responsibility for the safe custody and distribution of toxic chemicals and substances, including pharmaceuticals and other medicines.

Drugs and poisons legislation also provides for the scheduling of drugs, medicines and other dangerous substances to regulate whom may store, handle and sell these items. Schedules 2 and 3 provide that listed over-the-counter medicines must be sold only by a pharmacy (Schedule 2) or personally by a pharmacist (Schedule 3). Schedule 4 relates to prescription medicines, usually dispensed by pharmacists, and Schedule 8 to highly potent drugs such as drugs of addiction.

These scheduling requirements, and safety and handling restrictions imposed on pharmacists by drugs and poisons legislation, have a bearing on who may own a pharmacy and be accountable for its professional services. Drugs and poisons legislation also relates to registration requirements for pharmacists. If Schedule 2 medicine items were delisted, for instance, this would have some effect on the competitive profile of pharmacy businesses as formerly scheduled items would be sold in competition with general retailers.

Relevant drugs and poisons provisions will be taken into consideration, particularly in relation to the registration of pharmacists and of pharmacy businesses and premises. For example, in some jurisdictions both *Pharmacy* and *Poisons Acts* require pharmacy premises and individuals to be registered for compliance and enforcement purposes. Such overlaps are relevant to the inquiries of this Review.

Drugs and Poisons legislation is, however, being examined by a separate National Competition Policy review, due to report to the Council of Australian Governments in mid 2000. As this other Review is dealing with the advertising of drugs and poisons, this Report will not deal with the related matter of regulating of pharmacy and pharmacist advertising.

Pharmaceutical Benefits Scheme (PBS)

The PBS is a Commonwealth Government programme. Its objective is to provide timely, reliable and affordable access for the Australian community to necessary and cost effective medicines⁷. A variety of mechanisms are in place to administer the PBS, including the approval of new medicines for PBS listing and setting of their costs. Access to medicines under the PBS mostly is provided through the community pharmacy network⁸.

The PBS is connected with the sale of 95 per cent of all medicines prescribed in Australia. Like Medicare, it is a demand-driven programme whose cost to the community each year depends on the volume of pharmaceuticals dispensed, their listed prices, and the fees paid to pharmacists for their dispensing services. In 1997-98, the PBS involved total government outlays of \$2,541 million, with a further \$571 million in patient contributions (co-payments). Of the \$3,112 million total cost of the PBS in 1997-98, \$773 million was spent on dispensing remuneration to pharmacists⁹. The remainder of the outlay represented reimbursement for the retail and wholesale costs of the listed medicines supplied.

Overall, PBS sales and dispensing fees comprise about two-thirds of most pharmacies' turnovers. In some areas where there are high concentrations of low-income consumers, beneficiaries and retirees, industry evidence suggests that the proportion of PBS revenue for a pharmacy can be 80 per cent or even higher¹⁰.

Through the scale of its PBS subsidies, the Commonwealth effectively purchases such a volume of medicines by way of PBS outlays that it has a near monopsony on prescription drugs. That purchasing power brings it considerable leverage at all points of the pharmaceutical supply chain. It negotiates prices with pharmaceutical manufacturers, factors pharmaceutical wholesalers into remuneration calculations, and pays dispensing remuneration per item dispensed to pharmacists at the point of retail.

It is this leverage, coupled with its ability to approve which pharmacies can supply PBS items and where they can be established, that gives the Commonwealth profound influence in the community pharmacy market. PBS considerations also overlap the pharmacy regulatory responsibilities of the States and Territories, and the PBS is a factor that those jurisdictions cannot ignore in examining the relevance and efficacy of their own legislative regulation of pharmacies and pharmacists.

⁷ Commonwealth submission to the Review, para 2.18.

⁸ A fuller background on the PBS's operation is at Appendix 3 of this Report.

⁹ Commonwealth submission to the Review, paras 2.26 – 2.27.

¹⁰ These observations emerged from the Review team's private discussions with individual pharmacist proprietors operating pharmacies in such areas, and with pharmacy brokers.

The Australian Community Pharmacy Agreement

The Agreement is a contract between the Commonwealth and the Pharmacy Guild of Australia (the Pharmacy Guild) about the terms of pharmacists' remuneration for PBS dispensing activities, and the conditions applying to that remuneration. It sets out the methods for calculating the prices paid to pharmacists to dispense items listed under the Scheme, as well as conditions relating to the approval of new pharmacies and the relocation of existing pharmacies for PBS purposes.

Details of current PBS remuneration arrangements under the Agreement are outlined in Appendix 3. The Review notes that the parties to the Agreement are, at the time of writing, negotiating the terms of a new Agreement, expected to commence on 1 July 2000.

For the Commonwealth, a main objective of the Agreement is to provide access to essential medicines at a sustainable cost to the community. For the Pharmacy Guild, a necessary objective is to achieve the best possible remunerative and related outcomes – including higher goodwill and business sale values for its pharmacy proprietor members.

Relationship of the Agreement to the Terms of Reference

The Terms of Reference for the Review do not include all parts of the Agreement. The PBS and the Agreement are factors that are, however, highly relevant for pharmacy ownership and location questions, because of a range of factors including that:

- The fixed remuneration fees and prices for PBS items effectively discourages price competition on PBS-related dispensing;
- The pharmacy location restrictions arising from the Agreement severely constrict the market's power to distribute pharmacies according to consumer demand;
- The dispensing privileges of the PBS are almost entirely exclusive to community pharmacies, and this is reinforced by PBS arrangements;
- Without PBS dispensing rights a pharmacy business is almost unsustainable;
- PBS remuneration per dispensed item is crucial to most pharmacies' operating margins; and
- The exclusive and demand-driven PBS market makes pharmacies attractive as a new growth opportunity for non-pharmacist retailers such as supermarkets and department stores¹¹, as well as making them highly desirable assets for currently eligible pharmacy proprietors.

Relationship between pharmaceutical wholesalers, distributors and retail pharmacy

Over many decades an interdependent relationship has evolved between wholesalers and retailers in the pharmacy industry. The pharmaceutical wholesale sector is concentrated: most wholesaler activity takes place under the umbrellas of just three main wholesale distribution companies, F H Faulding and Co, Australian Pharmaceutical Industries and Sigma.

Pharmacies across Australia are very well serviced in terms of the delivery of medicines, with virtually every pharmacy in Australia receiving at least one delivery per day from one or more of three major pharmaceutical wholesalers. This wholesale delivery system ensures that consumers have prompt access to essential medicines.

¹¹ This point was made in the Review's consultations with several non-pharmacy retailers with an interest in pharmacy ventures.

Indeed, a cost component for wholesalers is factored into the subsidy arrangements for listed medicines in the PBS¹².

The major wholesalers depend heavily on a diffuse community pharmacy network placing constant orders, and work hard to protect their considerable investment and exposed risk by nurturing strong relationships with individual pharmacy businesses and individual pharmacists. Activities in which wholesalers interact very closely with community pharmacy include:

- Sponsoring and managing “banner groups” of pharmacies such as *ChemMart*, *Chem World* and *Amcal*. Although they have the outward appearance of franchise operations the groups provide their services, signage and support arrangements to pharmacists for a fixed fee, thereby allowing participating pharmacies to remain “independent” and not tied formally to the wholesaler;
- Developing positive arrangements with young and growing pharmacy businesses by standing as guarantors for pharmacy business improvement and start-up loans¹³;
- Promotional activities, such as sponsoring professional and business training and continuing education for pharmacists and their staff, either directly or through professional bodies such as the Pharmaceutical Society of Australia.

While not required to consider the regulation of the pharmaceutical wholesaling sector, the Review needs to take into account the web of relationships between the pharmacy wholesale and retail sectors in assessing aspects of the net public benefit of existing regulation.

SCOPE AND APPROACH OF THE REVIEW

The Competition Principles Agreement provides that:

The Guiding Principle of the Agreement is that legislation (including Acts, enactments, ordinances or regulations) should not restrict competition unless it can be demonstrated that:

- (a) *the benefits of the restriction to the community as a whole outweigh the costs; and*
- (b) *the objectives of the legislation can only be achieved by restricting competition*¹⁴.

The Review therefore needs to ask:

- What are the objectives of the legislation;
- What are the restrictions on competition that the relevant legislation imposes;
- What are the objectives of those restrictions;
- What are their costs and benefits to the community as a whole;
- What are the alternatives to those restrictions that are capable of achieving similar outcomes; and
- Whether the benefits to the community outweigh the costs of the restrictions.

APPROACH OF THE REVIEW TO ITS TERMS OF REFERENCE

In examining relevant legislative restrictions on competition referred to it, and their costs and benefits to the community as a whole, there needs to be a preliminary judgment about

¹² For more details, please see Appendix 3.

¹³ A pharmacy broker indicated to the Review that this guarantee arrangement makes pharmacy business proposals very attractive to banks as lenders.

¹⁴ *Competition Principles Agreement 1995*, Clause 5(1).

whether regulation is necessary in the first place in each of the areas being examined. If regulation is thought necessary, it then becomes a matter of assessing what should be the scope of any such regulation in the pharmacy profession and community pharmacy industry.

In respect of these questions, the Review believes that if pharmacy regulation is to be considered necessary and justifiable, it needs to be most effective way of:

- Protecting the safety of the Australian public by ensuring that pharmacy services are provided in a competent and accountable manner; and
- Ensuring that all Australians have reasonable equality of access to competent and efficient pharmacy services.

The Review sees its task as identifying and recommending the retaining of those regulations that may be justified as being of net public benefit against these tests, and the removing of regulations that are not.

This Report therefore is looking at the content and interpretation of each referred Act, regulation, or statutory instrument that appears to restrict the commercial and competitive ability of community pharmacies to operate as commercial businesses, or professionals to practise freely, and to assess whether the nature and extent of these restrictions is of net public benefit.

Limits of justifiable regulation

In its findings and conclusions about the justifiability of legislation in a given area of interest, the Review sees its role as setting out the boundaries of acceptable legislative restrictions on competition. It is seeking to draw a line beyond which regulation should be withdrawn as not being justifiable restrictions on competition.

Where a jurisdiction's regulation does not extend as far as the Review's recommended line, that jurisdiction should not be compelled to extend that regulation. If a jurisdiction's regulations go beyond that line, however, any excessive regulation should be wound back.

Consideration of market failure

In competition theory, market failure can arise where the operation of a free and competitive market does not produce a socially desirable outcome.

As stated in the *Guidelines for the Review of Professional Regulation* prepared for the Victorian Government, legislative reviews for National Competition Policy purposes need to identify legitimate reasons for legislative intervention by governments¹⁵. As part of such assessments, these *Guidelines* suggest that these can be mapped to assess their correspondence to various forms of market failure, with closer reference to those that especially might apply to professional services¹⁶.

Market failure arguably may be found in the presence of one or more of the following factors:

- **Public goods:** Situations where particular goods would not be provided at all if left to the actual market;

¹⁵ Department of Premier and Cabinet, Victoria, *Guidelines for the Review of Professional Regulation*, 1999, pages 4-5.

¹⁶ *Ibid.*

- **Externalities:** An activity or transaction confers benefits or imposes costs on people or entities other than those involved directly in a given market activity;
- **Natural monopolies:** A situation where it is open for a firm or entity to exploit unfairly its position in the market; and
- **Information asymmetries:** The seller of a good or service has more knowledge about that product than the buyer, and that therefore the buyer is dependent on the seller's superior expertise to benefit from the transaction.

Some parties making submissions to the Review, especially the Pharmacy Guild of Australia (the Pharmacy Guild) and the Pharmaceutical Society of Australia (the Pharmaceutical Society), stressed very strongly that in the area of professional pharmacy, market failures should be taken into consideration in assessing the public benefit of relevant legislative regulation. Indeed, it is important to do so in the interests of a comprehensive analysis.

Of these four cases of possible market failure, the Review believes that only one definitely applies to pharmacy: information asymmetry. It also believes, however, that to a limited extent an externality case may apply in some circumstances.

Information asymmetry and the Terms of Reference

Drugs and medicines are highly complex chemical substances. They interact with the biochemistry of the human body, and indeed with each other if taken simultaneously by a patient. If administered incorrectly, or administered in spite of being contraindicated, a prescribed or over-the-counter medicine can cause great physical harm to a person.

Very few lay people, even those who have developed consumer sophistication due to their health care needs, can do anything but rely on the expertise of medical practitioners as prescribers of medicines, and pharmacists as their dispensers, to ensure that their care needs are met adequately and safely. This is a genuine asymmetry of information.

The Review believes that the market failure argument of information asymmetry applies most directly to the regulation of who may practise pharmacy (ie pharmacist registration) and how pharmacy is practised by pharmacists and staff under their direction.

Regulation in these areas is intended to protect the public from unsafe and incompetent practice, and to assure the community that the pharmacy professionals they rely on are competent and proficient. Given that very few members of the public have expert knowledge of biochemistry, pharmaceuticals and pharmacology, pharmacist registration in particular is a shorthand way for consumers to identify that the professionals who serve them are qualified to do their jobs, and that they satisfy accepted professional standards of competence and ability.

Market failure based on information asymmetry may also be relevant, however, to the consideration of pharmacy ownership.

The core of the case for the profession's case for pharmacist ownership of community pharmacies is that a pharmacy is essentially a professional practice in the guise of a small shopfront business. Given this mixture of characteristics, it is argued, a pharmacy needs to be controlled by a registered professional to assure the public of the safety and quality of pharmacy services that their businesses provide. Some would argue that pharmacist ownership is integral to providing safe and competent pharmacy services; others would not.

Consequently, this suggested application of the information asymmetry case to ownership regulation needs to be taken into account in assessing the net public benefit of related regulation.

Externalities and the Terms of Reference

The externality case may also apply to an extent in the pharmacy profession and industry.

As a community, we rely on our health care professionals to reassure the community about the quality of their care, and depend on competent professional practice to minimise the overall cost to the taxpayer of providing that care. To the extent that pharmacists' activities are subsidised by the public purse, or make savings for the taxpayer by reducing or removing the need for a publicly-funded intervention (say by selling a cold or flu medicine to a customer who obtains temporary relief without needing a Medicare-funded visit to a doctor), an externality outcome may be said to have occurred.

As the Pharmacy Guild and Pharmaceutical Society pointed out in their submission to the Review, there may be social costs and benefits of pharmacy regulation that exist separately to the private benefits to the patient and consumer. These may include costs to the community's health and safety, which may be felt through by the wider community through contagious disease or the abuse or misuse of medicines. Such costs could be measured both in terms of health care outlays and in the overall quality of the community's health¹⁷.

It could also be argued, as it was implicitly in the Commonwealth's submission¹⁸, that there are significant public policy considerations that cannot adequately be addressed if the pharmacy market is left entirely to its own devices.

An example of such considerations is the public policy desirability of ensuring reasonable access to safe and competent pharmacy services in rural and remote localities that may be commercially less viable or attractive as propositions for pharmacy proprietors.

DEFINITIONS

As part of its inquiries, the Review identified several crucial terms that need definition for its analysis of relevant pharmacy legislation and regulation.

Pharmacy services

As *Pharmacy Acts'* definitions of pharmacy business, practice and services are varied or absent, the Review has adopted for this Report a working definition of "pharmacy services":

Pharmacy services mean those services to the public carried out exclusively or largely in the provinces of qualified and registered pharmacists. These services include:

- (a) *The preparation, compounding and dispensing of prescription drugs and medicines;*
- (b) *The safe and secure storage, sale or distribution of drugs and medicines which may be scheduled as being pharmacy only, pharmacist only or otherwise restricted to sale or distribution by persons including pharmacists;*
- (c) *The providing by a person of advice, counselling and consumer medicines information, and of medication management services to the public, governments, community agencies, hospitals and clinics,*

¹⁷ Pharmacy Guild and Pharmaceutical Society submission to the Review, Volume 1, pages 25-26.

¹⁸ Commonwealth Government submission to the Review, passim, particularly in relation to pharmacy ownership and location.

- aged care facilities and to other health care professionals on the basis of that person holding himself or herself out as a qualified and registered pharmacist; and,*
- (d) *Matters relating to the permissible handling, preparation, storage, sales and advisory services able to be carried out by non-pharmacist staff under the direction and supervision of a qualified and registered pharmacist.*

This definition is broad and indicative. It is intended as a working guide to analysis, rather than presenting a paradigm for best or good professional practice. It does not presuppose or build upon any one assumed practice model. Making effective judgments about good practice is a matter for the pharmacy profession, and for the professional men and women who comprise it.

Other definitions

There are three particular terms, crucial to the Review's task, which are either not defined in current pharmacy legislation or are subject to imprecise usage and interpretation. These relate to the terms "pharmacist ownership (or alternately proprietorship)", "proprietary interest" and "pecuniary interest".

For the purposes of this Report:

Pharmacist ownership means that a registered pharmacist has or registered pharmacists have the effective and undisputed proprietary control of an entity operating a community pharmacy, whether that entity be a sole tradership, partnership or body corporate.

Proprietary interest means a natural person's or body corporate's ownership of, or a partnership, shareholding or directorship held in, an entity operating a community pharmacy.

Pecuniary interest includes a proprietary interest, but also includes lawful commercial associations with the operator of a community pharmacy that may confer a pecuniary benefit or consideration on a natural person or body corporate.

CHAPTER 2: PHARMACY OWNERSHIP

NATURE OF THE RESTRICTIONS

INTRODUCTION

State and Territory legislation contains a number of specific inter-related restrictions on the conduct and operation of pharmacies as businesses. These include:

- Restrictions on who can own pharmacies;
- Restrictions on the numbers of pharmacies in which a registered pharmacist may have an proprietary interest;
- Restrictions on the ownership structures of pharmacy businesses; and
- Pecuniary interest measures to prevent persons and corporations other than registered pharmacists having a pecuniary or proprietary interest in a pharmacy business.

These measures are part of a broad collective restriction that can be labelled “pharmacy ownership”, even though “ownership” as a concept is not defined in any *Pharmacy Act*. Their effects on pharmacy businesses tend to overlap and are difficult to assess in isolation as they operate collectively. They therefore need to be examined collectively.

PHARMACIST-ONLY OWNERSHIP OF PHARMACIES

Under State and Territory *Pharmacy Acts*, the ownership of pharmacies is confined to registered pharmacists, with certain limited exceptions. By implication rather than formal definition, all Acts with ownership restrictions appear to characterise “ownership” as, at minimum, the holding by a pharmacist or pharmacists of the effective and undisputed control of the decision-making of a pharmacy business.

Other than transitional arrangements for bankrupt businesses and deceased estates, the only statutory exceptions to this general rule in State Acts are for pharmacies owned and operated by friendly societies, and for the remaining handful of pharmacies owned by corporations or individuals who did so before present ownership restrictions came into force.

There is no express provision in the Territory Acts for pharmacist ownership of pharmacies. These Acts simply require that only a registered pharmacist can carry on the business of a pharmacist¹⁹. While the wording of the relevant provisions is ambiguous, and is the source of some dispute²⁰, their *Pharmacy Acts* appear definitely to provide only that a pharmacy must be supervised and managed by a registered pharmacist.

In some jurisdictions, new friendly society pharmacies are also prohibited, or are made subject to special ministerial approval processes before they can be established. In practice, these restrictions make new friendly society pharmacies very unlikely in those States or Territories.

¹⁹ *Pharmacy Act 1931* (ACT), section 45; *Pharmacy Act 1996* (NT), section 32.

²⁰ The Pharmacy Board of the Northern Territory submitted a legal opinion to the Review that concluded that the relevant provisions of the Territory's *Pharmacy Act* imply pharmacist ownership of pharmacy businesses. Nevertheless, the relevant provisions can be read simply as requiring a registered pharmacist to direct the affairs of the business, which could be done by a pharmacist in charge as well as by a pharmacist proprietor. See also the comments on the Australian Capital Territory and Northern Territory *Pharmacy Acts* in Part B of this Report.

The Western Australian *Pharmacy Act 1964* also requires that the proprietor be a resident of that State. Generally, however, a State's *Pharmacy Act* requires a proprietor pharmacist to be registered in the State if they own or have an interest in a pharmacy there.

Over 4,700 of the 4,950 pharmacies approved to provide medicines under the Pharmaceutical Benefits Scheme (PBS) are owned by pharmacists or by companies controlled by registered pharmacists. This represents about 95 per cent of community pharmacies.

OWNERSHIP STRUCTURES

Consistent with the principle of pharmacy ownership by pharmacists, jurisdictions also impose limitations on the permissible permutations of persons and bodies corporate that can control a pharmacy business. These combinations are:

- Sole trading pharmacists;
- Partnerships of two or more pharmacists;
- Limited partnerships between a practising pharmacist or pharmacists and external sources of capital, provided that those persons are also pharmacists;
- Bodies corporate, in which all the shareholders and directors are pharmacists; and
- Bodies corporate, in which pharmacists hold the majority of shares, with the balance held as non-voting shares held by specified relatives of the pharmacist.

NUMBERS OF PHARMACIES OWNED BY A PROPRIETOR

Each State has restrictions on the number of pharmacies that can be owned by an individual pharmacist proprietor. The Northern Territory and the Australian Capital Territory, which share commonly-worded provisions in this regard, do not regulate numbers of pharmacies in this way.

By State, the numerical restrictions on pharmacies in which pharmacists may have a proprietary interest²¹ are:

- **Two:** Western Australia and Tasmania;
- **Three:** New South Wales and Victoria; and
- **Four:** Queensland and South Australia.

PECUNIARY INTEREST IN A PHARMACY BUSINESS

Except for South Australia and the Northern Territory, all State and Territory *Pharmacy Acts* provide in some form that no-one apart from a registered pharmacist may have a direct or indirect pecuniary interest in a pharmacy. The Victorian *Pharmacists Act 1964* extends this to include a proprietary interest²².

These provisions generally are construed by regulatory authorities and the profession to provide that no non-pharmacist can hold a share in a pharmacy business, nor profit from the transactions of that business. Several Acts also provide that particular matters such as leases and rents, bills of sale, mortgages or securities on a pharmacy business must not carry specific conditions implying the control or interference of a pharmacy business's decision making. Conditions prohibited expressly by legislation include allowing the supply

²¹ As defined in Chapter 1.

²² *Pharmacists Act 1974* (Vic), section 21(1).

of goods or services by specific parties, and giving other parties a say in the running of the business, a share of its profits or turnover, or rights of access to its accounts.

Generally, pecuniary interest is not defined in *Pharmacy Acts*, and therefore interpretation relies on relevant definitions in other legislation or in common law. In effect, regulatory authorities responsible for administering *Pharmacy Acts* have a considerable need and discretion to interpret what is a pecuniary interest in a pharmacy business, with the appropriate external review mechanism at hand to adjudicate in disputes arising from those interpretations.

REGISTRATION OF PHARMACY BUSINESSES AND PREMISES

Most jurisdictions provide that pharmacy premises and, in some cases, pharmacy businesses must be registered with their regulatory authorities. Registration of businesses means furnishing details to authorities about matters relating to ownership structures, the persons involved in the business, and the address or addresses of pharmacy premises operated by the business.

The registration of premises relates to regulatory authority approvals of pharmacy sites, and of their fitting out as pharmacies, before they can operate lawfully. To gain approval to operate, a pharmacy needs to satisfy specifications on matters such as shop layout, equipment, and entrances and exits, as specified in Acts and regulations. To gain registration, pharmacies are usually inspected by agents of the regulatory authority.

OBJECTIVES OF THE RESTRICTIONS

In most States and Territories the existing legislative restrictions on non-pharmacist ownership, pharmacy numbers and pecuniary interest go back many decades and even beyond. In some cases, their introduction was a policy response to the community pharmacy industry's lobbying against the entry into the Australian market of an overseas-based pharmacy chain.

Whatever the origins of the restrictions, their current objectives may include some or all of the following:

- Promoting the integrity of pharmacy as a professional activity as opposed to a commercial activity;
- Industry-wide awareness of professional pharmacy objectives as well as commercial objectives;
- Keeping pharmacy businesses small enough to facilitate the close personal supervision of their professional operation by the proprietor pharmacists;
- Protecting independent pharmacy businesses from perceived “unfair competition” and market dominance from large pharmacy-owning corporations and chains and, in some jurisdictions, friendly societies;
- Making the proprietor of a pharmacy business professionally and directly accountable to regulatory authorities, and through them the community, for the pharmacy services provided by his or her pharmacy or pharmacies; and
- Protecting the public safety and promoting competent professional practice by involving pharmacy proprietors, as professionals, in the supervision of professional services under their control.

EFFECTS OF THE RESTRICTIONS

The primary effect of restricting ownership of pharmacies to registered pharmacists, and the related measures, is to exclude – with limited exceptions - all other persons and corporations from operating pharmacy businesses, or from extracting a pecuniary or proprietary benefit from them.

This restricts the commercial rewards of financially attractive business sector essentially to a single class of persons. The total turnover of the community pharmacy industry is about \$6,000 million a year²³. Of this, about three-quarters is derived from the sale of prescription and of scheduled “pharmacist only” (Schedule 2) and “pharmacy only” (Schedule 3) over-the-counter medicines, such as aspirin, certain ointments and lotions, and cold and flu tablets²⁴. In short, the sale of products with a retail value of around \$4,500 million a year is reserved for pharmacies, to the detriment of other retailers.

Related restrictions, particularly on the number of pharmacies in which a pharmacist may have a proprietary interest, and the types of permitted ownership structures for pharmacy businesses, also help to ensure that pharmacy businesses remaining mostly small enterprises. While this may be in keeping with the character of community pharmacy as a localised shopfront service, such limitations impose constraints on at least some businesses in ways that may frustrate them achieving their potential scale and scope.

Some would say that this is in keeping with the community pharmacy industry’s image as a network of local small businesses providing convenient shopfront services to consumers. Others would say that this industry fragmentation frustrates movements towards genuine economies of scale and scope in pharmacy, that could then be passed on to consumers in terms of lower prices for pharmacy goods and services, including lower PBS outlays for taxpayers.

An indirect effect of pecuniary interest restrictions and the registration of pharmacies and pharmacy businesses is that regulatory authorities have a considerable indirect say in the management of pharmacy businesses. In some jurisdictions, the ambit of the authority is interpreted as ranging over all the activity in a pharmacy shop, including the sale of goods and services that otherwise have nothing to do with professional pharmacy services²⁵.

The Review notes that the scheduling of medicines is being examined by the separate national Review of Drugs and Poisons Legislation, and that recommendations from that Review may affect the eventual extent of pharmacies’ exclusive access to currently scheduled medicines, and their ability to advertise medicines and related services.

COSTS AND BENEFITS OF THE RESTRICTIONS

The guiding principle of the National Competition Policy is that legislation should not restrict competition unless it can be demonstrated to be to the net benefit of the public.

If it is to conclude that legislative restrictions relating to ownership should be removed, the Review must therefore analyse whether the benefits of the ownership restrictions to the community as a whole outweigh the costs.

²³ Productivity Commission submission to the Review, page 8.

²⁴ Review’s consultations with the Pharmacy Guild and the Pharmaceutical Society, 7 September 1999.

²⁵ In the case of New South Wales, this broad interpretation was endorsed by the Supreme Court: see *Chappuis v Filo*, (1990) 19 NSWLR 490.

Consistent with its Terms of Reference, the Review also needs to identify which interests potentially lose or gain through the operation of existing regulation, and comments on who may lose or benefit are included with each cost and benefit argument.

COSTS OF THE RESTRICTIONS

Costs arising from ownership-related restrictions are not easy to describe and quantify. Rather, they relate to the efficiency and performance of the community pharmacy industry in general, and of individual pharmacy businesses in particular. They also relate to the monetary costs of pharmacy goods and services to the consumer, and the circumscribing of the range of choice consumers may have in terms of who provides them with their pharmacy needs.

Identifiable social and economic costs of the restrictions include:

- Putting barriers in the way of achieving greater efficiencies in the community pharmacy industry, and in individual pharmacy businesses;
- Not allowing fully effective price and professionally-based service competition between pharmacy businesses;
- Limiting fresh sources of innovation, leadership and ideas that could improve the overall efficiency of the community pharmacy industry; and
- Constraints on consumer choice.

Barriers to greater efficiency

By prescribing who can own a pharmacy, current State legislation keeps non-pharmacist entrepreneurs, managers and enterprising non-pharmacist businesses out of the community pharmacy market.

This particularly excludes owners and managers of non-pharmacist retail enterprises that could either host or integrate a pharmacy as part of their wider infrastructures and cost bases. Businesses that could easily own integrate a pharmacy into their complementary operations could include supermarkets, department stores, specialty health and beauty chain stores, experienced overseas-based pharmacy chain operators, and large shopping centre complexes.

In turn, integrating into large corporate structures could enable pharmacies to be operate at a lower unit cost per item sold, by lowering average overheads through sharing infrastructure with other parts of a retail shop or complex. Pharmacies in chain companies, and even franchises, could benefit from the benefits of shared corporate and administrative costs, and from common stock purchase and ordering arrangements with wholesalers and manufacturers of medicines and general products.

The consumer may expect that lower overheads and better operating margins in these circumstances may lead to lower unit costs, and hence to lower prices and more services.

At present, however, community pharmacies are limited by regulation to being small to medium businesses. Under State *Pharmacy Acts*, no private pharmacy proprietor legitimately can have a direct interest in no more than four pharmacies in any one jurisdiction. The only legal way to exceed local limits is to accumulate pharmacies to the local limits in other States

and Territories²⁶. Even so, such limits put a cap on the maximum size of a pharmacy proprietor's holding and business size, although they do not constrain the physical size, stock range, and sales volumes of each pharmacy owned by a proprietor. A 1997 industry survey suggested that pharmacies then had an average of 3.8 full-time and 4.8 part-time staff, and average annual turnover per pharmacy of \$1.2 million²⁷.

Pharmacies themselves tend to be of relatively small scale as businesses, which in itself affects their ability to generate genuine economies of scale and scope. In 1997-98, Health Insurance Commission prescription data indicated that only 28 per cent of pharmacies had a PBS prescription volume of more than 30,000, and 45 per cent had a volume of less than 20,000²⁸.

Given that the 1997-98 average number of PBS prescriptions per pharmacy was 36,900²⁹, it appears that by far the greater number of pharmacies are operating below a volume of 35,000 prescriptions per year. This figure was calculated in the 1980s as being the point of minimum average cost per prescription dispensed in a pharmacy³⁰. Even though the proportion of pharmacies dispensing at or above 25,000 prescriptions is well above the paltry four per cent doing so in 1980³¹, this data suggests that many pharmacies are operating on relatively low turnover bases and tight cost margins that could be improved if greater returns to scale were attained.

Numerical limitations on pharmacies owned also frustrate pharmacist proprietors who have entrepreneurial and managerial flair. No matter what their business's level of efficiency and growth potential, proprietors are stopped from growing beyond the statutory ceiling in any one State – although they could collect pharmacies in other jurisdictions as well. If smaller-scale pharmacies could group together in a single business with a critical mass greater than presently permitted, they could share common management and support structures, information systems and stock purchasing arrangements. They could also share a common management and professional practice decision-making structure, which could help all its pharmacies attract clients to the business.

It may then be that this multi-pharmacy business can realise savings in areas such as bulk purchasing, single ordering points and corporate services, and the business as a whole could realise effective operating margins per pharmacy that would effectively be greater than each pharmacy could each were a single business. While buying and banner groups do offer similar benefits, they still depend on the voluntary and selective participation of individual pharmacies and small groups of pharmacies in the arrangement³².

²⁶ It appears, from advice given to the Review by some Pharmacy Boards, that very few pharmacists have cross-border holdings. A handful of pharmacists, or combinations of pharmacists, control significant cross-border pharmacy groupings, but these are exceedingly rare. As a guide to the limits of this possibility, for a non-Western Australian pharmacist (due to the requirements in that State barring acquisitions by non-residents), the maximum number of pharmacies that can be held across States is 18, plus unlimited numbers in each of the Territories.

²⁷ Pharmacy Guild of Australia, *1998 Guild Digest*, Tables 17 and 2.

²⁸ Commonwealth submission to the Review, para 2.43.

²⁹ *Ibid.*, para 2.42.

³⁰ Bureau of Industry Economics, *Retail Pharmacy in Australia – An Economic Appraisal*, 1984, page 95. The Bureau was commenting on work by Professor John Deeble's modelling for the 1980 Joint Committee on Pharmaceutical Benefits Pricing Arrangements.

³¹ *Ibid.*

³² Banner groups in particular provide a service to pharmacies in the form of branding, promotion, stock lines and other areas, in return for flat participation fees. This arrangement avoids the possibility of banners being classified as having a pecuniary interest in a pharmacy based on receiving a consideration based on turnover or profit. Banner groups are not franchises, where the proprietor commits him or herself to managing the business in terms of the framework and corporate philosophy of the franchisor. If a proprietor does not wish to use an aspect of a banner group's product, generally they can decline to do so.

As the then Industry Commission observed in 1995, “the abolition of the (number) restriction would increase the productivity of the industry and reduce the costs to the economy in general”³³.

When combined with the attractions of a stable source of income from PBS sales, which helps to create a safe foundation for pharmacy earnings, and has remuneration structures that assist smaller businesses to derive benefit from the Scheme³⁴, the range of existing ownership-related restrictions offer little incentive for inefficient proprietors to make way for others.

Who bears these costs?

Consumers arguably bear a cost in this regard. A generally less efficient industry means that average costs across that industry are probably higher than they otherwise may need to be, as owners seek to maintain viable operating margins. Community proprietors bear the consequences for their businesses of being limited in their activities to develop and grow by the operation of constraining regulation.

The community as a whole also pays indirectly for efficiency limitations because remuneration structures for the PBS are devised with reference to averaged industry costs, rather than being linked to marginal or best practice cost frames of reference. If the remuneration structure does not take into account inbuilt inefficiencies that may exist in the performance of the pharmacy industry, the result is higher PBS dispensing remuneration per item than otherwise may have been justifiable.

Not promoting fully effective competition in pharmacy services

Another cost of maintaining the present restrictions, especially when considered with PBS remuneration and sales arrangements, is that the current pharmacy ownership environment is stable to the point of discouraging strong competition between pharmacy businesses. In a climate underpinned by the security of government subsidy and regulation, providing the best possible professional service to consumers at the best price may not always be the strongest driving factor in pharmacy proprietors’ business outlooks and decision-making processes.

This is not to say that competition between pharmacies for the consumer dollar does not exist. It does, and particularly in crowded local pharmacy markets is very aggressive and determined³⁵. But it is arguably competition sheltered by a background of government subsidy and wholesaler loan guarantees, which help to ensure that poor performers are unlikely to “go under” as a result of being outperformed³⁶. Good professionals do not necessarily make good managers and businesspeople, yet regulatory arrangements in the industry make it easier for these poorer business performers to be protected from themselves.

This relative lack of incentive to create generally competitive market conditions is reinforced by perceived consumer behaviour in pharmacy patronage. Market research complementing the Commonwealth’s submission to the Review suggests that consumer patronage is dictated

³³ Industry Commission, *The Growth and Revenue Implications of Hilmer and Related Reforms: A Report by the Industry Commission to the Council of Australian Governments*, March 1995, page 119.

³⁴ This is discussed at more length in Chapter 3 of this Report.

³⁵ This factor was highlighted in the Pharmacy Guild and Pharmaceutical Society submission to the Review, Volume 1, pages 29-31.

³⁶ In consultations with the Review on 20 August 1999, Pharmacy Guild officials advised that, to their knowledge, in recent years no pharmacist-owned pharmacy business had closed altogether due to financial difficulties. Anecdotal industry comment to the Review suggests that loan guarantors generally move to assist a proprietor in financial difficulty (including assisting in selling the business to another pharmacist) rather than see the business fail outright.

partly by loyalty, but much more by a pharmacy's proximity to home, work or place of regular shopping³⁷.

Quality of service, such as ready access to medicinal counselling and advice was also seen as a reinforcing rather than a motivating factor for consumers³⁸. Separate market research commissioned for the submission of the Pharmacy Guild and the Pharmaceutical Society went further, and indicated that such good pharmacy service is largely taken for granted by consumers³⁹. Nevertheless, consumer evidence to the Review tends to suggest that many pharmacies' emphasis on quality of service is relatively indifferent and patchy⁴⁰.

Any indifferent approaches to customer service by at least some pharmacist proprietors and their staff is understandable. A poorly performing pharmacist proprietor can be comfortable in the knowledge that he or she is not exposed to the competition of more aggressive and commercially able non-pharmacist competitors. They are also reassured that the PBS and its pharmacy location rules help to buffer them against competition from new pharmacies entering their immediate catchment area⁴¹.

Indeed, the reservation of PBS income largely for community pharmacists, and therefore for pharmacist-owned pharmacies, is itself a factor discouraging genuine price competition in much of a pharmacy's activities. The prices to consumers of listed PBS items are fixed by the PBS Schedule. Pharmacies are not permitted to discount that retail list price, although they may profit by buying the drug at a discounted wholesale price.

Generally, there is thus no point consumers are less likely to shop around when it comes to their PBS prescriptions, which may flow on to non-PBS medicines obtained from a pharmacy. Given this, and while it is accepted that for non-PBS medicines pharmacies can set their own prices⁴², on the greater part of their business there is no great incentive for a proprietor to compete with other pharmacies on price.

Nevertheless, as consumer groups meeting with the Review highlighted in their evidence, there is some latent but mostly unutilised scope for limited price competition in significant elements of PBS dispensing. PBS items costing less than the patient contribution of \$20.60 can also attract a discretionary point of sale surcharge of up to \$2.53. This sum is not recorded for PBS safety net purposes, and is intended to compensate the pharmacist for the costs of dispensing and advising patients on that low-cost item⁴³.

The Australian Consumers Association⁴⁴ and the Health Consumers Council of Western Australia⁴⁵ separately made the point that pharmacists do not have to pass this cost on to consumers, giving them the opportunity to differentiate themselves from their rivals on price

³⁷ Campbell Research and consulting, *Pharmacy Choices by Australian consumers*, July 1999, pages 3-4. This survey found that 71 per cent of consumers use a pharmacy in their local neighbourhood shopping centre and 25 per cent use a pharmacy in a major shopping centre.

³⁸ *Ibid*, page 5.

³⁹ Pharmacy Guild and Pharmaceutical Society submission to the Review, Volume 6, pages 6-8 and supporting data.

⁴⁰ See, for example, the Consumer Health Forum's submission to the Review. In the course of its informal discussions with stakeholders and consumers, the matter of variable standards of service was also acknowledged needing the attention of professional and industry bodies.

⁴¹ Discussed further in Chapter 3 of this Report.

⁴² In consultations with the Pharmacy Guild and the Pharmaceutical Society, the Review was presented with evidence for specified non-PBS prescription and over-the-counter items that charted, on a price survey of a considerable number of pharmacies, significant price variations. This evidence was argued as demonstrating healthy price competition in the community pharmacy industry. The Review noted this evidence but it also noted, however, that the survey did not show price differences between pharmacies in the same or a nearby locality, and it did not indicate the factors that pharmacies considered in pricing the items. More tellingly, it did not compare non-prescription medicines, such as paracetamol and aspirin (which are also available in certain quantities from general retailers as well as pharmacies) with the prices charged by a sample of those non-pharmacist retailers.

⁴³ These figures are correct as of 1 January 2000.

⁴⁴ Australian Consumers Association submission and consultations with the Review, 19 August 1999.

⁴⁵ Western Australian Health Consumers Council consultations with the Review, 24 August 1999.

grounds. Yet, as the Western Australian Branch of the Pharmacy Guild agreed in its evidence to the Review⁴⁶, few if any pharmacies pass up the opportunity to waive the discretionary surcharge. The Review understands that this charge is seen as by many pharmacists as some compensation for the professional time spent on dispensing and advising on prescription items that in themselves bring a limited profit return to the business.

In respect of genuine price competition, therefore, the PBS and ownership restrictions sustain an operating environment in which pharmacy proprietors are insulated from the need to compete with equally or more efficient and price-minded businesses.

Removing restrictions on the entry of non-pharmacist proprietors to the community pharmacy industry might well introduce different entrepreneurial perspectives into a largely homogenous industry. Quite apart from potentially being more competitive in terms of their cost and operating margins, such new entrants could also go a long way to shaking up any pharmacies' complacent attitudes to both price and service competition.

To their credit, the pharmacy profession and community pharmacy industry are facing up to these challenges in terms of major revisions of professional standards by the Pharmaceutical Society, and the Pharmacy Guild's implementing a Quality Care accreditation programme for pharmacies and pharmacy staff. If such initiatives were brought about at least partly by the possibility of competition reform, they demonstrate the benefit what should be an achievable ongoing commitment to the needs and expectations of their customers and clients driving pharmacies' business-related planning and decision-making.

Who bears these costs?

The community carries the overall cost of this restriction on competition in terms of the prices paid for subsidised and unsubsidised pharmacy goods and services, although this is as a trade-off for its access to a diffuse and localised community pharmacy network. It also pays a cost if a significant number of pharmacies are not highly driven by competitive pressures to offer consumers the best possible service at the lowest possible price.

Potential but ineligible pharmacy proprietors carry the cost of being deprived of the opportunity to enter the community pharmacy market, and therefore being deprived of the opportunity to offer consumers similar services, still provided by professionals, but potentially at lower costs and prices than many existing providers. Those efficient and enterprising current providers also lose to an extent by way of an industry climate and a PBS structure that do not necessarily stimulate strong competition between providers, and may frustrate their scope to expand their operations.

The industry, as a whole, bears the cost of having to confront and change a customer service culture overshadowed by regulation and subsidy. The actual outlay costs of developing and implementing quality development and assurance programmes for pharmacies and pharmacists when quality service should be axiomatic is a financial consequence of this culture.

⁴⁶ Western Australia Branch of the Pharmacy Guild, consultations with the Review, 26 August 1999.

Restricting sources of industry innovation

Ownership restrictions carry costs to consumers and the community in terms of regulation both promoting the stability of the community pharmacy industry's profile, while keeping out of the industry of potential new sources of talent, drive and innovation.

At present, community pharmacy is a relatively closed professional community. Recent statistics suggest that pharmacist proprietors tend to be older, predominantly male, and many are no longer in active practice⁴⁷.

The long tradition of interdependence between retail pharmacy and pharmaceutical wholesalers also promotes a static industry outlook. This is reflected in major wholesalers' sponsoring pharmacy banner group and franchise arrangements, and advancing business loan guarantees to pharmacists and assisting pharmacists' raising of business capital. This very intimate relationship between community pharmacists and wholesalers is highly central to the way that the community pharmacy industry is presently distributed and constituted⁴⁸. Pharmacists could seek similar assistance from other sources of capital, but on the whole the wholesaler-pharmacist nexus remains predominant through its accessibility.

The arrangements between government and industry, incorporated in the Australian Community Pharmacy Agreement, also lean towards favouring the *status quo* in terms of who are eligible to own and operate a pharmacy. The fact that the Pharmacy Guild negotiates the Agreement with the Commonwealth on behalf of all pharmacy proprietors itself implies that independent pharmacist proprietors are seen as a pharmacy ownership norm by policy-makers.

These can be benefits, but there are also several significant and notable costs.

Significantly, this environment discourages the widening of potential sources of industry capitalisation and financing, diversifying potential influences on pharmacy businesses' shapes and directions. Current restrictions, including not allowing non-pharmacist minority shareholdings in pharmacy businesses, make such capital diversification unlikely. They also commit pharmacy businesses to their traditional reliance on debt financing backed by generous "white knights" as guarantors.

The prevention of new entrants to the industry also prevents the development of a more heterogenous pharmacy industry and market. These new entrants would have to establish and keep market share against established and experienced pharmacist competitors. To establish their credentials with consumers, and to perform competitively against seasoned rivals, they would need to offer better and consistent professional services. In return, established pharmacies wishing to maintain their own competitive edges over non-pharmacist competitors would have a great incentive to improve and maintain their own quality of professional service to their customers.

The narrow structure, and interpretation, of existing pecuniary interest provisions in State *Pharmacy Acts* also discourage new and innovative associations between pharmacies, other businesses and "non-traditional" sources of capital. If these restrictions were simplified or removed, there would not only be progress toward greater economies of scale and scope but,

⁴⁷ Australian Institute of Health and Welfare, *Pharmacy Labour Force 1994*, December 1996, Table 10.

⁴⁸ Sigma Pty Ltd's submission to the Review sets out the working nature of this interdependent relationship between wholesalers and retail pharmacies.

just as importantly, there would be an inflow of capital investment and outside ideas into an industry that has traditionally been relatively insular and self-contained⁴⁹.

As an indicator of what might be possible, the ongoing presence of friendly society pharmacies in most States, however circumscribed, seems to act as a spur to independent pharmacies to enhance their own performances and to maintain such quality. Was pharmacy proprietorship opened up further, it is possible that change could bring overall benefits to the community, and to the industry itself, in terms of diversity, vibrancy, and entrepreneurial thinking.

The question is thus whether the costs arising from restricting pharmacy ownership outweigh any community benefits from opening it up.

Who bears these costs?

Arguably, in this respect the community bears a cost because new entrants to the community pharmacy industry, who can bring fresh ideas and innovative practice, or spur established competitors to perform better, cannot contribute to the industry.

Potential new entrants to the industry also bear a cost, as they themselves are deprived of the opportunity to put their entrepreneurial vision and leadership into practice, and gain appropriate returns from such investment and initiative, simply because they are not registered pharmacists.

The existing community pharmacy industry itself is a potential bearer of a cost, if it is closed to fresh ideas from outside its ranks of achieving satisfactory business and professional outcomes.

Constraints on consumer choice

Restrictions on pharmacy ownership can be seen as guarantees of the nature and quality of pharmacy services. They also act, however, to preserve and entrench a particular mode of delivery of those services – mostly small to medium sized shopfront pharmacies in street shopping strips and shopping centres, trading in isolation from other.

If ownership arrangements were made more open, consumers might see cost savings and more competitive service from all pharmacies. They may also see real convenience gains from such opportunities as doing a range of shopping on the same site, and having easy access to community pharmacy services up to 24 hours a day.

Similarly, if a pharmacy is linked to a department or chain store, a mail order or Internet distributor or even to a small to medium general business, consumers may benefit by the range of shopping and convenience choices available to them. This is especially so if those choices are reinforced by lower prices and greater range of selections for at least some products and services. Current restrictions either prevent such possibilities, or make them unlikely.

⁴⁹ This is acknowledged even by key supporters of pharmacy ownership restrictions: see the Commonwealth's submission to the Review, para 3.7.

Who bears these costs?

The community bears a cost in that consumers have access only to the mode and range of pharmacy providers that governments, and the pharmacy industry, determine to be appropriate for them. Individual consumers lose from being not being able to have their demands for convenient and flexible services listened to and acted upon by both governments and pharmacy businesses.

Many pharmacy proprietors also lose, in that they are constrained from being more innovative in meeting consumer needs and demands if they see an opportunity. Potential commercial partners, including non-pharmacist retailers wanting to develop an association with a pharmacy business, are also deprived of the possibility to participate in an area of challenge and opportunity. This is especially so if they lose the opportunity to both benefit commercially themselves and to add value to consumers' pharmacy services.

BENEFITS OF THE RESTRICTIONS

Against costs such as these, however, the overall restrictions on pharmacy ownership also have a range of benefits of an economic, administrative and social nature. These include:

- Underpinning the ease of Australians' access to community pharmacies wherever they live;
- Assisting the efficient allocation of scarce public resources on pharmacy services, and medicines generally;
- Improving the capability to link community pharmacy, through professional proprietorial involvement, to overall health care provision and multi-disciplinary service provision;
- Promoting industry-wide awareness of professional pharmacy objectives as well as commercial objectives; and
- Maintaining a direct line of accountability for professional services conducted in pharmacies.

Access to pharmacy services

Promoting local access to pharmacy services and medicines

There is a strong case for suggesting that there is a public benefit in ensuring, through appropriate regulation, that all Australians have reasonable equality of access to community pharmacy services wherever they may live.

As the two government submissions to the Review suggested⁵⁰, community pharmacy is central to the delivery of quality health and welfare service to all Australians, regardless of their social background or where they live. The presumption, particularly in the Commonwealth's submission, is that pharmacist ownership of most community pharmacies is a key to a professional yet local pharmacy presence, and therefore to the equality of access to pharmacy services.

The Pharmacy Guild and Pharmaceutical Society also stressed this community service role very strongly in developing their submitted case in favour of preserving existing restrictions on ownership⁵¹.

⁵⁰ The Commonwealth Government and the Government of Western Australia.

⁵¹ Pharmacy Guild and Pharmaceutical Society submission to the Review, Volume 1, pages 26-27.

Community pharmacies have become integral participants in the overall network of community-based health care services. Pharmacists are being expected to widen their professional role, and to diversify the services that they are expected to provide while still maintaining the localised shopfront service that they have provided to the community over many decades.

A localised pharmacy presence also seems to be something that many consumers want, whether or not pharmacies are actually owned by a pharmacist. As market research commissioned for the Commonwealth indicates, convenience, proximity and ease of access is the most important choice for many pharmacy customers⁵².

The other significant access factors to be considered in this context are the access and equity questions of ensuring the reach of pharmacy services to Australians in rural and remote areas, and their relationship to promoting regional and community development⁵³. These areas may be commercially unattractive to large non-pharmacist retailers such as supermarkets and large department stores, which could be expected to concentrate their services in a given regional centre. If so, those smaller pharmacy businesses in surrounding areas may close, to the detriment of local communities' access to services, and with flow-on effects to those communities such as losses of jobs and of social and economic infrastructure⁵⁴.

Who benefits?

The community benefits from having a diffuse network of community pharmacies in locations that are convenient and accessible. This is particularly important for Australians in rural and remote areas who may fear for the continued existence of not only their pharmacy services, but for their entire regional health and social infrastructures. There is also a community benefit in that the system of small and medium scale pharmacies convenient and proximate to where people live.

Federal, State and Territory governments benefit because they have a reasonable coverage of pharmacy services, which is especially important given the general policy priorities of maintaining and enhancing essential services in rural and remote areas. They also have access to pharmacies as potential outlet points for not only medicinal, but also for other health services and programmes.

Pharmacists themselves also benefit because a diffuse network of pharmacy businesses means a greater potential for ownership-minded pharmacists to buy their own pharmacy business, or to enter partnerships and corporate associations with other pharmacists.

More effective use of scarce community resources

An arguable benefit of present ownership arrangements is that the stable Australia-wide network of mostly pharmacist-owned pharmacies helps governments to keep a lid on the overall costs of health care. It assisting the Commonwealth to manage a large demand-driven PBS outlays. Pharmacists may also, in individual cases, make low-level interventions in clients' health treatment that may remove or reduce the need for more complex and expensive treatment, such as through admissions to public and private hospitals.

This could be said to be an externality issue.

⁵² Campbell Research and Consultancy, *Pharmacy Choices of Australian Consumers*, July 1999.

⁵³ This was an intangible benefit of present arrangements as suggested by the Review's commissioned report by Applied Economics Pty Ltd.

⁵⁴ Review's consultations with a representative of the Rural and Isolated Pharmacists Association of Australia, 2 September 1999.

Pharmacy and pharmacist intervention in patient care

In a professionally-controlled pharmacy environment, pharmacist interventions in the diagnosis and treatment of minor ailments and other conditions can result in savings to the health care system through reduced or avoided outlays. Pharmacist ownership, while probably not itself responsible for such interventions, can promote a culture in community pharmacy encouraging pharmacist and staff commitments to professional care and service.

This has been a major part of the case for the retention of ownership regulation, but generally has been based on observation rather than empirical evidence. In light of this, the joint Pharmacy Guild and the Pharmaceutical Society submission to the Review included a commissioned analysis by KPMG Pty Ltd of the quantifiable benefits, in dollar terms, of pharmacy-level interventions against the quantifiable costs of ownership restrictions⁵⁵.

KPMG sought to adapt and apply earlier American research and analysis examining pharmaceutical-related hospital admission rates to comparable Australian cases. Using some complex methodology and analysis, the KPMG study concluded that Australia's lower comparable admission rate, and the quantifiable savings per foregone admission and other cost offsets (such as workplace absenteeism and sick leave costs) could be attributable directly to differences between an localised and customer-friendly and pharmacist owned Australian community pharmacy system, and the American largely chain-dominated pharmacy industry with different perceived customer priorities⁵⁶.

The Review considered this analysis, having taken into account the broader analysis of the 1985 Bureau of Industry Economics (BIE) study of community pharmacy⁵⁷. While looking at a range of factors, the BIE study did not, however, seek to quantify care-based costs and benefits of specific activities by pharmacists in areas such as advice and counselling to patients, low-level treatment of common ailments (such as recommending medications for colds and flu), the provision of public health services such as diabetes and blood pressure screening, and the delivery of drugs of dependence interventions such as methadone and naltrexone programmes.

KPMG concluded that these annual quantifiable benefits could be valued in the range of \$640-\$1,365 million, against a quantifiable cost of the restrictions of \$93 million⁵⁸.

To consider these KPMG findings, the Review commissioned a critical evaluation of that study by another consultancy group, Applied Economics. Applied Economics concluded that the actual quantifiable benefits of pharmacist ownership, in dollar terms, can be the subject of

⁵⁵ The KPMG analysis is reported in detail in the Pharmacy Guild and Pharmaceutical Society submission to the Review, Volume 3, pages 55-64.

⁵⁶ Ibid.

⁵⁷ Bureau of Industry Economics, *Retail Pharmacy in Australia – An Economic Appraisal*, Canberra 1985.

⁵⁸ Using Australian and relevant overseas data, including the costs of pharmaceutical-related hospital admissions, savings arising from pharmacists' early trouble-spotting and the treatment of minor ailments, and savings on prescription costs based on a survey finding that consumers may be willing to pay more to have their prescriptions filled by a pharmacist-owned pharmacy, KPMG sought to quantify the annual benefits of the current system. Their summary conclusions were:

Lower levels of hospitalisation	\$230-415 million
Economical health care	\$410 million
Contingent valuation estimate Of ownership provisions	\$347-\$540 million
Total estimated benefit	\$640-\$1,365million

Against this, KPMG suggested that the cost to the community of the ownership restrictions, particularly in terms of applying brakes on efficiency gains due to economies of scale and scope, is in the region of \$93 million a year.

debate⁵⁹, but it did not dismiss the KPMG conclusion of a quantitative net public benefit from the regulatory framework of the community pharmacy industry, including pharmacy ownership.

While the two studies differed on the estimated dollar value of the net dollar benefit and the basis on which it is calculated, the Review believes that quantifying outcomes of this nature is complex and difficult. The equation contains too many potential variables to ever settle on a precise figure, or even a range of figures. There is, therefore, probably no one definitive answer to the question of how many dollars the community may save due to pharmacy-related interventions in health care, and how these may be offset against outlays such as funded GP visits taken on a pharmacist's advice.

The crucial analytical question is to ask simply whether the evidence suggests pharmacist ownership adds value to the community's overall state of health, and to the quality and efficacy of the nation's overall health and community care infrastructure. The evidence of the Applied Economics and KPMG analyses seems to support this contention.

Management of Pharmaceutical Benefits Scheme costs

While it is not related directly to the operation of State and Territory *Pharmacy Acts* and their regulation of ownership matters, the other relevant area of cost control is the management of PBS outlays.

Section 90 of the Commonwealth's *National Health Act 1953* accepts as a "pharmacist", for the purposes of the Act, an entity approved under a State or Territory law to operate a pharmacy. While stability in the community pharmacy system has its costs, in terms of the managing the PBS it clearly has its benefits. By dealing with a relatively narrow class of pharmacy providers, the Commonwealth can plan PBS growth and service provision on a basis of considerable certainty, having greater confidence that practice across the industry is more or less consistent, and not having to adjust provision strategies to reflect a variety of owning entities⁶⁰.

As a result of cooperation between the Commonwealth and the Pharmacy Guild (as the body representing independent pharmacy owners), the two Australian Community Pharmacy Agreements have realised new savings to government of around \$200 million⁶¹. If this is the case, there does seem to be some validity in the proposition that a stable PBS distribution system based on pharmacies with restricted ownership arrangements helps the community to obtain a reasonable equality of access to pharmaceuticals to the Australian community, at a broadly manageable cost.

In its submission, the Commonwealth also notes that the cost of delivering medicines to consumers under the PBS, as set out in the Agreement, is underpinned by a pharmaceutical wholesale network geared to the needs of individual community pharmacies. Any changes to these arrangements could change the cost structures of the pharmacy wholesale-retail network as a whole⁶².

Working with a wider range of pharmacy proprietors arguably could make the task of reaching a workable set of outcomes would be more difficult for government to administer

⁵⁹ Applied Economics, *Qualitative Evaluation of Public Benefit from Pharmacy Legislation*, October 1999, pages 14-15.

⁶⁰ Commonwealth submission to the Review, especially para 3.33-35.

⁶¹ *Ibid*, para 1.31.

⁶² *Ibid*, para 3.25.

and achieve in taxpayers' best interests. It would probably also require the Commonwealth to open up industry-wide negotiations on PBS pricing and remuneration matters with a broader range of parties than it does at present, with the consequent difficulties that would mean for obtaining consensus on PBS remuneration levels and how these are arrived at.

Who benefits?

Under this argument, the community benefits in terms of lower and more manageable health outlays, and through avoiding or reducing other costs of illness and injury (including indirect costs such as workplace absenteeism) that might otherwise have been incurred if not for pharmacy or pharmacist intervention. The community also benefits through existing industry arrangements, including pharmacy ownership generally restricted to professional pharmacists, working harmoniously with the operation of the PBS.

The community pharmacy industry benefits through being able to plan on the basis of systemic stability, and the pharmacy profession benefits through the stimulation of a professional environment that stimulates community pharmacists to use their professional training and talents to the fullest possible extent as members of a wider health care "team".

Better linking pharmacy to overall health care provision

Ensuring that pharmacies and pharmacists, as professional facilities and individuals, play a legitimate part in Australia's overall health care infrastructure is an important consideration in looking at ownership-related restrictions. This can be seen as beneficial to use appropriate regulatory mechanisms by ensuring that pharmacies are effective participants in a wider health care framework, and that professional and patient considerations are foremost concerns for the pharmacy proprietors responsible for services delivered in their pharmacies.

As health care trends and clinical practice continue to evolve, pharmacy and pharmacists are increasingly being called upon to participate in a range of health and community care activities going beyond the traditional role of filling prescriptions, medication management and advice. This includes encouraging the quality and wise use of medicines by consumers, delivering public health programmes to the Australian community, such as methadone dispensing and needle exchange, baby and maternal health, and screening and care management programmes for acute and chronic conditions.

Most recently some pharmacists have been involved in coordinated care trials aimed at exploring new and innovative ways of practitioners coordinating the care needs of aged and chronically ill patients.

As pharmacist training continues to gear itself to the needs of multi-disciplinary health care provision, the ability of proprietors and staff pharmacists to work cooperatively with other health professionals is expected to become more important.

The submissions of the Commonwealth, the Western Australian Government and the Pharmacy Guild and Pharmaceutical Society, amongst others, placed some emphasis on this wider health care management role in the regulatory equation. The Commonwealth put the position thus:

With a different ownership structure, different strategies would need to be considered to ensure that pharmacists participate in public health campaigns and cooperated with other health services providers in providing coordinated care to those in the community with chronic and/or complex health conditions. It could

*be expected to become more difficult to design such strategies when part of the industry was incorporated within a broader retail structure.*⁶³

The Pharmacy Guild and Pharmaceutical Society were blunter. In doing so they highlighted the inherent paradox in community pharmacy proprietors between their roles as health care practitioners and commercial businesses. They commented:

*In an unregulated environment where there was greater pressure on margins, community pharmacists would be forced to rationalise services not fully recovering costs, such as their health advisory services*⁶⁴.

Presumably, on this view pharmacist proprietors would continue to offer free and low-cost advice and counselling services if the restrictions on pharmacy ownership are maintained.

More specifically, pharmacies are an integral part of rural and remote areas' health infrastructure. If small pharmacy businesses leave country towns, particularly outside larger regional centres, as matters stand they are unlikely to be replaced.

Besides the detrimental effects on the overlapping network of country doctors, nurses, dentists and other health workers, there is a loss of employment opportunities in those localities for pharmacists and support staff. Small pharmacist-owned businesses may have a greater affinity and commitment to these places, and their small business nature would be consistent with the character and needs of many rural and remote communities⁶⁵.

Who benefits?

Involving pharmacists more fully in the health care delivery framework could benefit the community as a whole, and governments in particular. This is because it may help open up new and innovative approaches to care delivery, and do at a reasonable cost. It also benefits pharmacy businesses and professional pharmacists in that it both opens up new possibilities for earning income and profits, with accompanying potential benefits for returns on business and professional investments.

Placing professional considerations first in pharmacy decision-making

A benefit of restricting pharmacy ownership is that a pharmacist proprietor is arguably more likely to place professional judgments before commercial considerations than a non-pharmacist or, as it is sometimes expressed, "put people before profit". This assumes that a pharmacist is prepared *not* to sell or provide a given medicine or service to a consumer, if there is a professional judgment that the sale would be unwise or unnecessary.

Being accountable directly to regulatory authorities for the professional direction of their pharmacy practice, registered pharmacist owners arguably have an obligation as both proprietors and professionals to ensure that the provision of pharmacy services under their control is safe and competent. As businesspeople, pharmacist proprietors can be reminded by regulators and their professional associations that they have community obligations as professionals, as well as having a profit motive for themselves.

Even if they are not active in the day-to-day affairs of the pharmacy, pharmacist proprietors' status as members of their profession has given them a sense of tradition and ethics which

⁶³ Commonwealth submission to the Review, para 3.34.

⁶⁴ Pharmacy Guild and Pharmaceutical Society submission to the Review, Volume 3, pages 57-58.

⁶⁵ Review consultations with the National Rural Health Alliance and the Rural Pharmacists Association, 31 August 1999.

should help them at least to understand and promote ethical and competent practice in their pharmacies. This is especially important when the interaction between pharmacists and members of the public on professional matters involves an information asymmetry between the parties, where the pharmacy business as a whole holds itself out as competent and expert in matters which to lay consumers are arcane, mysterious and highly complex.

This is not to say that non-pharmacist proprietors are not capable of building such a professional culture into pharmacies that they operate. Friendly society and surviving corporately-owned pharmacies in Australia do promote professional values in their operations. What this argument takes into account, however, is that a professional as a pharmacy proprietor is more likely to guarantee that if a judgment needs to be made between the business's interests and the customer's medicinal and health-related needs, the interests of the client will prevail.

Who benefits?

Regardless of who actually owns a pharmacy, the community benefits if pharmacies and pharmacists are encouraged through regulatory arrangements to treat individual customers as clients deserving of quality care and attention.

If pharmacist proprietorship of pharmacies reinforces and adds value to the professional dimension of a pharmacy business, even in the face of basic commercial pressures such as running a viable and profitable business, then the community may well be better off with the current ownership restrictions in place.

Professional pharmacists benefit in that their "boss" is likely to be a fellow pharmacist, with a similar professional outlook and a similar commitment to quality pharmacy care. Communication between a pharmacist proprietor and a staff pharmacist on professional matters may also be easier to manage and act upon than a similar dialogue between a non-pharmacist proprietor and a pharmacist staff member.

Consumers benefit because it is easier to identify or assume that the pharmacy is a professional service run on professional lines. Just as registration is a signpost to a pharmacist being competent to practise, pharmacist proprietorship can be seen as a signpost to the pharmacy being a professional practice first, to which other lines of business conducted on the premises should be secondary.

Simplifying lines of accountability for professional pharmacy services

The existing ownership restrictions simplify lines of professional accountability in pharmacies. A professional proprietor can be liable for not only his or her own professional conduct, but also for that of staff pharmacists and non-qualified staff working under professional direction. Keeping the number of pharmacies per proprietor to a finite number can be seen as the regulatory enforcement of this concept of personal proprietorial supervision.

A non-pharmacist individual or corporation arguably would not be as easy to deal with in terms of a regulatory authority's supervision of professional activity within a pharmacy. This is especially so given that authorities are generally self-funding and have limited resources of their own. Not only would a non-pharmacist corporation's directors probably also be non-pharmacists, a well-resourced corporation unhappy with a regulatory outcome would

possibly be more financially able than the regulatory authority to fight protracted litigation on contentious matters⁶⁶.

This is not to say that non-pharmacist corporations would not be responsible for professional actions taken under their control⁶⁷. Indeed, the existing examples of overseas corporations, and friendly societies and grandparented proprietors in Australia suggest that, on a moderate scale, there are precedents for suggesting that this is feasible. The provisos would be that a pharmacist is always in charge of a corporately-owned pharmacy, and that there is a point of accountability for the corporation itself to regulatory authorities for professional matters.

On the other hand, the wide-scale presence of non-pharmacist corporations, however, inevitably would mean a significant reconfiguring of professional regulatory processes to undertake the supervision of their operations. State and Territory regulatory authorities, as part-time and self-funding bodies, would need to have the resources to deal effectively with new and cashed up non-pharmacist proprietors and related accountability arrangements.

Jurisdictions may also need to amend legislation, and to provide Boards with additional resources, to cover the additional costs of administering both these arrangements and from defending Board decisions in administrative and judicial review processes against corporations with resources large enough to contest these decisions aggressively.

Who benefits?

Under this case, the community benefits in terms of ensuring that their pharmacies, and those who own them, are readily accountable to regulatory authorities, and ultimately to the community, for their actions.

Regulatory authorities and governments benefit in that the regulatory structures currently governing pharmacy practice are manageable and affordable, and that all proprietors and managers are not beyond the reach of their accountability mechanisms.

Non-proprietor pharmacists themselves benefit because their chain of accountability is clear, and because their employer, if also a registered pharmacist, cannot leave them to take sole blame as professional scapegoats for unsafe and incompetent practices in their pharmacies.

ALTERNATIVES TO THE RESTRICTIONS

If the purpose of the overall ownership restrictions is to ensure equal access to safe, competent and independent pharmacy services, there may be other alternatives to the various restrictions on ownership and pecuniary interest in a pharmacy that may achieve similar results with more open ownership arrangements.

Alternatives include:

- “Negative licensing” of pharmacy proprietors;
- Establishing an enforceable industry code of practice to be upheld by all pharmacy proprietors;

⁶⁶ See, for example, the arguments put by the Pharmacy Board of Queensland in its submission to the Review, pages 2-6.

⁶⁷ Indeed, friendly society pharmacies are already accountable to Pharmacy Boards through their own boards of management. In its consultations with regulatory authorities, the Review found general satisfaction with the working of these arrangements. There is no reason to believe that the same principle could not be extended to non-pharmacist individuals and corporations.

- Allowing the participation of non-pharmacists in ownership structures who are not relatives of the pharmacist or pharmacists in control; and
- Replacing pecuniary interest rules with penalties for improper interference in the professional practice of a pharmacist.

NEGATIVE LICENSING

Under a negative licensing model, persons and companies could be assumed eligible to own a pharmacy unless they breach prescribed prohibitions. If a person or entity was found by a regulatory authority, review body or a court to have breached these prohibitions, they could then lose the right to own or have a shareholding in a pharmacy.

In a hypothetical negative licensing model, some possible prohibitions could be:

- A person not being of good character or a fit or proper person to practise pharmacy;
- A person or corporation being convicted of specified criminal offences;
- A person or corporation found to have directed or influenced a pharmacist so that the pharmacist engages in unsatisfactory professional conduct or professional misconduct; and
- A person who has been found in breach of a provision of a *Pharmacy Act* and is under a specified professional penalty (eg suspension of registration or deregistration)⁶⁸.

Breaches or offences applying to a company could also apply to the directors and officers of that company. Such criteria could apply to both prospective and existing owners of pharmacies.

Under a negative licensing model, therefore, natural persons and corporations would be entitled to enter the community pharmacy industry as proprietors or shareholders, provided that they do not breach the specified prohibitions. As proprietors or shareholders, they would still be expected to be committed to the safe and competent performance of pharmacy services by their businesses, and to be held accountable by regulatory authorities and the courts for the professional services provided under their supervision.

COMMUNITY PHARMACY CODE OF PRACTICE

Perhaps associated with negative licensing, an alternative to restricting ownership could be to put in place, either on a jurisdiction-by-jurisdiction or national basis, a Community Pharmacy Code of Practice. Such a code could be voluntary or legislative, and could specify minimum standards for the conduct of a competent and professional pharmacy business in a manner that would apply to all pharmacy proprietors, whether they are pharmacists or not.

In consultations with the Review, one major non-pharmacist retailer that argued for open pharmacy ownership made the point that they were bound by a number of industry and statutory codes of practice, in areas such as food handling and public health. This retailer indicated that there would be no difficulty in their complying with a community pharmacy code of practice. Indeed, it was suggested that compliance would not only be in the public interest: it would be in the retailer's interest to assure the consumer of their commitment to providing quality pharmacy services⁶⁹.

⁶⁸ NSW Department of Health, *Review of the Dentists Act: Discussion Paper*, 1999, page 40, has a helpful discussion of negative licensing principles.

⁶⁹ Confidential consultations of the Review with a general retailer, 7 September 1999.

By way of observation, the Review notes that the Pharmacy Guild has invested considerable time and resources in developing its Quality Care accreditation programme for pharmacies. The Quality Care programme is essentially a set of benchmarking standards against which the performance of pharmacies can be measured, and accreditation can be withdrawn if they fail to comply. This programme is notable in this context as a potential model of an industry code of practice, as it has been developed with and adopted by friendly society and grandparented corporate pharmacy groups.

INVOLVING NON-PHARMACISTS IN PHARMACY OWNERSHIP STRUCTURES

In all Australian jurisdictions, corporate ownership structures for pharmacies limit direct shareholding involvement to no wider than controlling pharmacists and certain non-voting shareholder relatives designated by law⁷⁰. If pharmacists' control of pharmacy businesses is in the public benefit, then it may also be permissible to consider the opening of pharmacy ownership structures to non-pharmacists, provided that they do not have the effective control of that business due to either the size of their shareholding or the nature of their interest.

It may not be desirable, for example, to have a medical practitioner as a shareholder, partner and/or director of a pharmacy business if it is possible that that person, as a prescriber of medicines, effectively can control the dispensing activities of that business.

A limited model of non-pharmacist shareholding is operating in at least one overseas jurisdiction⁷¹. If adopted in Australia, such ownership structures may achieve the pro-competitive purposes of injecting new people, ideas and investment into the pharmacy industry, decrease pharmacies' traditional reliance on debt financing, and on guarantees of that financing from wholesaler sources. Such arrangements could still be consistent with the principle of the effective pharmacist control of pharmacy-owning bodies corporate.

REFORM OR REPLACE PECUNIARY INTEREST PROVISIONS

Existing pecuniary interest provisions, however broadly phrased or interpreted, are intended to ensure that the practice of pharmacy by pharmacists can occur without undue or improper outside interference from their peers and from non-pharmacists. Specifically, they are intended to buttress ownership restrictions limiting pharmacy ownership to pharmacists and existing excepted operators, particularly friendly societies and grandparented corporations.

The reach of these provisions arguably has become so broad as to stifle innovation in pharmacy businesses outside the practice framework the provisions themselves were intended to protect. In some jurisdictions, pecuniary issues have been tested by litigation arising from decisions taken by regulatory authorities⁷².

A simple solution would be to replace these provisions with a statutory offence of inappropriate or improper interference with the professional conduct of a pharmacist. The offence, with appropriate penalties for both persons and corporations, would prohibit an outside party from directing a pharmacist, whether a proprietor or employee, in exercising his or her competent and comprehensive professional judgment in the course of his or her duties as proprietor or pharmacist.

⁷⁰ See South Australia's *Pharmacy Act 1991*, section 18.

⁷¹ This jurisdiction is New Zealand. Under the New Zealand *Pharmacy Act 1991*, non-pharmacists may own up to one-quarter of the equity in a pharmacy company, but the operating company may only own one pharmacy.

⁷² See, for example, the 1998 New South Wales District Court and Court of Appeal litigation, *Terry White and Ors v Pharmacy Board of NSW*.

The offence could also apply to pharmacist and non-pharmacist proprietors who may direct their professional and lay staff to act in a professionally dangerous or reckless manner, or to implement commercial decisions ahead of their own professional judgment.

FINDINGS AND CONCLUSIONS

On considering the costs and merits of each of the restrictions on ownership that it has examined, the Review has reached some in-principle conclusions. These are outlined under each set of restrictions.

OWNERSHIP OF PHARMACIES: GENERAL PRINCIPLES

The Review has given very careful consideration to this issue, taking into account identified costs and benefits of existing restrictions and who gains and loses from them, the possible alternatives to them, and the various categories of the Public Benefit Test of the 1995 Competition Principles Agreement.

Determining who may lawfully be a pharmacy proprietor is a question complicated by the fact that the system of community pharmacy itself can be seen as a separate matter from determining who can own a pharmacy. It may be, as industry and professional stakeholders argue, that a professionally-owned pharmacy is integral to its ability to fulfil its professional responsibilities to consumers and the community, and that the system would be damaged or destroyed if current ownership restrictions are amended.

If this argument in itself does not resolve the question, however, it needs to be decided whether any value that pharmacist ownership and control of pharmacies adds to the system justifies maintaining the present regulation of who may own or have a proprietary interest in a pharmacy.

On balance, it is hard to agree with the argument that the whole operation of community pharmacy in Australia depends overwhelmingly on who may or not operate a pharmacy. Clearly, pharmacies run by friendly societies and grandparented for-profit corporations not only survive, but flourish. Similarly, pharmacies run by non-pharmacist corporations, whether independently or part of a wider retail operation, do operate viably and competently overseas, although there is some debate about the nature and quality of their professional services⁷³.

That non-pharmacist proprietors are capable of providing safe and competent pharmacy services suggests that allowing new non-pharmacist proprietors would not necessarily destroy the local pharmacy network and infrastructure to which Australians have become accustomed. It certainly would not be in non-pharmacist proprietors' commercial interests to expose themselves to the risks of loss or income or profit, or litigation, due to their pharmacies being unsafe or incompetently run.

The question then becomes whether the value added to the provision of safe and competent pharmacy services, through pharmacists' ownership of pharmacies, itself justifies the regulation that underpins it in the States, if not the Territories.

⁷³ See, for example, the Pharmacy Guild and Pharmaceutical Society submission, Volume 8; and Alistair Lloyd, *The Regulation of Pharmacists and Pharmacy Businesses*, 1998, volume 1.

Having considered the evidence, and the cost-benefit arguments set out earlier, the Review believes that there is a net public benefit from the value-added dimension of pharmacist ownership of pharmacies, as it defines ownership in Chapter 1 of this Report. It also believes that these factors outweigh the costs associated with maintaining these restrictions, particularly in terms of the costs of a relatively static industry character, an enforced absence of the innovative energies of non-pharmacist entrepreneurs, managers and businesspeople and, particularly, a freer market for pharmacy services.

How does pharmacist ownership add value to pharmacy services?

One of the hidden factors behind the Australian community pharmacy sector is that it has not been dominated by large corporations. Rather, it has concentrated on localised pharmacies in shopping strips around Australia, and more recently in large suburban and regional shopping centres. It has based its presence on a foundation on thousands of small businesses, providing localised services to local communities.

In the Review's opinion pharmacist proprietorship, as underpinned by existing restrictions on who may own pharmacies, confers a range of public benefits that outweigh the cost of associated regulatory restrictions. These can be expressed in terms of the actual and potential quality of professional services under the supervision of a professional proprietor, and accessibility to those for people in all parts of Australia. Pharmacist proprietorship also assures a line of professional accountability for pharmacy services from consumer, to supervising pharmacist, to proprietor to regulatory authority.

More specifically, pharmacist ownership of pharmacies adds value to pharmacy services and public confidence in those services in a number of ways. These include:

- A pharmacist who owns or has a proprietary interest in a pharmacy has a professional, as well as a commercial, interest in the safe and competent provision of pharmacy services and products by his or her business;
- It is important that, in the interests of public safety and the best use of medicines, pharmacies focus on their professional responsibility in ways that recognise the effects of information asymmetries between the pharmacist and their consumers;
- As a pharmacist as well as a proprietor, the business owner is accountable directly to a regulatory authority for the safe and competent provision of those services, while non-pharmacist proprietors would not be able to be made readily accountable without a major and potentially costly readjustment of the regulatory infrastructure;
- There is a net public policy benefit in promoting pharmacist proprietorship and control in the community pharmacy industry to maximise the distribution of pharmacies into the wider Australian community, to encourage proprietors to have a more direct relationship with a local community to promote through the wise use of medicines, and to ensure the maximum possible social and geographic reach of the community pharmacy network;
- The Pharmaceutical Benefits Scheme, as the prime vehicle for distributing subsidised essential pharmaceutical medicines to all Australians, is predicated on the stability of this distribution network. While this may mean that new entrants are discouraged, undue changes to that network could mean the costlier and less effective delivery of PBS medicines to people in need of them; and

- There is a significant net quantitative benefit to the community from reduced and unnecessary expenditure due to the sensible intervention of professionally oriented pharmacies in the health care cycle, such as in reducing pressure on general practitioners in the treatment of minor ailments. Having pharmacists owning as well as managing pharmacies helps to reinforce this professional role and culture.

Maintaining the value

These conclusions are, however, tempered by evidence given to the Review, particularly from consumer interests, that consumer experience indicates that the levels of services received at pharmacies is often less than optimal. Those pharmacist proprietors who allow themselves and their staff to be complacent or indifferent to the needs of their clients do not strengthen public perceptions of the quality of their fellow proprietors⁷⁴.

In favour of the Review's on-balance conclusion, however, are positive indications that the pharmacy profession and industry as a whole are taking seriously the need to keep substantiating their ownership privileges. As part of professional self-regulation activity, professional standards and industry quality assurance benchmarks have been given considerable attention since competition matters went on to pharmacy's agenda some years ago.

Such initiatives are essential to the ongoing support of a professionally-oriented community pharmacy sector. It is important that pharmacists should take responsibility for and participate in such programmes and follow such standards, even if this involves considerable personal investments of their own time and money. Such measures are disregarded by pharmacists at the risk of attracting considerable future questioning of their ongoing ownership privileges.

Coverage of Territory Acts and other ownership-related regulation

The Review also believes that the Australian Capital Territory and Northern Territory *Pharmacy Acts* are ambiguous on the pharmacy ownership question. As they stand, they could fall within the boundary of acceptable regulation as set out in Recommendation 1, and therefore there is no need for the two Territories to amend their Acts to conform to the recommendation⁷⁵.

Beyond this basic principle, however, it is important that as much regulation as possible is removed from the conduct of community pharmacy practices and businesses.

Much of the existing regulation on ownership-related matters, in areas such as the number of pharmacies a proprietor may own, dates from another time and an earlier era of pharmacy practice. It either has limited public benefit, or holds pharmacy operators back in the maintaining and enhancing of quality of services by innovation and the adoption of flexible and contemporary business structures and practices.

The recommendations in this Chapter seek to address key elements of these regulatory failings, from the starting point of Recommendation 1.

⁷⁴ See, particularly, the submissions to the Review by the Consumers Health Forum and the Australian Consumers Association. The Review's consultations with the Health Consumers Council of Western Australia told a similar story.

⁷⁵ For further comment, please refer to the reports on each Act in Part B of this Report.

Recommendation 1

The Review recommends 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.

Residential and local registration requirements

On a related matter, the Review also concludes that legislation requiring a proprietor to be a resident of a given State or Territory restricts competition in the community pharmacy industry, and runs contrary to established national principles of mutual recognition and occupational mobility. In the one State where such legislation is in place, Western Australia, it is highly desirable and in the interests of national regulatory consistency that residential restrictions on ownership be removed.

It is equally desirable that other jurisdictions do not institute residential requirements of their own, as has been suggested by some pharmacy profession and industry stakeholders⁷⁶. On the other hand, the Review notes that ownership provisions in most *Pharmacy Acts* provide that the owning pharmacist is registered under that Act – that is, registered in the jurisdiction in which the owned pharmacy is located. While this does not require a pharmacist to be registered in a jurisdiction, it is still a location-based restriction.

The Review accepts, however, that requirements of this nature are justifiable for the time being, but should ideally be removed over time. If a proprietor is to be accountable to local regulatory authorities for the conduct of a pharmacy, they have to be assumed as being conversant with the laws and professional requirements of the local jurisdiction. Registration in the jurisdiction is a mechanism that helps to assure this.

It would, however, also be highly desirable if jurisdictions moved over time to recognise each other's registration for pharmacy ownership purposes. If so, the step of acquiring parallel registration to own a pharmacy in another State or Territory would become unnecessary, and the costs to potential proprietors of having dual or multiple registration would be avoided.

Recommendation 2

The Review recommends 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.

OWNERSHIP STRUCTURES

Types of ownership structures

At present, State and Territory legislation permits a number of ownership structures for pharmacy businesses. These can be grouped as:

- Single pharmacists sole trading;

⁷⁶ See especially the Pharmacy Board of New South Wales's submission to the Review, page 6.

- Partnerships of registered pharmacists; and
- Incorporated bodies consisting, with a notable exception in South Australia, entirely of registered pharmacist shareholders.

In several jurisdictions, current or impending reviews of *Pharmacy Acts* are considering legislative coverage of pharmacist-controlled bodies corporate to enable pharmacy proprietors to take greater advantage of modern corporate structures, and the taxation and other benefits that these may bring. Nevertheless, the majority of pharmacy businesses are either sole traders or traditional partnerships.

Existing ownership structures

The Review considered the ownership structures for pharmacy businesses permitted currently by *Pharmacy Acts*. It believes that, on balance, these permitted structures are consistent with the basic principle of effective and undisputed pharmacist control of pharmacy businesses.

These structures are not consistent across all jurisdictions. The family company model, for instance, is confined to South Australia. There would be merit, in promoting cross-border competition and occupational mobility, to have a national consensus on permitted ownership structures, so that the existing permitted ownership structures are the same in every State and Territory.

As a starting point, all *Pharmacy Acts* should permit appropriate corporate structures that acknowledge pharmacist control. Given the major changes to companies and corporations law, and the taxation system, in recent years, the Acts are lagging well behind good commercial practice. Proprietors should have the benefit of the ownership structure that best meets the needs of their business, and of their customers.

Non-pharmacist shareholdings in pharmacy businesses

Consistent with Recommendation 1, the Review believes that ownership structures for pharmacy businesses need to reflect the general principle that registered pharmacists have effective and undisputed control of for-profit pharmacy businesses. As outlined in Chapter 1, the Review believes that one or more pharmacists effectively own a pharmacy business if they have the effective and undisputed control of that business, whether or not they themselves own all shares in the business.

To have effective ownership, therefore, does not necessarily require registered pharmacists to have possession of all shares in a corporatised pharmacy business. Indeed, the South Australian *Pharmacy Act* allows designated family members to own minority shareholdings without voting rights, giving registered pharmacists effective and undisputed control of the corporation. This shareholding option was endorsed enthusiastically by the Pharmacy Guild and the Pharmaceutical Society in their submission⁷⁷.

In the Review's considered opinion, minority non-pharmacist shareholdings are acceptable in theory, whether or not they are shares held by family members. Provided that they do not have prevailing directorial authority or other leverage over the direction of the business, the mere possibility of minority shareholders cannot simply be ruled out as being inconsistent with pharmacist ownership and effective and undisputed control of a pharmacy business. Minority shareholders could be, as well as relatives of the pharmacist principals, external

⁷⁷ Pharmacy Guild and Pharmaceutical Society submission to the Review, Volume 4, pages 20-22.

investors, business associates or friends of the pharmacist's family, as well as incorporated bodies willing to buy an interest in but not control the pharmacy business.

The registered pharmacist members of the company could still be able in theory to outvote their non-pharmacist colleagues, and thus ensure the effective professional control and management of the business.

Nevertheless, attracting minority shareholders, who may see the possibility of realising dividends from a type of business that has an enviable track record of success and profit-making, would be a major structural innovation for the community pharmacy industry. It would help break the dependency of pharmacy on debt financing based on the steady guarantees of interested third parties such as pharmaceutical wholesalers.

In examining regulatory prohibitions of non-pharmacist minority shareholdings, the question therefore is not whether these should be permitted, but whether they can be made **workable** in practice to justify loosening present restrictions on ownership structures.

Are non-pharmacist shareholdings workable?

If non-pharmacist shareholding beyond non-voting family members is to be allowed, then it is necessary to establish:

- The type of shareholding that would be acceptable;
- The extent of shareholding that would be acceptable; and
- Who could obtain and maintain an acceptable shareholding.

The Review believes that, in addition to “family and friends” investors, the following interests would be most likely to want to consider becoming shareholders and/or directors in a pharmacy business:

- Pharmaceutical wholesalers, perhaps by converting their “banner group” affiliations into direct stakes in affiliated pharmacies;
- Medical practitioners;
- Owners and operators of medical centres and private hospitals, particularly in relation to a pharmacy that may be located in their facility;
- Shopping centre owners and managers, who see the value of developing a standing relationship with one or more pharmacy businesses in their centres; and
- Pharmacy chains and franchises based in Australia and overseas.

This is not to say that any of these parties would necessarily take up an opportunity to take a shareholding in a pharmacy business or businesses. Several pharmaceutical wholesalers, for example, indicated to the Review that they had no plans or interest in moving in such a direction, and indeed were strong advocates for no change in present ownership arrangements⁷⁸.

In each of these identified cases, for different reasons, the Review believes that the nature of the party's interaction with a pharmacy business would carry with it such influence so as to make that influence felt very strongly, and perhaps overwhelmingly, by the pharmacist controlling shareholders. If the minority shareholders can dominate a pharmacy's line of

⁷⁸ See, for example, Sigma Pty Ltd's submission to the Review.

supply, or exert control over dispensing practices by linking these to allied prescribers, or hold or otherwise influence a head or sub-lease, the pharmacists' control of the business is certainly not undisputed, and unlikely to be effective.

In such cases the size of the shareholding may not be the key issue. A person or company could have a 49 per cent shareholding and be an effectively silent partner, or have a nominal shareholding and yet have sufficient influence to challenge the majority registered pharmacist shareholders for control. If a shareholder is of a certain background, such as being the managing company of a medical centre which is considering a pharmacy's lease in that centre, even non-voting shares could represent a disproportionate leverage on a pharmacy business.

This problem may relate to possible worst-case scenarios, as have the sometimes knee-jerk calls from stakeholders to maintain existing prohibitions⁷⁹. Even the most sober judgment, however, needs to consider that community pharmacy is providing a service of a highly specialised and client-sensitive nature. Every pharmacy business has to be seen as free of suspicion of any undue and inappropriate influence on the safe and competent practice of pharmacy under its direction and management. The presence of minority shareholders or directors may not necessarily guarantee this although some, such as a pharmacist's solicitor or accountant as a non-voting shareholder or director, would most likely be innocuous.

Managing and policing shareholdings, actual and potential agents of influence and the like may also exercise disproportionately the time and attention of regulatory authorities compared to their principal and proper responsibilities for supervising the safe and competent practice of pharmacy by pharmacists. Business watchdogs, such as corporate affairs commissions, also could find their time unduly occupied by scrutinising the activities of "small-time" companies operating pharmacies because of the roles of their "big-time" shareholders.

Given the possibilities for potential conflicts of interest among shareholders, and for determining at which point a minority shareholding might dispute the effective pharmacist control of the pharmacy business, it appears that the potential difficulties outweigh the benefits of opening up minority shareholdings in pharmacy operating companies.

It may well be, however, that clarifying and liberalising the treatment of permissible pecuniary interests in a pharmacy business may go some way to allowing non-pharmacist individuals and corporations to benefit commercially from non-proprietary associations with pharmacies owned by pharmacists, friendly societies and grandparented corporations. These matters are discussed in relation to Recommendation 6.

New corporate structures

If a new workable company structure can be established, however, that can be consistent with legislative requirements, then these could be considered by jurisdictions with a view to them being permitted by *Pharmacy Acts*.

To this end, the Review has developed a proposal that would maintain the principle of ownership and control of pharmacies by pharmacists that, if adopted, may enable pharmacists more readily to become proprietors and develop a greater sense of professional responsibility. This could also assist in the growth and development of rural pharmacy services, and provide

⁷⁹ Pharmacy Guild and Pharmaceutical Society, *Response to National Competition Policy Review – Preliminary Report*, page 3.

greater competition overall in both a commercial and professional service sense, with benefits for the community.

The Review briefed a legal firm, Phillips Fox, to work with it on outlining a practical framework for structuring limited companies consisting wholly of registered pharmacists and prescribed relatives. Their advice is at Appendix 4. The model could sustain the pharmacist control and direct proprietorial supervision principles over the management of a considerable number of pharmacies. Each affiliated pharmacy would be under the personal control of supervision of a managing pharmacist who would be required to have a minimum equity shareholding in the company of 10 per cent, or a minimum cash value equity share constituting an appropriate and a genuine shareholding in the business vehicle.

A corporate model of this nature would be consistent with Recommendation 3(b) and could:

- Retain the personal supervision concept in terms of one equity-holding pharmacist, one pharmacy;
- Encourage younger and other enthusiastic pharmacists to take equity in a pharmacy business, with the potential to bring the best of current thinking to practice management and the pharmacy business;
- Promote more lively competition between proprietor entities in the community pharmacy industry; and
- Encourage more efficient, competent and entrepreneurial pharmacist businesspeople to realise economies of scale and scope in terms of pharmacy management and administration (for example, by centralising payroll management and stock ordering), with consequently lower unit costs for the business as a whole;
- Be consistent with any legislative requirements for corporations owning a pharmacy to be controlled by pharmacists, and limited to pharmacist shareholders;
- Sit alongside existing ownership structure options.

Fuller details of the multi-pharmacist equity model are contained in the Phillips Fox advice at Appendix 4. Any development of such a model would need to be in consultation with stakeholders and with the benefit of available expertise in professional and commercial aspects of community pharmacy and pharmacy practice.

Recommendation 3

The Review recommends 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 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.

NUMBER OF PHARMACIES OWNED BY PROPRIETORS AND PHARMACIST SUPERVISION OF PHARMACIES

If pharmacies are to remain basically pharmacist owned and controlled, on the assumption that a proprietor's professional supervision is a principal key to providing a safe and competent community pharmacy service, the numbers of pharmacies that can be held by a single proprietary entity is highly relevant.

The current numbers per proprietor in each State are haphazard and inconsistent with each other. This inconsistency appears to be for no convincing reason other than that the number in any one jurisdiction is consistent with the concept of personal proprietary supervision. Pharmacy practice is more or less the same across Australia, and it therefore stands to reason that the numbers of pharmacies a proprietor can hold, if indeed it is prescribed, should also be consistent nationally.

Moreover, existing numerical restrictions are based on policy decisions that date back, on the whole, a long time. They reflect the concept of community pharmacy being a network of small, personally supervised businesses.

Nevertheless, these restrictions now frustrate the development of more efficient pharmacy businesses, and help to protect those less efficient pharmacies and their proprietors from competitive advantages that may be enjoyed by their more efficient colleagues. This may suit some proprietors, especially those who may be more talented as professionals and practice managers than as businesspeople, and who may run less efficient businesses than do some of their peers.

Removing these restrictions may appear at first glance to run contrary to the principle of pharmacist ownership supporting a localised and highly professional pharmacy service. This, however, need not be so.

Modern communications and information technology has the potential to develop and implement contemporary business management systems and databases, not just those developed by individual proprietors but also those contracted in, for example, as part of a banner group or franchise agreement. These can apply great consistency of practice across widespread and numerous individual pharmacies, and ensure that a pharmacist proprietor can be involved with a pharmacy or a number of pharmacies off-site without compromising their personal supervision of their operation.

Indeed, key stakeholders themselves highlight how contemporary information and communications technology has been embraced by pharmacies. In their submission to the Review, the Pharmacy Guild and the Pharmaceutical Society highlighted the industry's track record including implementing electronic commerce in relation to stock ordering, as well as the general computerisation of pharmacies from the mid 1980s onwards. They also expressed their considerable pride in community pharmacy's achievements in such collective matters as performance benchmarking, staff training and innovative management practices⁸⁰.

There are also mechanisms outside *Pharmacy Acts* to protect the public from market dominance or inappropriate market conduct, particularly the Australian Competition and Consumer Commission under Part IV of the *Commonwealth Trade Practices Act 1974*, and State and Territory fair trading legislation. *Pharmacy Acts* therefore should not be the

⁸⁰ Pharmacy Guild and Pharmaceutical Society submission to the Review, Volume 3, pages 34-35.

vehicle for business-limiting restrictions of this nature, and if these provisions remain the decisions of regulatory authorities may increasingly be challenged in this regard.

Finally, anecdotal evidence and comments by several regulatory authorities to the Review suggest that the current numerical restrictions are easy for a determined and enterprising pharmacist to breach, using various lawful means to mask the true size of their pharmacy holdings⁸¹. It was also suggested that it is very difficult to prove a breach of the rules if such a breach is suspected. If these rules can be so easily bent or broken, and non-compliance is so hard for authorities to deal with, their retention has to be questioned on that ground alone.

On balance, the Review believes that generally it is no longer practical or appropriate to prescribe a number of ownable pharmacies per proprietor in pharmacy legislation, as there is not a net public benefit in the existing restrictions.

If these restrictions are relaxed, however, developments should be monitored by the States and Territories. Regulatory authorities and particularly professional and industry organisations could assist proprietors with guidelines, or even a code of good practice, on personal supervision and professional liability issues if necessary. More importantly, the Australian Competition and Consumer Commission could be asked to ensure that there is no undue market dominance in respect of pharmacy proprietors taking sharp advantage of the changes.

If they are to be lifted the restrictions in each State and Territory should be, in the interests of market consistency and fairness, lifted simultaneously with those in other jurisdictions.

Pharmacists in charge and pharmacists in attendance

A reason that numerical restrictions have survived in *Pharmacy Acts* is that they have been seen as ensuring that a pharmacy is under the close personal supervision of a registered pharmacist proprietor.

These requirements exist over and above standing requirements in all State and Territory Acts that each individual pharmacy operate under the direct and personal supervision of a pharmacist. If the supervising pharmacist is not a proprietor, then it is a managing pharmacist, or pharmacist in charge. Similarly, Acts also require that pharmacies operate at all times with a registered pharmacist in attendance.

If safe and competent pharmacy services are to be provided to the Australian public, it is important that a pharmacist is in charge of the professional operations in each pharmacy, whoever owns that pharmacy. Indeed, it is access to a pharmacist on request that is one of the elements of the Australian community pharmacy system that is most attractive to and prized by consumers.

The Review believes that any legislative requirements to have a designated registered pharmacist in charge of a given pharmacy, or to have a registered pharmacist in attendance at all times that a pharmacy is open, therefore are justifiable in the public interest.

⁸¹ One Pharmacy Board told the Review that it has had clear indications in a number of instances of blatant disregard of their Act's pharmacy holding limit, but they rarely had evidence sufficient to take matters further.

Recommendation 4

The Review recommends 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 the 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.

PERMITTED EXCEPTIONS TO PHARMACIST OWNERSHIP

Principal permitted exceptions

There are three groups of pharmacy proprietors who are not necessarily registered pharmacists.

These are:

- Administrators of deceased estates and bankrupt or insolvent pharmacy businesses;
- Non-pharmacist companies and individuals who were permitted to own pharmacies before existing “pharmacist-only” restrictions came into force; and
- Friendly societies.

In practice, the total number of these pharmacies is fractional alongside those owned and controlled by registered pharmacists.

Deceased estates and bankrupt individuals and businesses

Most State and Territory *Pharmacy Acts* make provision for transitional arrangements for disposing of the business estates of deceased pharmacists, and of the businesses of bankrupt or insolvent pharmacy proprietors.

These are temporary arrangements, pending closure of a pharmacy business or its sale to an eligible party. The Review sees such contingency provisions, with a reasonable transition time allowing the winding up and disposal of the deceased proprietor’s business, as being justifiable regulation.

Grandparented corporately-owned pharmacies

These pharmacies are survivors from ownership regimes in place before pharmacists became the preferred proprietors of for-profit pharmacies. There are only a handful of these pharmacies still remaining, and it is likely that industry attrition may reduce their numbers still further over time.

The non-pharmacist ownership of these for-profit grandparented pharmacies runs counter to the basic concept of pharmacist ownership and effective control of pharmacies. Given this, and given that provisions relating to these pharmacies are either not included in *Pharmacy Acts* or else are relatively consistent across jurisdictions, does not propose any changes in this area.

Friendly society pharmacies

The treatment of friendly society pharmacies varies from jurisdiction to jurisdiction. In some jurisdictions, such as Western Australia, friendly society pharmacies are grandparented, and/or are subject to special procedures in relation to their establishing new pharmacies. In others, such as South Australia, the treatment of friendly society pharmacies is relatively benign.

On balance, the Review sees the situation of friendly society pharmacies as different to grandparented non-pharmacist owned pharmacies. Unlike corporate pharmacies, the treatment of friendly society pharmacies is not consistent around the country. In some jurisdictions, notably South Australia and Victoria, friendly society pharmacies are an accepted part of the community pharmacy market, and their presence is encouraged actively by policy as expressed in the appropriate provisions of their *Pharmacy Acts*.

In other jurisdictions, although they are lawfully permitted to operate, friendly society pharmacies are placed under a range of strictures that make it hard for them either to establish new pharmacies or to continue operating. In one jurisdiction, Western Australia, their presence is reduced to one grandparented pharmacy, and that presence will disappear if that pharmacy closes, can no longer operate in its immediate vicinity or is sold to an independent pharmacist proprietor. At least two other States have requirements clearly hostile to the ongoing presence of friendly society pharmacies.

The Review believes that friendly society pharmacies are survivors of an earlier era of health care, when governments did not operate or fund health services such as pharmacy. With the introduction of the PBS the role of friendly societies diminished but they continue to coexist with the private pharmacy system. Indeed, a characteristic of the friendly society pharmacy sector is that is on the whole, like their pharmacist-owned competitors, concentrated in relatively local areas, whether suburban or country⁸².

Given this observation, it is hard to justify the future entry of new players into the friendly society pharmacy sector. It therefore would be reasonable to suggest that the existing societies' owning privileges are grandparented to those currently operating pharmacies, and entities that may be formed as a result of existing societies amalgamating with each other.

Should grandparenting be adopted, the future ability to own and operate pharmacies in a State or Territory should apply only to those actually operating them in the jurisdiction on a given date. This would exclude friendly societies that may have been eligible to operate a pharmacy but have not done so, or have ceased to do so. A suitable grandparenting date would be 1 July 1999, the day on which friendly societies came under the jurisdiction of the Australian Securities and Investments Commission (ASIC). Another date could, however, be prescribed.

With this qualification, the Review concludes that the operation of pharmacies by eligible friendly societies should continue to be permitted. This leaves the question of the acceptability of the scope and consistency of coverage of existing regulation in terms of net public benefit.

⁸² Australian Friendly Societies Pharmacies Association, *Directory of Societies' Pharmacies*, February 2000.

Number of pharmacies per friendly society

The Review believes that restrictions on the number of pharmacies per friendly society in a given jurisdiction, as well as overall numbers of friendly society pharmacies in a jurisdiction, should also be re-examined. If restrictions on the numbers of pharmacies owned by private for-profit proprietors are lifted, numerical restrictions on pharmacies operated by existing friendly societies should also be lifted in the interests of consistency and of balanced competition between lawfully permitted pharmacy operators.

In the end, however, the market should determine how many friendly society pharmacies there are. This includes the effects of other regulation, such as the Commonwealth's statutory rules governing pharmacies' access to PBS dispensing approvals. Indeed, in the end it is largely PBS access that determines whether a for-profit or not-for-profit pharmacy is a viable proposition.

While these suggestions may give rise to fears of market dominance by friendly societies or large friendly society pharmacy chains, the Review believes that it is unlikely on the whole that friendly societies' national share of pharmacy outlets will increase markedly as a result of such changes. Of the 35 friendly societies operating pharmacies, only three operate more than six pharmacies, and most of them confine their operations to a local area such as a country centre or a segment of Sydney, Melbourne or Brisbane suburbs⁸³. Even if some of these existing societies do acquire more pharmacies in a less regulated environment, the sector as a whole is too limited to ever be in a position to challenge seriously the market predominance of private pharmacists.

In addition to such practical considerations, there are also mechanisms outside *Pharmacy Acts*, notably the Australian Competition and Consumer Commission under Part IV of the Commonwealth *Trade Practices Act 1974*, that are capable of monitoring and addressing such market concentration and dominance concerns if this becomes necessary.

Location of friendly society pharmacies

In some States legislation places severe restrictions, including the need for express ministerial approval, on friendly society pharmacies relocating from a "grandparented" site, and then allowing them to move only within the immediate vicinity. While most friendly societies operating pharmacies are linked to a specific locality by their charters, restrictions of this nature are inherently discriminatory, as they apply only to one class of proprietor rather than all parties eligible to own pharmacies. They restrict competition between friendly society and independent pharmacies, but to no clear public benefit.

If existing friendly society pharmacy operators are grandparented in the future, the Review believes that such location controls should be removed.

Relative financial advantages of friendly society pharmacies

It was suggested frequently to the Review by independent pharmacists, the Pharmacy Guild and the Pharmaceutical Society⁸⁴, and by some regulatory authorities that, because of the more generous taxation treatment of their income derived from mutual sources – that is, income from memberships and largely discounted sales of relevant goods and member

⁸³ Australian Friendly Societies Pharmacies Association, *Directory of Societies' Pharmacies*, February 2000.

⁸⁴ Pharmacy Guild and Pharmaceutical Society, *Supplementary Submission to the Review*, 20 August 1999.

services – that friendly societies have a decisive advantage over their private competitors. This, it was argued, operates in conjunction with other relative financial advantages, such as corporate infrastructures generating relatively superior economies of scale and scope⁸⁵.

Conversely friendly societies themselves, and the Australian Friendly Society Pharmacies Association, argued that mutuality was a disadvantage rather than an advantage, and effectively that with swings and roundabouts of corporate and taxation arrangements, and the costs of actually servicing members, any competitive advantages in one aspect of their operations were cancelled out by disadvantages in others⁸⁶.

It appears to the Review that these contentions need to be resolved if legislative reform in this area is to be undertaken confidently. The Review has not had, however, the time and resources to test this presumption definitively.

To resolve the question once and for all, it therefore may be desirable for an appropriate authority to be asked to examine the operation of mutuality and other competition-related factors in the community pharmacy industry. This authority could then conclude whether the financial and corporate basis of friendly society pharmacies, including the treatment of member-generated income under mutuality rules, does in fact create unfair competitive advantages for a small segment of the community pharmacy industry.

The Review believes that the Australian Competition and Consumer Commission (ACCC), or another authority of comparable and appropriate standing could undertake such a task authoritatively and quickly, should the matter be so referred.

Any such examination would, however, need to take into account the competition effects of the Corporations Law, financial and prudential requirements, and corporate structures on the community pharmacy industry as a whole. It should therefore be broad-based, and not simply be a revisiting of taxation treatment of certain entities, such as the operation of the mutuality principle in the sector⁸⁷.

The Review believes that the undertaking of any such analysis should be not be able to hold up States and Territories' timely consideration of any amendments to their legislation arising from the Review's recommendations.

Implications of possible friendly society demutualisation

As the Australian Friendly Society Pharmacies Association has pointed out to the Review⁸⁸, recent legislative changes have brought friendly societies generally under the coverage of the Corporations Law. Parallel to this, since 1 October 1997 all States and Territories have adopted new friendly societies legislation.

The commercial and revenue-raising activities of friendly society operations, including pharmacies, are therefore now governed by the Corporations Law, and overseen by the Australian Securities and Investments Commission. Provided that they continue to operate in accordance with their objects of their constitutions, and this overall legislative framework, it

⁸⁵ Pharmacy Guild and Pharmaceutical Society, *Supplementary Submission to the Review*, 20 August 1999.

⁸⁶ Submission to the Review by the Australian Friendly Societies Pharmacies Association, Appendix B.

⁸⁷ Indeed, mutuality as a taxation concept was considered by the recent Ralph review of business taxation, and by the Productivity Commission as part of its reference on gambling. The Review also notes that, as part of the Commonwealth's response to Ralph, mutuality was retained for friendly societies and certain other not-for-profit organisations.

⁸⁸ Australian Friendly Societies Pharmacies Association, letter to the Review, 21 December 1999.

appears that friendly societies may be able to demutualise and still retain their friendly society character.

If, after a process of demutualisation and corporate change, a friendly society is still recognised as such by the relevant State or Territory legislation, its ability to own pharmacies presumably is not affected. If, however, the nature of the organisation changes fundamentally, for instance from a not-for-profit corporation to a for-profit company, it may be that these pharmacies would need to be divested, as private for-profit corporations cannot own or acquire them⁸⁹.

Consistent regulation of friendly society pharmacies

The present inconsistent ownership and related treatment of friendly society pharmacies across State and Territories causes uncertainty and confusion for those friendly societies, and indeed for privately owned pharmacies competing with them.

Therefore it is desirable, as part of implementing recommendations arising from this Report, that State and Territory jurisdictions consider making the treatment of friendly society pharmacies as nationally consistent as possible. In the context of the Review's recommendations below, relevant provisions of the Victorian *Pharmacy Act* are a good guide to implementing a nationally consistent legislative standard in this regard.

Recommending national consistency, or removing specific regulatory restrictions, in respect of the treatment of friendly society pharmacies is not seen by the Review as granting special favours to these societies, or as being inconsistent with the general principle of Recommendation 1 of this Report. Rather, it is seen as a matter of promoting greater certainty and consistency across jurisdictions in a difficult area of regulation. It also promotes a more stable basis for genuine competition between pharmacies.

Recommendation 5

The Review recommends 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 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 grandparenting 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 these 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.

⁸⁹ Advice obtained by the Review on 28 January 2000 from the law firm Phillips Fox suggests that *Pharmacy Acts*, with the possible exception of the New South Wales Act, appear not to need amendment to deal with changes to the structures of friendly societies under changes to the Corporations Law.

PECUNIARY INTERESTS IN A PHARMACY BUSINESS

In looking at the practical implications of restricting the ownership and effective control of pharmacies to registered pharmacists as a guarantee of a safe, competent and professional community pharmacy industry, the Review is concerned to ensure that commercial competition and innovation in the community pharmacy industry is balanced with the public's expectation of safety and competence in the delivery of pharmacy services.

In most States and Territories, pecuniary interest in pharmacy businesses by non-pharmacists is prohibited by way of blanket provisions in *Pharmacy Acts*. Some specific activities, such as bills of sale imposing a creditor's or guarantor's conditions on the operation of the business, also are prohibited expressly in some jurisdictions. In no jurisdiction, however, is the term "pecuniary interest" (and, in Victoria, "proprietary interest") defined in the relevant Act. Instead, it is left to regulatory authorities and the courts to use their discretion and precedent in interpreting their Acts for the purpose of determining whether a non-pharmacist party has a pecuniary interest in a pharmacy business.

By implying that any non-pharmacist association with the non-professional aspects of a pharmacy business is undesirable, however, broadly interpreted pecuniary interest provisions may hamper innovative ways of planning and delivering pharmacy services, and the better management and support of pharmacy businesses as a whole.

On balance the Review believes 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 relationships 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.

Defining proprietary interests in a pharmacy business

If this is accepted, it is reasonable to propose that definitions of pecuniary interest be spelt out in *Pharmacy Acts*, and be made to apply specifically to the *proprietorship* of pharmacies. In this way, individuals and bodies corporate otherwise precluded from the lawful owning of a pharmacy would continue to be excluded from proprietorship.

On the other hand, such parties would not be precluded from entering into lawful business arrangements with a pharmacy business beyond a proprietary interest, provided the pharmacy proprietor retains direct control of the business and professional discretion on professional matters and products.

Simplifying regulation in this area would stimulate competition between pharmacy businesses, assist proprietors to make effective commercial decisions according to their best judgment, and benefit the consumer in terms of the quality and price of goods and services obtained through pharmacies.

A possible form of words for a new proprietary interest definition to replace existing pecuniary and proprietary interest provisions in *Pharmacy Acts* is set out in the definition of "proprietary interest" in as ownership of, or a partnership, shareholding or directorship in, an entity operating a pharmacy.

The uncertainty and imprecision of existing statutory provisions relating to pecuniary interest give rise to broad, catch-all interpretations in order to assure the narrow aim of ensuring only those who lawfully control the operations of a pharmacy business can do so. Given this, clarification of what legislation intends would be an important step in the right direction.

Acceptable pecuniary relationships with a pharmacy business

As far as possible, the commercial aspects of a pharmacy business should be a matter for the proprietors and managers of pharmacies, and not subject to the undue intrusion of professional regulation and regulatory authorities.

It should be acceptable, for instance, for a pharmacy proprietor to enter into a franchise agreement involving profit or turnover-sharing with a franchisor, a preferred-supplier arrangement with a pharmaceutical wholesaler, or a joint venture with a non-pharmacist company or entrepreneur (such as a supermarket or department store), as long as they have full control of and responsibility for the delivery of professional services in their pharmacies.

There will always be grey areas between what aspects of a pharmacy business relate directly to professional services and those that do not. In many if not most cases, however, such as a cosmetics concession, or a banking or lottery agency, the matter is relatively clear-cut. To assist regulatory authorities in enforcing more liberal pecuniary interest rules, a general definition of pharmacy services, similar to that adopted for this Report in Chapter 1, may assist⁹⁰. Such a definition for the purpose could be incorporated in an Act, regulations or appropriately endorsed guidelines.

Franchising

It has been argued to the Review that there is a particular case for restricting the development of franchise agreements in the community pharmacy industry, on the grounds that “any changes to the pecuniary interest provisions should not lead to the introduction of franchise style arrangements and consequential loss of professional control”⁹¹.

Generally, the argument against franchising runs that the application of a full franchise agreement currently is an unlawful pecuniary interest because (1) they impose precise instructions on franchisees in relation to the organisation of business, and to the lines of goods and services that they retail, and (2) if they involve a share of turnover or profit they effectively give the franchisor a direct proprietary interest in the pharmacy business⁹².

Conversely, the case for allowing full franchise arrangements assumes that pharmacy proprietors enter an agreement of their own free will, that they cannot be forced by the franchisor to act against their professional and ethical judgment, and that the franchisee remains responsible under the franchise agreement for the full management of his or her business. Additionally, franchises are now covered under *Franchising Code of Conduct* administered by the Australian Competition and Consumer Commission under the *Trade Practices Act 1974*. The Code provides for franchisees entering into franchise agreements on the basis of informed choice, and for cooling-off periods once an agreement is signed⁹³.

⁹⁰ As defined on page 22 of this Report.

⁹¹ Pharmacy Guild and Pharmaceutical Society, *Response to the Preliminary Report of the National Competition Policy Review of Pharmacy*, December 1999, page 5.

⁹² This was raised in consultations between the Review and several Pharmacy Boards, and in consultations with the Pharmacy Guild.

⁹³ These points were drawn to the Review's attention in consultations with the Hon Terry White, who as a pharmacy proprietor and entrepreneur has been involved in developing pharmacy franchises.

In pharmacy, a franchise agreement should put no restriction on the professional judgment of a pharmacy proprietor, manager or salaried pharmacist. It remains essential that a franchisee's professional duty remains unambiguously with meeting each client's pharmacy care needs in the best way possible. Beyond this, however, a franchise arrangement – including franchise fees and their basis of calculation on a flat fee, or on proportion of turnover or profit - should be left a matter between franchisor and franchisee, and not be a matter of concern for regulatory authorities.

Conditions on commercial documents and access to commercial records and other commercial documents

Provisions in several *Pharmacy Acts* render a pharmacy business's bills of sale void if they attach conditions in relation to a range of matters, including the supply of goods by a particular supplier, and the right to gain access to the accounts of that business for other than limited purposes.

These conditions in large part reflect the prevalence of debt financing in the pharmacy business, especially the widespread reliance on pharmaceutical wholesalers and other parties as guarantors of loan finance to pharmacists to start or improve their businesses. They seek to ensure that guarantor support is given to pharmacists with no strings attached, notwithstanding the guarantor's exposure to the risk of there being a default on the loan⁹⁴.

It would also appear that conditions restricting access to the books of a pharmacy business would place obstacles in the way of commercial associations such as pharmacy banner groups, full franchises and joint ventures with non-pharmacist entities. If a party enters into an association with a pharmacy relatively blind as to the financial health of the business or the commercial competence of its proprietor, there is an unfair element of commercial risk for the other party, or the potential association may be deterred at the outset.

The terms of such financial and commercial support should only be limited by ensuring that proprietors of pharmacy businesses have the direct responsibility for the safe and competent delivery of their pharmacy services, and that third parties cannot interfere with or control this responsibility. Provided that pharmacists retain a reasonable discretion to override the arrangement on grounds of professional necessity, there is no reason why preferred supplier arrangements should not be negotiated with pharmaceutical wholesalers and other parties in return for financial guarantees or other support.

Similarly, there is no reason why regulatory authorities should inspect or veto agreements to open books to business associates, or scrutinise leaseholds, partnership and franchise agreements and the like.

Any such provisions in *Pharmacy Acts* should therefore be removed.

Rents for pharmacy premises

In a number of jurisdictions, regulatory authorities consider the rents paid by pharmacy businesses in assessing whether a pecuniary interest arises from a leasehold agreement. The reason for such assessments is that, in many cases, the rent of the pharmacy premises is based

⁹⁴ One major guarantor indicated to the Review that the balance sheet value of their exposed liabilities to pharmacist guarantees is in the region of \$500 million.

on a proportion of the business's turnover, and that if that share is too high it may undermine the ability of the pharmacy business to provide a comprehensive professional service⁹⁵.

The Review believes that the level of rent paid by a pharmacy business is a matter for the pharmacy proprietor alone. Rent paid is a commercial arrangement between the lessor and lessee, and their agents if these are involved. They are not a matter for professional regulating authorities, unless in the unlikely circumstance that a lessor seeks to direct the professional affairs of the pharmacist proprietor or his or her staff. If a lessee exercises poor judgment in relation to the provisions of his or her lease, that is a matter for him or her, and not the professional regulatory authority to bail them out.

The Review therefore believes that any regulatory provisions under *Pharmacy Acts* enabling regulatory authorities or other parties to intervene or require information on matters relating to leaseholds and rents should be removed.

Joint ventures with non-pharmacy businesses

There has been much concern about the possibility of supermarkets, department stores and other non-pharmacist retailers having outright ownership, or a proprietary interest, in pharmacies. The advent of e-commerce, with the possibility of a pharmacist entering a joint venture with an e-commerce or Internet portal company, opens up new and otherwise unanticipated variations on this theme.

Currently, there are no statutory or other regulatory provisions in any jurisdiction that prevent non-pharmacist bodies corporate entering into commercial associations or joint ventures with lawfully-owned pharmacy businesses.

Provided that any appropriate regulations regarding the establishment of pharmacy premises are complied with, a pharmacy business could locate a pharmacy within a supermarket or department store. Professional control would remain in the hands of the pharmacist proprietor, and under regulatory frameworks the safe and competent practice of pharmacy on those premises would continue to be his or her paramount concern.

The Review believes that *Pharmacy Acts*' current pecuniary interest provisions are, however, capable of being interpreted broadly by regulators to discourage such associations.

It therefore sees clarifying proprietary and pecuniary interest provisions as essential to the innovative development of the industry. As far as possible, pharmacy proprietors should be able to act on their own commercial judgment of the potential and actual benefits of such a joint venture to his or her business. If the proprietor fears a loss of control of their arrangements to the "host" company, then they presumably will not enter into a joint venture arrangement, or withdraw from according to the terms provided in the joint venture agreement. In short, ultimately it is a matter of judgement and risk for them, and not for the profession's regulatory authorities somehow to rescue them if they misjudge.

⁹⁵ One Pharmacy Board indicated to the Review that a rent greater than 10 per cent of a pharmacy's turnover is seen by it as exorbitant and unconscionable.

Preventing undue, unethical and improper interference on the professional conduct of a pharmacist

If the purpose of the current broad-brush pecuniary interest provisions of *Pharmacy Acts* is to prevent non-professionals exerting improper influence over the conduct of a pharmacy business, the same aim can be achieved by alternate means. Particularly, Acts can provide that the undue, unethical and inappropriate influencing of a pharmacist in the course of his or her professional activity is unconscionable, and should be a punishable offence.

On balance, the Review therefore believes that *Pharmacy Acts* should contain a statutory offence of exercising improper or inappropriate influence over the professional conduct of a pharmacist in the course of his or her practice.

While directed principally at third parties, this offence should apply to all those who seek to influence inappropriately a pharmacist's professional judgment. This should include pharmacy proprietors who seek to direct or override a dispensing salaried pharmacist's decisions for reasons other than professional responsibility. It could also include the giving of inappropriate directions to or applying pressure on a pharmacist in a hospital or clinical setting, say by an administrator, private hospital operator or health authority.

In the interests of promoting the greater freedom of operation of pharmacy businesses, especially where these may own and operate pharmacies in more than one State or Territory, it would be desirable to ensure that any definition of proprietary interest, and the terms of the related offence of undue and improper influence of a pharmacist, be consistent across jurisdictions.

To complement this provision, and to reinforce upon practising pharmacists the public interest in exercising their clear professional judgment, acting under undue and inappropriate influence, or applying such influence to other pharmacists should be construed as being professional misconduct, subject to appropriate disciplinary action.

Case for the suggested offence

Rather than focus on a financial connection with a pharmacy business, the offence would focus regulation on the need to protect public safety through the safe and competent practice of pharmacy, rather than on who benefits financially from the conduct of the business.

A possible form of words for the proposed statutory offence could be:

Any person (whether natural or corporate) whose conduct causes or contributes to or influences the professional conduct of a registered pharmacist such that there is an act of professional misconduct by that pharmacist, shall be guilty of an offence.

If the offence was in place, the attention of regulatory authorities would be shifted from pecuniary and business management matters to focusing on ensuring that any aspect of that management does not impinge or impose on the professional conduct of a pharmacist or pharmacists. Indeed, acting willingly under inappropriate influence could itself constitute a ground of professional misconduct by a pharmacist, and make him or her liable to investigation and disciplinary action.

A person or corporation could be accused of the offence after investigation of a complaint from a practitioner or member of the public, a referral from a health complaints commission

or similar body, or initiated following the conviction of a pharmacist in an Australian court of a prescribed offence.

A flow-on benefit of this approach to pecuniary interest and third-party influence would be that while pharmacists continue to control and manage pharmacy businesses, non-pharmacists would not be deterred from assisting the promotion of greater competition, innovation and growth in the community pharmacy industry. All the while, non-pharmacist parties associated with pharmacy businesses would be reminded that their involvement in a major health care area involves responsibilities to the wider community, and that their involvement is not to be abused for personal or corporate gain.

It would also be essential to ensure that the penalties for the offence should be adequate and sufficient. They would need to ensure that all parties, whether individuals or large corporations, understand the severe consequences of their exercising undue, unethical or inappropriate influence over the conduct of a professional whose misfeasance or malfeasance can cause innocent parties injury or death.

Recommendation 6

The Review recommends 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.

REGISTRATION OF PHARMACY PREMISES AND PHARMACY BUSINESSES

Most States and Territories require the registration of pharmacy premises by their regulatory authority. Some also require the registration of pharmacy businesses. This involves a cost to the business in terms of arranging paperwork and the payment of registration fees, over and above those paid by pharmacists for their personal registration.

Registration of premises

There is certainly a public interest case for pharmacy premises to conform to safety-based siting, fitness for purpose and fitting-out standards. Similarly, there is a case for regulatory

authorities to inspect pharmacy premises if it appears that such standards are being breached, and to take appropriate action to remedy any danger to the public.

Pharmacists are also recognised under State and Territory drugs and poisons legislation, and they have the responsibility under those Acts to store and distribute dangerous and toxic drugs and poisons safely and responsibly according to their requirements. Indeed, regulatory authorities are mindful of this dual line of responsibility for registered pharmacists. At least some jurisdictions see pharmacy regulatory authorities as essential agents for ensuring compliance with drugs and poisons legislation, as well as for administering their *Pharmacy Act*.

On the other hand, an efficient business arguably is a safe business. Unduly mandating and regulating these aspects of their operation is unnecessary given that owners can face disciplinary action as responsible professionals for incompetence, recklessness and wilful disregard of proper practice in their professional duties.

Regardless of their public safety dimension, premises registration requirements can be anti-competitive in their operation. They can be interpreted in such a way to frustrate new and innovative pharmacy delivery ideas, such as co-locating a pharmacist-owned business within the premises of a non-pharmacist retailer, or preventing mobile pharmacies being operated by insisting that a pharmacy operate from a fixed site.

If registration of premises requirements are removed, poor practice can still be addressed and rectified by regulatory authorities either on the basis of a public complaint, reasonable suspicion of dangerous practice, or as part of the process of re-registering a pharmacist. Regulatory authorities can continue to monitor compliance with regulations and guidelines without requiring premises to be registered. Ideally, such premises requirements, as they relate to the safe storage and handling of drugs and poisons, should not duplicate similar provisions of State and Territory *Poisons Acts*, nor should they over-regulate the practice of pharmacy on those premises.

As part of that compliance role, regulatory authorities may have the power to enter and inspect those premises to investigate complaints relating to the quality of the premises and their fittings, or to spot check compliance with guidelines. In return for removing premises registration requirements and associated costs, proprietors might still have an obligation to notify an authority, in writing, of the location or relocation of their premises.

On balance, the Review believes that the prescriptive registration of pharmacy premises should be removed as not being justifiable restrictions on competition. Regulatory authority inspections as part of establishing new and relocated premises, or on the transfer of proprietorship of a pharmacy business should, however, be a voluntary quality assurance mechanism rather than compulsory fee-generating requirement.

Registration of pharmacy businesses

Requiring pharmacy businesses to be registered sends a message to the pharmacy profession and industry that pharmacy regulators have a legitimate interest in the commercial and business structures and operations of a business, over and above the considerations of safe and competent professional practice.

The Review believes that pharmacy business registration should be removed as an unnecessary impediment to competition. Provided the ownership structure is lawful in terms

of a *Pharmacy Act*, regulatory authorities should have no other interest in the corporate or commercial activities of a pharmacy business. This is more for appropriate Commonwealth, State and Territory corporations, trade practices, fair trading and consumer affairs law.

Additionally, a pharmacist's personal registration is fully capable of delivering a similar administrative outcome. Details of a pharmacist's pharmacy proprietary, managerial or employment interests could, for instance, be recorded as part of his or her register entry. If State and Territory registration databases are consistent in their content, information exchanged between jurisdictions should perform much the same function as business registration, and that this would be a more efficient way of achieving similar results.

Any such information requirements for personal registration, however, should be limited to the trading name and address of the proprietor, the address of each of its pharmacies, the pharmacist in charge of each pharmacy if not the proprietor, and the shareholders in that business. Details on matters such as leasehold agreements, loans and guarantees, mortgagors, and guarantors should not be required. Such things are a matter for the pharmacist, not for the eyes of regulatory authorities.

Recommendation 7

The Review recommends that:

- (a) Legislative 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.

A CLOSING COMMENT

In making these conclusions and recommendations, the Review is responding to evidence about the present state of the community pharmacy industry, and how it might develop in the foreseeable future to meet the Australian community's ongoing and evolving medicinal and wider health care needs. It does not see itself as having the last word on pharmacy ownership issues.

The Review concludes on balance that there is a net public benefit in leaving pharmacist ownership regulations in place. It does not, however, see ownership as an inalienable and perpetual right for pharmacists. It is a privilege, conferred by the community in return for the high and consistent quality provision of pharmacy services at a reasonable cost.

Pharmacy proprietors need to work hard to maintain and justify the ongoing need for that privilege. Current experience suggests that elements of the consuming public are looking for alternatives to their pharmacy providers. The limited exceptions to pharmacist-owned pharmacies – friendly society and grandparented non-pharmacist owned pharmacies – appear

to work well as competently-managed and professionally sensitive pharmacy businesses. Increasingly, the success and growth of mail-order and Internet pharmacy services suggest that consumers are not always simply content to patronise their local pharmacy and seek face-to-face advice, or are not satisfied with the quality of the service they are receiving.

As a consumer organisation's submission to the Review said:

Consumers go to pharmacies because they have no choice. The expert information and advice provided by pharmacists about medicines is what sets them apart from supermarkets, and it is why there are government protection's such as pharmacy ownership by pharmacists ... (P)harmacists need to be able to show that these services are consistently provided through pharmacy to an acceptable standards, which is cost-effective for consumers and for the health system through facilitating the wise use of medicines⁹⁶.

Pharmacies and their pharmacist proprietors need to heed messages such as this. Besides their basic dispensing service, they need to consistently live up to the goal of adding value to their services by providing adequate personalised advice and consumer information on medicines to their customers. If they do so, they maintain the role in the provision of professional pharmacy services that the community expects of them as both individuals and as an industry. If they do not, the net public benefit in favour of the existing ownership arrangements could disappear by the time any future review takes place.

It is in the public interest for governments to intervene so that the community pharmacy network reaches all Australians fairly. It is, however, equally in the public interest for governments to intervene to ensure that community pharmacies provide, at an enforceable high standard, a range of relevant health services for which there is a demonstrable community need. This may not only include "core" programmes like the PBS. It could include public health and other less commercially attractive programmes, such as methadone supply and providing access to needles and syringes for people with drug dependency problems.

Recommendation 8

The Review recommends 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:

- (a) An acceptable range of services to be provided; and
- (b) Appropriate quality assurance and professional practice standards to be adopted by community pharmacies covered by the agreements.

⁹⁶ Consumers' Health Forum submission to the Review, page 2.

CHAPTER 3: LOCATION OF PHARMACIES

NATURE OF THE RESTRICTIONS

As part of the administration of the Pharmaceutical Benefits Scheme (PBS), and the Australian Community Pharmacy Agreement (the Agreement), a ministerial determination (the Determination) made pursuant to section 99L of the Commonwealth *National Health Act 1953* imposes strict conditions on:

- Granting PBS dispensing approvals to a new pharmacy; and
- Approving the relocation of a PBS-approved pharmacy from one locality to another.

NEW PHARMACY APPROVALS

A new pharmacy cannot be approved to dispense PBS-subsidised medicines unless the applicant can satisfy a set of “definite community need” criteria set out in the Determination. These criteria include that a catchment area for the proposed pharmacy must have:

- More than 3,000 permanent residents;
- A proportion of aged persons and persons who are unemployed or receive pensions that is more than 10 per cent of the area’s population and who cannot be serviced reasonably by other means;
- The equivalent of a full-time medical practitioner;
- Inadequate services by other approved pharmacists;
- PBS and Repatriation Pharmaceutical Benefits Scheme prescription volumes of more than 3,000 in the previous 12 months;
- Isolation from, or a poor public transport system to, general shopping hinders the bulk of the population;
- An largely immobile population without a high proportion of commuting workers;
- General shopping facilities⁹⁷.

RELOCATION OF PHARMACIES

The Determination also sets tight boundaries around the assumed catchments of existing pharmacies. The principal conditions that it imposes are:

- Local relocations: pharmacists may relocate within **one** kilometre of their existing location provided that they have been in their current premises for at least two years. This may be in any direction, and does not depend on the proximity of another pharmacy to the new site;
- Long distance relocations: pharmacists may relocate more than one kilometre from their current site provided that (1) the proposed site is, by the “shortest lawful access route” not less than **two** kilometres from another pharmacy and (2) does not leave behind an area of “definite community need”;
- Pharmacists may relocate to a shopping centre of more than 30 shops, on the basis of a ratio of shops by the size of the complex (eg 100 shops = 2 permissible pharmacies); and
- Pharmacists may relocate to a private hospital if that hospital has more than 150 beds⁹⁸.

⁹⁷ Determination under sub-section 99L (1) of the *National Health Act 1953* (PB13 of 1998), Clause 2.

⁹⁸ *Ibid*, Clauses 6-9A.

Applications for both new pharmacy and pharmacy relocation approvals for PBS purposes are considered by the Australian Community Pharmacy Authority (ACPA), which then makes recommendations to the Secretary of the Department of Health and Aged Care. The Determination is the basis of the Authority's decision-making processes.

OBJECTIVES OF THE RESTRICTIONS

While embodied in Commonwealth legislation, the PBS location rules are derived from the Agreement, and reflect outcomes negotiated between the Commonwealth and the Pharmacy Guild of Australia.

The immediate object of the provisions is to provide a mechanism for the Commonwealth to contain the growth of PBS dispensing costs after it reached unsustainably high levels by the late 1980s. In return for their cooperation, the Agreement provided that community pharmacists are assured of a reasonable and stable remuneration framework for PBS activity.

The first Agreement (1990-95) therefore assumed that there were too many pharmacies, and sought to reduce numbers by providing assistance to many pharmacies to amalgamate or close. The second Agreement (1995-2000), while it did not offer such direct assistance, did assume an inherent national oversupply of pharmacies that needs to be contained.

EFFECTS OF THE RESTRICTIONS

Against the background of the objectives, the location rules of the current Determination arguably have three specific restrictive effects:

- Keeping the PBS-linked approval of new pharmacies to a minimum in a national community pharmacy industry that is deemed to have an overall oversupply of pharmacies; and
- Facilitating the placement of new and relocated pharmacies in localities where there is genuine need for pharmacy services, particularly regional, rural and remote areas, and for areas of new population growth in metropolitan areas; and
- Protecting the catchment areas of existing pharmacies from new competition wherever possible.

Since 1990 very few new pharmacy PBS approvals have been granted. In almost a decade, only 98 approvals for new pharmacies have been agreed to by the ACPA. Since May 1995, only 26 new approvals were agreed to out of a total of 280 new applications⁹⁹.

Relocation approvals have been more forthcoming. Under the second Agreement, 940 of 1,128 applications have been approved to date¹⁰⁰. Most short relocation approvals are approved¹⁰¹. The Determination provisions thus are integral to deciding which pharmacies and proprietors have access to the PBS, and to its medicine sales and dispensing fees, by specifying where they may establish.

⁹⁹ Commonwealth submission to the Review, paras 4.22 – 4.24.

¹⁰⁰ *Ibid*, para 4.35.

¹⁰¹ Advice to the Review from the Australian Community Pharmacy Authority secretariat.

COSTS AND BENEFITS OF THE RESTRICTIONS

The position of both the Commonwealth and the Pharmacy Guild is that matters relating to the Agreement ultimately are a matter for them to settle in the negotiation of a third Agreement. The Review is examining, however, the legislative consequences of the Agreement rather than the Agreement itself¹⁰².

PBS location regulations restrict competition in the pharmacy industry. They need to be assessed to determine whether the benefits of their retention to the community as a whole can be shown to outweigh their costs, and whether there are more effective methods, regulatory or otherwise, capable of achieving similar results.

COSTS OF THE RESTRICTIONS

The costs of the location restrictions can be seen in terms of their implications for inhibiting greater efficiency in community pharmacy, restricting consumer choice, and failing to provide adequate assistance to areas of “definite community need”. Specific cost effects include:

- Protecting inefficient pharmacies from effective competition, including service competition;
- Providing a disincentive for more intensive restructuring in the community pharmacy industry;
- Maintaining restrictions after the original need has passed and not recognising current health trends;
- Undue government intrusion into aspects of the community pharmacy market;
- Unintended consequences of the application of the location rules; and
- Creating pharmacy access and retention difficulties for communities in areas of need, and particularly for rural and remote communities.

Protecting inefficient pharmacies

The new approval and relocation restrictions are blunt policy instruments. They affect the size and competitiveness of local pharmacy markets. They are quantitative, not qualitative, in their scope.

The rules protect existing pharmacies from new competitors which otherwise may establish themselves freely where their proprietors believe that they can succeed commercially. Indeed, some of those potential competitors might have been more efficient, bigger or better resourced than the existing pharmacy or pharmacies, and would have the ability to make big inroads into existing pharmacies’ market shares. Alternately, the local competition may have been more vigorous and lively, and the quality of service to consumers enhanced, because of new local rivalries between able and efficient pharmacies.

For a more efficient pharmacy to move itself to challenge an established pharmacy, the only option under the rules is to relocate itself outside the 2 kilometre “exclusion zone” and then, over two-year intervals, move closer in 1 kilometre bounds to the established pharmacy. This is clumsy and expensive.

¹⁰² Commonwealth submission to the Review, para 2.6; Pharmacy Guild and Pharmaceutical Society consultations with the Review, 7 September 1999.

If the established pharmacy is not well managed, or generally finds it difficult to remain profitable, the relocation rules effectively insulate its immediate catchment area from new entrants. This applies even if the local community might have benefited from the new entrant's arrival through lower prices on a competing goods and services, and from competition-driven enhancements to the quality of pharmacies' services to consumers.

Who bears these costs?

Local communities bear a significant cost of maintaining inefficient pharmacies with little or no opportunity for more efficient competition to enter the local market. Consumers are, in effect, forced to deal with the established yet unsatisfactory pharmacy, unless they choose to take their business to a pharmacy in a less convenient location.

The pharmacy industry and profession also bears the cost of unfair community generalisations about pharmacist and pharmacy performance based on the unsatisfactory or inefficient service of a relative few of their colleagues. Potential competitors are shut out of a poorly served local market until such time as relocation rules are relaxed or removed, or they can "leapfrog" into contention by way of the short-distance relocations measure.

Avoiding the need for further industry restructuring

The location restrictions not only protect inefficient pharmacies. They also lessen the urgency for continuing the processes of community pharmacy industry restructuring started in the early 1990s, and realising the competitive benefits of a leaner and more efficient pharmacy industry. Coupled with restrictions on pharmacy ownership, which to an extent dampen down competitive forces in the industry by restricting ownership privileges to pharmacists, they encourage static conditions rather than innovation and positive change.

While the PBS location controls may have led to a general significant improvement in the efficiency of the community pharmacy industry in prescription volume terms, supporting statistics for 1997-98 quoted in the Commonwealth's submission suggest that there is still some way to go to a optimum performing community pharmacy industry¹⁰³. These statistics note that at that time there were:

- 13 per cent of pharmacies with dispensing volumes below 10,000 prescriptions;
- 32 per cent of pharmacies with dispensing volumes of between 10,000 and 20,000 prescriptions;
- 27 per cent of pharmacies with dispensing volumes of between 20,000 and 30,000 prescriptions; and
- Only 28 per cent of pharmacies with dispensing volumes over 30,000 prescriptions.

By making it easier for less efficient pharmacies to stay viable on the basis of a reasonable projection of PBS-related turnover, the location rules may reduce the incentive for small, low-volume pharmacies to close, or to merge with another pharmacy. If a catchment "patch" and PBS-related income are more or less guaranteed for a pharmacy, there is no great urge for the proprietors of these less efficient pharmacies to improve their performance or to review their futures.

In making these comments, the Review notes that a proportion of the lower-volume pharmacies still operating are in rural, remote and isolated areas, and that the social

¹⁰³ Commonwealth submission to the Review, para 2.43.

desirability of their ongoing presence may outweigh pure economic considerations. It also notes that there are other ways of achieving access-related policy objectives in these areas than the current PBS location rules.

Who bears these costs?

The community bears a cost of community pharmacies being funded through PBS mechanisms in ways that appear to discourage efficiency, productivity and cost effective operation. If remuneration focused on pharmacy performance ahead of simple geography, it may well be that PBS medicines could be delivered more efficiently and economically than they are now.

Consumers also may bear associated costs if the location system helps to prop up less viable and less efficient pharmacies that, to gain some return over their cost margins, have to charge higher prices for their non-PBS goods and services.

Continuing the restrictions after the original need has passed

Another effective cost of the location restrictions is that the overall numbers of pharmacies have remained relatively static since about 1993, notwithstanding their operation.

Before the commencement of the first Agreement in 1990, there were over 5,600 approved pharmacies in Australia. By the end of that Agreement, and assisted by the amalgamations and closure package negotiated by the Commonwealth and the Pharmacy Guild, the number of pharmacies had reduced to 4,950. In net terms (new approvals less closures), however, it has hovered around this lower figure ever since.

This relatively static number of pharmacies suggests that the initial need for the imposition of tight controls on pharmacy location may well have passed. By continuing to impose a regulatory straitjacket on the size and shape of the community pharmacy market, they have since gone from being a net benefit to a net cost to the community.

This may assist current proprietors, who benefit not only from a stable environment but also from the sale and goodwill values of pharmacy businesses rising steadily as the demand to purchase pharmacies outstrips the restricted supply. It may not, however, benefit the community as a whole, who subsidise the cost of pharmacy businesses through the cost of purchasing their goods and services, including pharmacist-determined mark-ups in the case of non-PBS items.

Who bears these costs?

The community bears some of this cost in that the location restrictions, and the bureaucratic machinery serving them, ensure that the demand for new and relocated pharmacies may lag significantly behind the perceived need for an enhanced local pharmacy service. Consumers might also bear point of sale costs if the money costs of a pharmacy going through the application and approval process add significantly to their operating margins.

Aspiring pharmacy proprietors also bear a cost because the collective operation of the restrictions create a seller's market in many localities, and the value of pharmacies as going concerns is inflated as the demand to purchase them outstrips supply. As a result many of these aspiring proprietors, particularly younger pharmacists with professional talent and

contemporary practice values, may largely be frustrated in their desire to proceed to owning a pharmacy business.

The restrictions have not kept up with evolving health care and consumer trends

The PBS location restrictions have been operating, with modifications, since 1990. In that time, there have been considerable changes in the modes of delivery for primary health care services, including pharmacy.

Multi-practitioner medical centres have continued to proliferate, offering hub points for allied services like pharmacy to join. Private hospitals have become increasingly more sophisticated, and a considerable number have evolved to the position of offering a full range of acute care services including accident and emergency care. The thrust of recent Commonwealth and State policy has been to encourage choice between public and private care. Additionally, aged care facilities covering both residential and community-based care, have themselves become more sophisticated and self-contained.

Exemptions from the rules' distance criteria for these facilities are very limited. Only private hospitals with more than 150 beds are eligible for consideration in this context. The other facilities have to be assessed against the full range of relocation criteria. In contrast, exemptions apply for shopping centres containing 30 or more retail shops are currently exempt from the distance criteria of the relocation rules.

By effectively standing still at the beginning of the decade, the current restrictions arguably have not served the community well. They reflect, and to an extent have locked in, the pharmacy and health care outlook of the early 1990s, rather than looking ahead to needs of the decade ahead.

A collateral cost of maintaining both the new and relocated pharmacy criteria is that they frustrate positive developments in pharmacy service planning and provision. They do not help to keep the shape of the community pharmacy industry abreast of current and likely future trends in consumer need and demand for pharmacy services, including:

- The ongoing popularity with consumers of “one-stop” shop medical centres containing a range of health care professionals under one roof;
- The development and expansion of care and multi-campus aged care nursing home and hostel facilities, which lend themselves to either on-site dispensaries or the contracting in of specialist pharmacy services not always provided readily by orthodox community pharmacies¹⁰⁴; and
- Specialist health care facilities such as Aboriginal Medical Services, which could also sustain their own dispensary facilities.

Who bears these costs?

The community and consumers bear a related cost. As a result of inbuilt features of the new and relocated pharmacy approval rules, it is very difficult to accommodate the rapid growth in non-public acute and community care facilities in the last decade or so, even as the population ages. Governments' options in planning for and providing a full range of public

¹⁰⁴ This point was made separately in submissions to the Review, including those by Integrated Pharmacy Services Pty Ltd, pages 14-15 and by the Australian Medical Centres Association, pages 7-9, and in the Review's consultations with Resthaven Aged Care Community (SA), 24 August 1999.

and private care choices are affected, partly, by the inflexibility of the pharmacy location rules.

Affected private hospitals and other facilities may also bear a cost of not being able to arrange their service provision requirements best according to their needs and those of their patients and residents.

Specialist pharmacy service providers, who in many cases may best be able to meet this need for a number of facilities, may find their opportunities to provide better service than many local community pharmacies circumscribed by the existing rules. This is notwithstanding that many private hospitals and aged care facilities have highly specialised patient and resident needs, which may better be addressed by pharmacists with a clinical or hospital pharmacy background.

Micro-managing the pharmacy market

By implementing the very tight and restrictive regulations on where a pharmacy can be located for PBS purposes, the Commonwealth is allowing itself to become involved in setting the terms of trade, at a very localised level, in the community pharmacy market. The rules take away much commercial discretion from pharmacy proprietors, including the final responsibility for key qualitative decisions about siting that go to a heart of the success or failure of a pharmacy business.

Given that the Commonwealth, or the ACPA as its agent, may have little direct knowledge of local pharmacy markets, this degree of market involvement by government may not be appropriate in an economy demanding less rather than more public intervention in commercial markets.

Who bears these costs?

There is a related cost to pharmacists, and to the community. This lies not only in terms of constraining pharmacy proprietors' commercial judgments through the artificial strictures of the location rules, but in the actual costs of applicants having to go through the processes of complying with those rules. The length of time taken to prepare, process and decide on applications also takes its toll on the time and money of applicants, and other interested parties.

There is also a cost to government, including agencies like the Health Insurance Commission, of maintaining the machinery to support the ACPA. This includes the costs of processing applications for approval, and to gather information needed for consideration by the Authority and the final decision-maker. It also includes the opportunity costs of not being able to commit those resources to other purposes.

Unintended consequences of rigidly defined and applied restrictions

The new approvals and relocation criteria are intricate and precise. From evidence to the Review, it appears that disputes over actual distances between pharmacies is the biggest source of pharmacist angst about the rules. Several submissions to the Review highlighted some absurd situations caused by the strict application of the "shortest lawful route" criterion¹⁰⁵.

¹⁰⁵ See, for example, the Peter Fardoulis (developer) and Graeme Levis (community pharmacist) submissions to the Review on the 2 km rule.

The Authority has little choice but to apply the rules as they stand, and is not itself to blame for these situations. It merely applies the rules that as they are. But because of its commercial importance to applicants, and to pharmacies objecting to applications, the ACPA process can be costly as consultants and legal advisers increasingly have become involved in documenting, advocating and contesting applications to the Authority. It can also attract administrative and judicial review, as dissatisfied parties take their complaints to the Administrative Appeals Tribunal or the Federal Court¹⁰⁶.

Who bears these costs?

Affected pharmacists bear the financial and time costs of applying for location approvals, preparing applications and supporting information to the Authority and the final decision maker, and if necessary in seeking the review of decisions taken.

Lack of relevance to the needs of underserved communities

A final point that calls the current rules into question is the extent to which they serve the community's best interests, and particularly those of Australians who live, in pharmacy terms, in less attractive areas. This is especially relevant to people who live in rural and remote parts of the nation who are struggling to hold on to not only pharmacy services, but to a whole range of services and the providers that could be considered integral to rural community infrastructure.

The Commonwealth's own submission noted that "the existing controls ... have only been effective at the margin in maintaining access to rural and remote areas"¹⁰⁷.

Even though the major proportion of those successful approvals have gone to rural and remote areas, the lack of new approvals have been so few in both Agreement periods suggests that it very difficult for any community to fulfil the definite community need criteria. Arguably most of these, such as the permanent population and full-time general practitioner provisions, make it very hard for a great many rural localities to demonstrate that they have a definite community need for pharmacy services.

Even the new approval criterion concerning lack of public transport works against such country localities. The fact that most people in these areas have access to private transport suggests that they can go down the road to the nearest pharmacy as necessary – but down the road might be a drive of an hour or more, involving tens or even hundreds of kilometres.

If the new approval rules are going to be retained for any period, the definite community need criteria may require considerable reform to ensure that the service needs of many rural communities have as much chance as possible of being met.

The relocation criteria discourage a pharmacist seeking ACPA approval to leave an area of need behind simply to relocate to a more viable locality. But that does not prevent that pharmacist declaring that they cannot carry on the business, closing it down for reasons of commercial difficulty, or simply retiring. Additionally, there would be nothing to prevent that pharmacist, once he or she had closed the business, simply moving away and buying an existing business elsewhere.

¹⁰⁶ Though the Commonwealth submission to the Review at para 4.41 indicates that only a small proportion of relocation applications rejected by the ACPA proceed to the AAT, and only a handful proceed to the Federal Court. Of these, very few have been successful.

¹⁰⁷ Commonwealth submission to the Review, para 4.49.

Who bears these costs?

Affected rural and other disadvantaged communities find that in spite of the existing PBS location rules, the endemic difficulties that they have experienced in both attracting and retaining pharmacists and pharmacies have not been overcome, and that these problems remain in spite of the rules' intervention.

In short, the location rules have not solved the problems of preserving and enhancing a reasonable community pharmacy presence in regional Australia.

BENEFITS OF THE RESTRICTIONS

Against the perceived costs of the location rules as they operate currently, there are beneficial effects which need to be taken into consideration. These include:

- Supporting the Australian Community Pharmacy Agreement, and keeping pressure on PBS outlay growth to a minimum;
- Maintaining stable local pharmacy markets and minimum market saturation;
- Supporting a stable distribution network for the PBS;
- Keeping the overall numbers of pharmacies at a level sustainable by the wider community; and
- Promoting industry stability generally.

Supporting the Australian Community Pharmacy Agreement

Maintaining the location restrictions is of central importance to the Australian Community Pharmacy Agreement, and through it to the efficient management of the PBS.

For the Commonwealth as the funder, a main object of the Agreement is managing the cost of the PBS itself, and keeping dispensing costs growing in manageable proportions. By entering into arrangements with the community pharmacy industry that create a stable environment for pharmacy businesses while enabling the Commonwealth to realise some efficiencies, the taxpayer receives a net benefit in terms of real savings. This savings benefit has been estimated at up to \$200 million over the life of the two Agreements to date, through revised pharmacist remuneration arrangements¹⁰⁸.

Who benefits?

From an industry perspective, the inbuilt restrictions on competition inherent in the PBS location rules translates to the stability of pharmacist income and, more particularly, to maximising the sale and goodwill value of pharmacy businesses and returns on proprietors' investments. Traditionally this value has not been drawn upon until a pharmacist retires, as a form of superannuation¹⁰⁹.

This can in turn apply to negotiating mutually satisfactory remuneration to pharmacy proprietors for the dispensing of PBS medicines. The Commonwealth may, for instance, gain some advantage for the taxpayer in negotiating lower dispensing fees. Pharmacy proprietors benefit as the overall profitability and sale value of their businesses is buffered from overly aggressive competition. Additionally, the overall compression of pharmacy numbers boosts

¹⁰⁸ Commonwealth submission to the Review, para 1.31.

¹⁰⁹ This point was made privately to the Review by an authoritative industry source.

the sale value of those existing businesses, particularly in localities where there may be a number of potential buyers for a pharmacy business.

The community as a whole benefits from a stable PBS distribution system, from manageable growth in medicine prices and pharmacist remuneration, from the ongoing presence of pharmacy service in areas of need, and from easy access to pharmacist advice services.

Supporting local pharmacy markets

Outside the one kilometre “short relocation” rule, which assumes that a pharmacy is already in a local market, the relocation rules create relative security and stability for proprietors in terms of their local catchment. Provided that they perform professionally, and meet local regulatory requirements, they continue to hold a PBS approval with relatively little threat of competition from new entrants to the local market.

Such mechanisms guarantee a catchment area for an established proprietor, while ensuring that the given catchment area has a guaranteed source of PBS-subsidised medicines. They can also ensure that proprietors can concentrate more on providing best quality services to their consumers.

These relocation rules potentially also act to prevent any given local area pharmacy market being packed with pharmacies while other areas, such as country localities, are underserved. As mentioned earlier, however, this may not always work as anticipated.

The rules as they stand make it difficult for a pharmacist to relocate from areas of otherwise definite need to a more financially attractive locality. In return for this constriction on freedom, the Commonwealth offers pharmacists Remote and Isolated Pharmacy Allowances to supplement pharmacy turnover in recognition of the inherent viability difficulties of operating in designated localities.

Who benefits?

Local pharmacy proprietors can benefit from the existing rules in better being able to plan and grow their business with the certainty of a reasonably stable competitive market. The staged “leapfrog” approach also assists existing pharmacies to plan for possible changes in local markets, arguably with the consumer’s best interest in mind.

There is a real dividend for the community in that the rational pharmacy location measures help to ensure that pharmacies continue to operate in areas of marginal viability. This is especially important in rural and remote localities.

Stability in the PBS distribution network

On behalf of the Australian taxpayer, the Commonwealth has an interest to ensure that outlays on the PBS medicines and related services, which are demand-driven, are kept under reasonable control and grow at a manageable rate.

While providing a direct framework for cost containment, the Agreement and the pharmacy location rules assist the Commonwealth in two more indirect ways. Firstly, they help to ensure that the numbers of distribution points for PBS medicines is not excessive in terms of the ratio of population per pharmacy. Secondly, they also make it easier for the

Commonwealth to monitor dispensing volumes per pharmacy and locality, and to plan for the growth of PBS outlays on the basis of a stable community pharmacy network.

This is consistent with the overall social goal of the PBS: promoting relative equality of access of all Australians to essential pharmaceutical and medicinal care.

Who benefits?

In this sense, the community as a whole benefits from the location restrictions, as the location and distribution of approved is a key underpinning of the current PBS system as a whole. Effective planning and needs identification helps governments to allocate scarce resources more prudently on behalf of the Australian community.

Keeping the overall number of pharmacies at sustainable levels

At a national level, a major argument for the new PBS approval restrictions is that there is a community benefit in managing the overall number of pharmacies, despite the adjustments undertaken through the two Australian Community Pharmacy Agreements to date.

As mentioned previously in this chapter, Commonwealth data suggests that there are still some relatively less efficient operators who have held on through the adjustments of the last decade¹¹⁰.

Allowing more new pharmacies than can be sustained by consumer demand simply creates further supply side pressure on PBS outlays, with much less scope for effective cost management. This was in part the triggering situation in the 1980s, before the first Agreement broached the rationalising of pharmacy numbers, when PBS outlays grew at considerably greater annual rates than now.

While the restrictions, and the Agreement, are not the sole reasons that PBS dispensing costs have been contained more effectively, the strict application of the new pharmacy approval criteria go a long way towards containing systemic-based growth pressures in return for a stable PBS income structure for the remaining pharmacies – which is in turn supported by the restrictions on pharmacy relocation.

Who benefits?

The community benefits from the location restrictions in that they help keep the numbers and distribution of pharmacies relatively rational. The overall number of pharmacies is kept relatively sustainable by the restrictions on new pharmacies, and the restrictions on pharmacy relocations go some way to ensure that pharmacies operate with reference to community need as much as to commercial potential.

Pharmacy values

The overall conditions of the Agreement, not least the resulting restrictions on overall pharmacy numbers and location, have led to (1) a significant increase of investment in pharmacy; and (2) the significant boosting sales values for pharmacy businesses¹¹¹.

¹¹⁰ See page 74.

¹¹¹ These comments are based on Review staff's private discussions with pharmacy industry experts.

Related factors appear to include that:

- Amalgamations and buy-outs within local areas have increased the value of the remaining pharmacies. This reflects both relieved competition pressures and the larger size, and the consequent ability to provide better and extended services, of many of the remaining pharmacies;
- Many pharmacists have invested more in continuing education and training for themselves, their professional staff and for pharmacy assistants;
- The more stable industry environment has made it more possible for pharmacies to participate in non-dispensing activities such as public health programmes, methadone dispensing and needle exchange; and
- The increased floor space of larger pharmacies has allowed a greater quantity of diversity in the variety of stock carried in the pharmacy.

There has been a significant growth of pharmacy values and profitability over the 1990s. While hard data on this point is difficult to come by, this observation is supported by the Pharmacy Guild's annual industry surveys, which indicate that the average total annual profit of surveyed pharmacies rose from \$65,806 in 1989 to \$138,714 in 1997— a net increase of approximately 110 per cent¹¹². Such movements are not, however, dissimilar to the experiences of other professions and areas of business.

Even allowing for variations above and below the industry average, and allowing for factors such as the cost of goods' increasing share of pharmacy turnover, this is a healthy rate of growth compared to many other industry sectors. To a considerable extent, this growth appears to have been nurtured by effective restrictions on new PBS-approved pharmacies entering the market, and by the cushioning of local competition offered to proprietors by the relocation rules.

Who benefits?

Clearly, pharmacy owners benefit from the valuation effects of the present restrictions. The fewer the pharmacies on the market, the higher the prices that can be asked for them. Higher business values translate to greater returns on investment for proprietors and shareholders. They also translate into a greater likelihood of pharmacy services being maintained and enhanced in a given locality, either by an existing provider or by someone who buys the business. This has flow-on benefits for local communities, including employment effects and helping local economies through purchasing local goods and services for the business. Such factors are particularly important for smaller rural communities.

ALTERNATIVES TO THE RESTRICTIONS

If the purpose of the restrictions on PBS-approved pharmacy numbers and the relocation of pharmacies is to create stability in the pharmacy environment while ensuring equality of access to pharmacy services, there may be other ways of realising similar outcomes. This is particularly relevant to meeting the needs of communities in rural and remote areas, many of which are struggling to keep basic health care services, including pharmacies.

¹¹² Pharmacy Guild of Australia, *1998 Guild Digest*, 1999, Table 1.

Other regulatory and non-regulatory approaches could include:

- Immediate or phased removal of the location restrictions, letting the market respond to consumer demand with minimal government intervention;
- Remuneration-based approaches to addressing pharmacy oversupply and undersupply in local catchment areas;
- Tendering for PBS approvals; and
- Measures aimed more directly at addressing the pharmacy access needs of people in rural and remote communities.

REMOVAL OF THE RESTRICTIONS

Assuming that the shape and size of the community pharmacy have been stable since the early 1990s, it may be time to remove the location restrictions altogether, and allow the geographic distribution of the PBS-based pharmacy market to take its course.

As an alternative to the present restrictions, letting the market operate more freely in this way could:

- Apply further pressure on less efficient pharmacies to perform;
- Let competition determine the survival of pharmacies in areas of oversupply;
- Introduce new competition to pharmacies previously constrained by the distance criteria of the relocation restrictions; and
- Encourage the development of alternative and more direct assistance to pharmacy services in rural and remote areas.

REMUNERATION-BASED APPROACHES

The principal policy response to the oversupply of pharmacies has been to reduce and then constrain the overall number of pharmacies.

The first Agreement provided cash incentives for pharmacy closures and amalgamations, and the second has kept a tight lid on new pharmacy approvals. Behind this, the remuneration of pharmacists for PBS dispensing is calculated on an industry-wide basis – it avoids the need to take account of relative differences in either the level of pharmacy supply in given localities, or between pharmacies in terms of relative efficiency as measured by their dispensing costs.

The two Agreements to date have used allowances – currently the Remote and Isolated Pharmacy Allowances – to bolster the incomes of pharmacists operating in designated areas of need. It is not clear, however, whether these allowances have proved altogether effective as retention incentives in those areas.

Remuneration structures can, if so designed, encourage less efficient pharmacies to consider closing if they are marginally viable or not viable, or to merge with more efficient pharmacy businesses.

In terms of alternatives to the current location restrictions, remuneration could be a more market and efficiency-based way of achieving both a manageable overall number of pharmacies and community-friendly distribution of pharmacies based on communities' ability to sustain those services.

Differential dispensing fees

If the parties to the Agreement decide to do so, higher dispensing fees could be offered by the Commonwealth to pharmacists operating in rural and remote areas, and in other designated areas of pharmacy undersupply. This would augment pharmacists' PBS derived income on an by item basis, and provide an incentive for those pharmacists now operating in these areas to carry on operating. It would also make the purchasing or establishment of a pharmacy business more financially attractive to pharmacists who may not otherwise have considered such an option.

To be effective as an incentive and to contain the overall costs of the approach, differential remuneration-based measures should also contain a disincentive for pharmacists considering moving to an area of pharmacy oversupply or saturation, such as a capital city CBD. Just as dispensing fees in undersupplied areas could carry a premium, fees in oversupplied areas could carry a downwards adjustment from the norm. This would make a proprietor's moving into an oversupplied area a less attractive proposition, and would put pressure on less efficient pharmacies already located in those areas to consider sensibly their trading futures.

Such differential arrangements particularly could be directed to newcomers in an area of oversupply, to discourage them from further saturating a local pharmacy market.

Pharmacies in areas where supply and demand are in balance would receive the standard negotiated remuneration for the PBS services that they provide.

Considering different PBS remuneration calculation bases

In its submission to the Review, the Commonwealth observed:

Controls on overall approval numbers are considered important because, under present remuneration arrangements that are driven by the historical 'average' cost of prescribing PBS drugs, lifting the cap on new approvals would probably lead to the same sort of inefficient industry structure that existed before the first Agreement. This would have implications in turn for the cost to the taxpayer of supporting the Pharmaceutical Benefits Scheme¹¹³.

Average cost-based remuneration structures support inefficient pharmacies while generally rewarding those who have lower fixed and variable costs. The less efficient performers therefore largely shape industry-wide PBS remuneration structures to their needs. Good performers are held back: mediocre performers largely set the pace for their fellows.

Moving away from average cost to industry good practice cost formulations – linking remuneration structures to pharmacy efficiency – could go a long way to shaking out marginally viable and inefficient pharmacies in oversupplied areas, and shake out the overall number of pharmacies by targeting their viability rather than their location. It could also effectively remove the need to regulate to cap pharmacy numbers and similarly to reduce the clustering of pharmacies by regulation.

It would, as well, promote greater service-based competition between pharmacies in areas of adequate supply and oversupply of pharmacies.

¹¹³ Commonwealth submission to the Review, para 4.56.

If a marginal cost-based formulation were introduced, however, there may need to be supplementary arrangements to ensure that the provision of services in rural and remote areas is not affected unduly.

To administer any remuneration-linked arrangements fairly, pharmacy distribution would need to be monitored by government, and adjustments to remuneration formulas made if and as distribution patterns change. If they are practical at one level, the overall effects on PBS and related outlays of remuneration-linked arrangements, which may be substantial and possibly exceed existing outlay trends, would also need to be taken into account in looking at the relative benefits of different measures.

Nevertheless, the Review notes that pharmacist remuneration is ultimately a matter for the Agreement and its parties, and that there would be additional administrative and implementation costs if these measures were adopted, over and above the likelihood of industry resistance to the implementing of such measures. If remuneration bases were changed, however, the needs for direct PBS controls such as those presently affecting the location of pharmacies would become redundant.

It is, of course, up to the Agreement parties themselves to consider alternatives to the existing controls in negotiating the next Agreement, being guided first and foremost by the need to ensure that pharmacy services are provided and distributed in the interests of the community as a whole.

TENDERING FOR THE SUPPLY OF PBS MEDICINES

A different approach would be to contract out the provision of PBS medicines by pharmacies by means of competitive tendering. The Commonwealth noted this possibility in its submission to the Review¹¹⁴.

Tendering would allow the market to determine the level of remuneration on a pharmacy by pharmacy basis. The market would thus be responsible for ensuring a competitive price for PBS services. Consequently, the overall number of PBS approved pharmacies therefore would be contained by the market forces rather than by direct regulation.

Under this approach the Commonwealth would call for tenders for the supply of PBS medicines, with licences granted to successful tenderers for a particular geographical area or areas. This could encourage a more competitive market with the potential for some savings in dispensing costs for the Commonwealth. It could also encourage imagination and innovation from tendering pharmacies in developing their proposals, and reward those more efficient businesses that could offer lower tender prices on the basis of lower unit costs.

In some rural and remote areas the dispensing cost per successful tenderer may be higher than present, but it also could be expected that these higher costs would be offset by the lower costs per pharmacy in more populated and better serviced areas.

There are significant risks with a competitive tendering approach, however. A successful tender does not in itself assure quality of service. As with other competitive tendering programmes, local communities may suffer if tenderers provide an inferior service and lose their contract, or if the tenderer underestimates their costs and closes down.

¹¹⁴ Commonwealth submission to the Review, para 4.30.

There would also be considerable financial costs involved in setting up the initial tendering process and ongoing costs for its administration, monitoring and evaluation. These effects would need to be estimated and taken into account against any benefits in any further assessment of this approach.

On balance, the Review believes that competitive tendering would not be the most practical and effective alternative mechanism in this instance.

DIRECT MEASURES TO ASSIST RURAL AND REMOTE COMMUNITIES

Instead of existing location-based measures, including Rural and Isolated Pharmacy Allowances, it may be more realistic for Commonwealth, State and Territory policy-makers to consider new initiatives aimed directly at rural communities, and to make better use of those existing measures.

Providing financial and material support to pharmacists relocating to rural areas

Subject to available funding, governments might consider working with the pharmacy profession to develop incentive packages to pharmacists wishing to locate to rural areas. Such packages might include a suite of measures, including financial grants for business start-up, assistance with relocation expenses, family support arrangements and locum relief cost assistance.

The highly successful Commonwealth General Practice Rural Incentives Scheme provides a ready-made model for evaluation and consideration.

Some development work along these lines is currently being undertaken by the Pharmacy Guild, with financial assistance from the Commonwealth. State and Territory governments, with an interest in health service provision to their outlying areas, could also consider their active involvement in such schemes if they are implemented.

Issuing approval numbers to localities in designated cases

A complaint from some rural communities is that while they may generally satisfy the PBS new pharmacy approval criteria, or could sustain a relocated pharmacy, they have little or no chance to attract a pharmacist to set up business in their area.

It was suggested to the Review that in such circumstances that a PBS approval could be issued to a local community and administered by a local council or community committee. Under the proposal as presented, the community would become the recognised approval holder for the purposes of the *National Health Act*. It would be able to sublet the approval to a pharmacist proprietor as part of a package of incentives for him or her to move to that community to run a pharmacy business. The approval would remain with the community in the event of the pharmacist moving on, but the business would be owned, controlled and operated by the pharmacist¹¹⁵.

Such a proposal might, perhaps with modifications and refinements, assist rural communities where the local pharmacy market fails to meet demonstrated need without such intervention.

¹¹⁵ Submission to the Review by Mr Ray Veal, of Stratford, Vic. Such a proposal also lends itself to the community employing a pharmacist, and running the business itself. This may, however, not be consistent with the general pharmacist ownership principle endorsed in Chapter 2.

It would not be inconsistent with the general principle of pharmacist-owned and controlled pharmacies, as the proprietor would still own the pharmacy business.

Ensuring regulation does not impede the flexible delivery of pharmacy services in rural areas

As part of ensuring that pharmacy services in rural Australia survive and flourish, all jurisdictions need to ensure that their regulation of pharmacies and pharmacy businesses does not unduly impede the development of flexible and innovative measures to deliver high quality pharmacy services to the residents of rural and remote Australia. This may require coordinated legislative action between jurisdictions, particularly between the Commonwealth and States and Territories.

In New South Wales, for instance, the *Pharmacy Act 1964* allows for the establishment of branch pharmacies to operate from a base location but have a series of other localities operated by the pharmacist as part-time branches of the parent pharmacy. Collectively, the New South Wales legislation treats the parent and its branches as a single pharmacy. The Commonwealth *National Health Act 1953*, however, has interpreted each site as a separate site for PBS purposes, and therefore each site requires a new PBS dispensing approval¹¹⁶. In dialogue with the Review, the Commonwealth Department of Health and Aged Care indicated that it is prepared to revisit this interpretation¹¹⁷.

Addressing such unintended consequences of legislation is important if rural-specific elements of the current location restrictions are to be dealt with by other means. It is also important that regulations are flexible enough to permit new and innovative ways of promoting the practical delivery of services such as, for example, delivering medicines by “mobile pharmacies” – something that is precluded by regulations in a number of jurisdictions relating to pharmacy siting and fitting out.

FINDINGS AND CONCLUSIONS

On considering the net costs and benefits of the Determination’s restrictions on pharmacy location, for PBS purposes, the Review has reached some in-principle conclusions. In doing so, it took into account the Public Benefit Test of the Competition Principles Agreement.

The Review therefore believes that the PBS location rules are inherently anti-competitive in their operation and their effects. While they have helped to rein in Commonwealth PBS outlays, they represent heavy government intervention in the market for pharmacy services, while generally protecting pharmacy’s established catchment areas from new competition.

NEW PHARMACY APPROVALS

There is a justifiable need to keep the overall size of the Australian community pharmacy industry to a level capable of being sustained by taxpayers and consumers in relation to government and individual contributions to PBS and other pharmacy-related outlays.

On the available evidence, it appears that the current 4,954 PBS-approved pharmacies – representing a ratio of one pharmacy for about 3,750 Australians, a figure comparable with

¹¹⁶ Commonwealth Department of Health and Aged Care consultations with the Review, 31 August 1999.

¹¹⁷ *Ibid.*

similar developed countries¹¹⁸ - is probably justifiable in terms of maintaining community access to pharmacy services. Indeed, if the still-substantial numbers of low and medium prescription volume pharmacies are taken into account, it may arguably be a generous figure.

The need for government to restrict the growth of pharmacy numbers is accepted by the Review for the following reasons:

- The overall level of spending on PBS medicines, and related pharmacist remuneration and the public policy need to manage the programme efficiently; and
- The social policy need to ensure that all Australians have reasonable and affordable access to pharmaceutical services needs to be linked to the affordability of those services.

The current tight criteria on approving new pharmacies for PBS dispensing is one way of keeping the overall number of pharmacies under control.

On balance, however, the Review questions whether the current restrictions are the best way of achieving desired outcomes. The definite community need criteria are set so tightly that it is not simply the pharmacy industry that is affected by their application. They also may affect the wider community's ease of access to pharmacy services, often to the detriment of many of the underserved regional communities.

The Review believes that ideally that the existing new pharmacy approval criteria should be replaced by more competition-friendly mechanisms that are as capable of achieving the desirable policy goal. These are discussed below.

Suggested replacement measures

Instead of the current PBS location restrictions, the Review believes that there are more direct and competition-friendly avenues to encouraging pharmacists to manage the overall number of PBS-subsidised pharmacies operating throughout Australia. Specifically, it believes that pharmacist remuneration is the vehicle most likely to deliver a manageably sized community pharmacy network while promoting vigorous internal competition in the pharmacy market.

Put simply, a competition-friendly package of remuneration for PBS services would:

- Reward pharmacies operating with more efficient cost structures;
- Promote larger pharmacies with higher dispensing volumes, enhancing the possibilities of those pharmacies achieving effective internal economies of scale and scope;
- Encourage smaller and/or less efficient pharmacies to either improve their internal efficiency to stay competitive, merge with other pharmacy businesses, or to close altogether; and
- To offset regional disadvantage, provide targeted incentives and allowances to pharmacy proprietors willing to open or maintain pharmacies in rural and remote areas, and other relatively underserved localities.

In this way, new pharmacies could be approved to supply PBS benefits as others merge or close.

The several remuneration-linked measures outlined earlier in this chapter, particularly changing the cost calculation basis for PBS remuneration to reflect better or best pharmacy

¹¹⁸ Commonwealth Department of Health and Aged Care consultations with the Review, 31 August 1999.

practice rather than use industry average costs, would be consistent with this approach. Such measures would also be more consistent with the Review's overall approach to pharmacy regulation that, as far as possible, pharmacy businesses should have as real freedom and discretion over their commercial decision-making, without undue interference from governments and regulatory authorities.

It may also be that pharmacist remuneration packages would still need to be adjusted to ensure that pharmacies in areas of disadvantage, particularly rural and remote Australia, are not worse off as a result of wider systemic change.

The Review acknowledges that adopting remuneration-based measures as a market mechanism involves significant political and policy judgments for Commonwealth, State and Territory governments, as well as for pharmacy stakeholders. This would involve a departure from existing practices, and may not necessarily be practical to implement without a transition period. The Review believes, however, that such an approach is more consistent with the tenor of National Competition Policy principles, and is more likely than existing controls to stimulate a more competitive market for pharmacy businesses.

Possible retention of existing or comparable measures

It may be, however, that the current restrictions are preferred as part of the next Australian Community Pharmacy Agreement, which is presently being negotiated by the Commonwealth and the Pharmacy Guild of Australia.

If so, they should be reviewed and reformed.

If it is decided to keep the new pharmacy approval restrictions temporarily or indefinitely, the existing definite community need criteria should be replaced with requirements that are more responsive to the overall health care needs of communities. They also must recognise more realistically that rural and remote communities need as few impediments as possible to attracting a pharmacy.

The Review notes that ultimately pharmacist remuneration matters are the concern of the parties to the Agreement. It stresses to the parties that controls of the present sort should be seen as a last resort measure rather than as a best option.

Appendix 5 models a possible approach to the reforming the current new PBS approval criteria, consistent with the suggestions in this chapter. These suggestions could be implemented either to cover a transition from the current remuneration structure to another, or if the parties to the Agreement take the more cautious route of retaining current geographical-based controls.

The model in Appendix 5 also assumes that not only the rules, but their administration is reformed. It is important that the Australian Community Pharmacy Authority, as the body responsible for adjudicating on applications for pharmacy location has the capability to do what is expected of it under any rules it administers. The powers and discretions of the Authority also need to be made clear, if indeed it is retained. Even so, these still kept flexible enough to achieve outcomes that are fair not only to affected pharmacies and pharmacies, but to the communities that serve.

Recommendation 9

The Review recommends 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 underserved communities, particularly in rural and remote areas.

RELOCATION OF EXISTING PHARMACIES

On considering the evidence, the Review is not convinced that there is a net public benefit to the community as a whole from the current provisions for pharmacy relocations from one site to another.

The relocation rules are highly restrictive and anti-competitive. They protect the vested interests of established pharmacy proprietors at the expense of ensuring the best possible quality of pharmacy service delivery to the wider Australian community. They deter more enthusiastic and entrepreneurial proprietors from pursuing opportunities to outperform less efficient rivals. More tellingly, they place a higher priority on protecting a pharmacy's catchment from new competitors than on communities being assured of high quality and efficient pharmacy services.

The affected community loses in two ways: it is deprived of the potential services of a better performer, and it is stuck with those of an indifferent performer – unless a potential rival "leapfrogs" closer a kilometre at a time in intervals of no less than two years. In practice, and given the expense and disruption to the relocating pharmacy, leapfrogging of this nature is unlikely at the best of times.

If the overall distance-based relocation rules were removed, however, there would be no need for "leapfrogging" measures.

Instead, inefficient performers would be flushed out as cost margins tighten against remuneration and turnover. There would also be greater incentive on pharmacy proprietors generally to improve service quality and client satisfaction, areas of pharmacy oversupply should move towards equilibrium over time, and complementary measures could be introduced to assist areas undersupplied with pharmacies.

Unlike the new pharmacy approval restrictions, the pharmacy relocations could be dispensed with even if the present pharmacist remuneration structure remains after the conclusion of the present Agreement.

Recommendation 10

The Review recommends that Pharmaceutical Benefits Scheme (PBS) related restrictions on the relocation of pharmacies from one site to another are phased out.

TIMING OF THE PROPOSED CHANGES

On balance, and in the case of new appeals, depending on what is put in that phase, the reform and/or removal of the PBS approval restrictions for new and relocated pharmacies PBS should be phased over a period of several years.

The Review believes that there needs to be a transitional period of several years to ensure that no pharmacy business suffers undue financial difficulty as a result of the changes.

Phased change would also ensure the relative stability in PBS dispensing arrangements while giving affected parties a reasonable notice period to prepare for changes. New arrangements could commence apart from the commencement of the next Agreement. Given the matters that would need to be resolved in implementing change, new arrangements could come into effect on 1 July 2001. This would represent a generous notice period to all parties.

Following the Review's *Preliminary Report*, when the abolition of existing location controls was first proposed, the Pharmacy Guild and Pharmaceutical Society stressed to the Review that if the current rules were to change, many pharmacy businesses' investments would be affected severely by sudden and immediate change¹¹⁹. Their response also suggested that a sovereign risk situation would apply in terms of the unanticipated regulatory change, and pharmacy business would be entitled to compensation due to the "large losses in pharmacy values for some pharmacy owners"¹²⁰.

If reasonable notice of changed arrangements is given, and businesses are given time to adjust to these, the compensation of affected businesses would not be necessary.

Recommendation 11

The Review recommends 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.

RURAL AND REMOTE PHARMACIES

The Review believes that funding and implementing specific measures to keep pharmacy services in rural and remote Australia is a highly worthwhile social goal.

Evidence given to the Review painted a picture of shortage, uncertainty and difficulty of pharmacies and pharmacists in regional Australia. To ignore the special service delivery needs of rural and remote areas simply on the grounds of reducing regulation is ignoring that the community pharmacy market does not, unaided, meet the needs of affected regional communities.

The Review therefore commends rural-specific measures such as those outlined in this chapter. It specifically endorses the concept of non-transferable PBS dispensing approvals being allocated to some underserved localities. This would be a valuable measure that could afford affected rural and remote communities a greater chance of attracting or retaining a pharmacy. It could also provide those communities with an incentive to invest in

¹¹⁹ Pharmacy Guild and Pharmaceutical Society, *Response to the Preliminary Report of the National Competition Policy Review of Pharmacy*, December 1999, page 12.

¹²⁰ *Ibid.*

supporting infrastructure for a pharmacy shop, and even to offer lifestyle and other incentives to a pharmacist taking up the practice opportunity.

Overall, legislation providing for location-specific PBS dispensing rights, and any other measures which governments may find effective, is justifiable regulation with a very important public benefit.

How such a locality-specific PBS approval arrangement could operate is canvassed further in the Appendix 5 model for the transitional location regulatory machinery. These arrangements could continue beyond the transition period.

Recommendation 12

The Review recommends that:

- (a) Legislation to support specific programmes 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.

MEDICAL CENTRES AND AGED CARE FACILITIES

The current rules give short shrift to emerging service provision trends, particularly medical centres in suburban and rural localities, private hospitals with less than 150 beds and to facilities formerly known as nursing homes and aged care hostels.

As it stands, pharmacies and dispensaries in these care providers are only considered for PBS approval purposes in terms of the application of the distance-based relocation criteria. In many cases these facilities may have sufficient and specialised demand to sustain a viable PBS service notwithstanding the demographic and geographic catchment areas presupposed by the current rules.

By not treating medical centres, private hospitals and aged care facilities more realistically, the rules impose competitive restrictions that are difficult to justify in public benefit terms. By comparison, relocations into shopping centres of over 30 retail shops are considered in isolation of distance criteria. It would be consistent, and perhaps more community-minded, to look at specific health care providers in a similar way.

If a pharmacy or dispensary is principally for the benefit of a facility's patients or residents, and provided other funding arrangements for pharmaceutical services (for example, under section 100 of the *National Health Act*) do not apply, it is desirable to allow currently-ineligible private hospitals and aged care facilities to host a pharmacy for PBS purposes without reference to any distance or definite community need criteria.

Such pharmacies as dispensaries could be, in fact, a branch of an external pharmacy, as provided for in New South Wales legislation¹²¹.

¹²¹ *Pharmacy Act 1964* (NSW), sections 24C and 38.

Defining eligibility for specific facilities

There is a case for taking into account projections of the demand for pharmacy services arising from the medical centre, private hospital or aged care facility, as a substitute for other criteria. Some parties to the Review suggested that this could, in the case of a medical centre, be based on the number of general practitioner consultations of that centre in a given period¹²². Similarly, eligibility criteria could take into account the number of projected admissions (private hospitals) or residents and care recipients by category of care (aged care facilities). Volumes of prescriptions per patient or resident could also be taken into account.

The Review believes such empirical measures merely impose undue extra bureaucracy and red tape. It would be preferable for the Commonwealth, in consultation with other jurisdictions, the community pharmacy industry and profession and other relevant health and aged care providers, to adopt agreed definitions of eligible facilities. If a facility then satisfies an agreed statutory definition, it should simply be eligible to be a site for a new or relocated pharmacy or dispensary.

Section 94 of the *National Health Act* possibly could serve the purpose for private hospitals and aged care facilities. Section 94 provides that the Commonwealth minister (or delegate) can approve that pharmaceutical benefits be supplied by a hospital authority “to patients receiving treatment in or at the hospital of which it is the governing body or proprietor”¹²³. The arrangement could be extended to aged care facilities as well as to private hospitals by including their managing bodies in the relevant statutory definition of “hospital authorities”.

As a passing observation, the Review notes that this “distance free” approach could also be applied to PBS approvals for distance dispensing arrangements, and for specialised external pharmacy service providers who are contracted by private hospitals and nursing homes to deliver PBS-subsidised medicines for their patients and residents. Similarly, in all cases, section 90 of the *National Health Act* could be amended to remove the requirement for designated facilities to supply pharmaceutical benefits “on demand” to all comers.

Of course, if the PBS relocation rules are removed altogether, and new approvals rules are appropriate and relevant, there would be little or no ongoing need for any measures of this sort.

Recommendation 13

The Review recommends 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.

¹²² Woodbridge Medical Centre and Woodbridge Pharmacy (WA), consultations with the Review, 25 and 27 August 1999.

¹²³ *National Health Act 1953* (Cth), sub-section 94(1).

CHAPTER 4: REGISTRATION OF PHARMACISTS

The framework that supports how professional pharmacy activities are governed, registration arrangements, practice monitoring, disciplinary matters and the structure and roles of regulatory authorities their institutions of governance such as regulatory authorities, is in the scope of the Review, insofar as this may affect the ability of persons to practise pharmacy both as a profession and as a commercial business.

Findings and conclusions can then be drawn about the nature and operation of existing legislative and related regulatory mechanisms in terms of how they may affect competition in pharmacy and between pharmacists. Detailed comment on specific provisions is contained in the closer consideration of each referred State and Territory Act in Part B of this Report.

NATURE OF THE RESTRICTIONS

INTRODUCTION

All State and Territory *Pharmacy* and *Pharmacist Acts* define who may practise as a pharmacist, and how pharmacists may practise. They also provide for the administrative machinery oversee the effective operation of these regulations, particularly the constitution and powers of regulatory authorities (or the Pharmaceutical Council of Western Australia) and set out how pharmacists are held to account for their conduct as professionals by thorough professional misconduct and disciplinary mechanisms.

The regulations that govern the registration of pharmacists can be analysed in terms of three particular areas of restriction on competition in pharmacy as an occupation. These are:

- Entry into the pharmacy profession;
- Ongoing practice as a pharmacist; and
- The constitution and activities of pharmacy regulatory authorities.

ENTRY TO THE PROFESSION

In each State and Territory pharmacy is a registrable profession.

To obtain registration, all jurisdictions require a pharmacist to have a recognised qualification from a tertiary institution in Australia or overseas, and to complete a period of pre-registration training. In the case of overseas-trained pharmacists, this may include a period of supervised practice as part of the Australian Pharmacy Examining Council (APEC) process for assessing these pharmacists.

The currently accepted standard of entry, which is being phased in around Australia, is a four-year undergraduate degree in pharmacy plus a period of supervised practice and on-the-job training. Since World War II, training requirements have moved relatively rapidly through apprenticeships and on-the-job training, to three-year degrees and supervised practice, to the new four-year degree requirement. This progression has mirrored rapid developments in pharmaceuticals, pharmacology and pharmacy practice itself.

A graduate who has completed an appropriate course of study and supervised work experience must then demonstrate this knowledge to the satisfaction of a regulatory authority. Their performance is measured against nationally recognised standards of competency¹²⁴.

All jurisdictions also have *Mutual Recognition Acts* implementing the 1993 COAG Mutual Recognition Agreement. Under mutual recognition principles, a pharmacist registered in one Australian jurisdiction can be registered in the other State and Territories.

Across States and Territories there are also other personal requirements that an applicant for initial registration in a given jurisdiction must meet to the satisfaction of the local regulatory authority. Although they vary from place to place, these include:

- Good character or being a “fit and proper person”;
- An understanding of the English language;
- Medical fitness to practise pharmacy;
- Possession of a first aid certificate; and
- Being over the age of 18.

RESTRICTIONS ON ONGOING PRACTICE

Titles and descriptions

State and Territory *Pharmacy Acts* reserve the privilege of practising pharmacy to registered pharmacists. The supply of drugs and poisons is only permitted by non-pharmacists in very restricted circumstances¹²⁵. In addition, most jurisdictions protect the lawful use of the term “pharmacist”, “pharmaceutical chemist” and similar titles and descriptions, by restricting these to registered pharmacists.

Acts and regulations also impose restrictions on the professional *conduct* of pharmacists including:

- Prescribed ethical and professional standards and related disciplinary sanctions; and
- Limitations on advertising such as the Queensland prohibition of advertising leading to “invidious comparison” with other pharmacists¹²⁶.

Re-registration

In the Northern Territory there are no re-registration requirements whatsoever. In other jurisdictions re-registration is basically a matter of paying an annual fee, and completing any required paperwork. Often, Acts and regulations permit regulatory authorities to impose additional requirements, particularly when a pharmacist is applying for re-registration after a period out of practice.

REGULATORY STRUCTURES

All jurisdictions have a pharmacy regulatory body whose role is to enforce the related provisions of their Acts, and standards set under those Acts and delegated legislation.

¹²⁴ A national competency test based on these standards, the Australian Pharmacy Competency Assessment Tool or APCAT, is being trialled currently.

¹²⁵ This restriction is the subject of a parallel NCP Review on Drugs and Poisons and is not discussed further here.

¹²⁶ Clause 15.1 Queensland *Pharmacy Regulations 1997*.

In most jurisdictions these bodies are known as Pharmacy Boards, and comprise representatives of the profession and, in some cases, representatives of the wider community.

In Western Australia, the functions undertaken elsewhere by Pharmacy Boards are performed by the Pharmaceutical Council of Western Australia. There is a requirement that all registered pharmacists in Western Australia become members of the Pharmaceutical Society of Western Australia, of which the Council is the executive arm. The Western Australian *Pharmacy Act 1964* specifies the Council's dual role as regulator and manager of the professional organisation for pharmacists.

Regulatory authorities generally consist of a number of members appointed by the responsible minister additional to those elected by registered pharmacists. This, and the mixture of elected and appointed members, vary between jurisdictions; for example, all Pharmacy Board members are appointed in South Australia while in Western Australia, all members of the Pharmaceutical Council are elected by registered pharmacists.

OBJECTIVES OF THE RESTRICTIONS

The core objective of these overall restrictions is to protect the safety of the Australian public by ensuring that pharmacy services are provided in a safe, competent and accountable manner.

However, restrictions resulting from the legislation under review have come to fulfil other incidental objectives such as defining whom:

- Is entitled to have carriage of drugs and poisons;
- Can own a community pharmacy; and
- Can fill certain positions in government, academe, and industry.

EFFECTS OF THE RESTRICTIONS

The primary overall effects of registration-related restrictions are to:

- Restrict the eligibility lawfully to practise pharmacy only to those who have satisfied registration and re-registration requirements;
- Place controls, through legislation and its administration by regulatory authorities and the courts, on the practice of pharmacy; and
- Establish, through regulatory authorities, mechanisms that govern professional practice and conduct, and which can guide a professional culture in the way that it interprets and applies the provisions of *Pharmacy Acts*, regulations, standards and guidelines.

ENTRY TO THE PROFESSION

Pharmacy has become a more difficult profession to enter since the increase in the period of university training has risen from three to four years, and the effective minimum pre-registration period (including academic study) to five years¹²⁷.

¹²⁷ Assuming that jurisdictions maintain requirements for a prescribed period of supervised practice before registration.

The core of this training remains a foundation in the biological sciences upon which pharmacy is based. As the nature of primary health care evolves, however, pharmacists are expected to have an understanding of basic health conditions and symptom control in addition to a comprehensive knowledge of the therapeutic use of medicines and pharmacology.

Expanded university curricula are also paying more attention to practice skills such as interpersonal communication and business management, which are part of the day-to-day life of a practising pharmacist, but until quite recently have been relatively neglected in pharmacist training. Ensuring that pharmacists training is focused on their ability eventually to practise in the community setting is, presumably, the main purpose of undergraduate training.

Notwithstanding the length of time taken in training, pharmacy is a very popular course of university study. Pharmacy is a highly esteemed profession, and the personal and financial rewards for a successful practitioner can be great. Not only is the demand for pharmacy school places exceeding supply, the competition for those scarce places means that Tertiary Entrance Scores for these places are very high. As a result many potential pharmacy students, who may be academically and temperamentally suitable for pharmacy, may be precluded from entering professional training on the basis of their academic results. Where selection methods are broader-based than straight academic performance, this helps to overcome such difficulties.

RESTRICTIONS ON PRACTICE

Once currently registered, in all States and Territories a pharmacist may continue on the register until retirement or death, unless he or she comes to the attention of their regulatory authority for a grave and fundamental breach of professional standards and is deregistered. The only basic requirement for renewing registration is the annual registration fee, which is used to help fund the operations of the regulatory authorities. In the Northern Territory, even this requirement is absent¹²⁸.

In no jurisdiction is there an explicit statutory requirement to meet ongoing professional development or education requirements to keep registration, or to demonstrate professional competence.

Pharmacy registers may include pharmacists who are not practising, although in most jurisdictions these pharmacists may be required, at the regulatory authority's discretion, to undertake refresher study and/or supervised practice if they decide to return to practice. Qualified persons who have allowed their registration to lapse and then apply for re-registration to return to practice may be treated similarly.

Pharmacists are expected to comply with set practice standards and codes of conduct. Breaches of these can be dealt with by disciplinary processes outlined in Acts and regulations, and administered by regulatory authorities. Disciplinary sanctions can range from cautions to fines, and ultimately de-registration whereby a pharmacist can lose his or her livelihood. In practice, suspension of registration for a period of time is generally the

¹²⁸ In the Northern Territory there is no requirement for pharmacists' re-registration or for an annual registration fee.

most serious sanction imposed on an errant pharmacist. Complete deregistration, as the ultimate professional sanction, is very rare.

REGULATORY STRUCTURES

Regulatory authorities (the Pharmacy Boards) are crucial to the effective administration and implementation of the regulatory frameworks that parliaments put in place.

Core roles

Essentially, the central roles of regulatory authorities are to:

- Maintain the register of pharmacists in their jurisdiction;
- Scrutinise the operation and practice of pharmacists and pharmacy businesses, and inspect pharmacy premises (as also discussed and considered in Chapter 2); and
- Investigate and adjudicate upon complaints against registered pharmacists made to it by the wider community, courts (where a matter has resulted in a conviction relevant to a pharmacist's professional standing and conduct) and health complaints commissions.

Some jurisdictions' Acts provide that Boards have the power to set and implement regulations, by-laws, guidelines and instructions for pharmacy practice, within the scope of those Acts. This may be either directly, or by making recommendations to the responsible minister.

Advisory and discretionary roles

Given their professional core membership, however, and given their role in administering *Pharmacy Acts* and professional matters, regulatory authorities have become convenient substitutes for governments when it comes to policy development for and consultation with the pharmacy profession¹²⁹.

More importantly, however, is the fact that the loose and undefined wording of key provisions in *Pharmacy Acts* and delegated legislation effectively place a great deal of discretion in the hands of authorities in terms of how they operate, and how they translate the intentions of their parliaments into action.

The reality of such discretion is that regulatory authorities can influence significantly both the practice of pharmacy and the conduct of pharmacy businesses in terms of compliance with their Acts. In terms of examining the effective restrictions on competition, the interpretation of legislation by regulatory authorities is therefore highly relevant. How provisions of Acts are interpreted and applied goes a considerable way to shaping the professional and market behaviour of both registered pharmacists and pharmacy businesses subject to that legislation.

The Review notes that, in general, regulatory authorities have tended to gain, have had imposed by governments and officials, or acquire by convention the discretion to intervene in any aspect of a pharmacy's activities that they deem relevant to the conduct of professional services. In some instances this discretion has been judicially upheld as appropriate and justifiable, as in the *Chappuis v Filo* decision in New South Wales¹³⁰.

¹²⁹ For example, section 15 (1)(c) of the *Pharmacists Act 1991* (SA) provides that the Pharmacy Board of South Australia is responsible for "keeping under review the law relating to pharmacy and making recommendations to the Minister in respect of that law".

¹³⁰ (1990) 19 NSWLR 490.

This sense of perceived responsibility, on behalf of the public, for all aspects of activity in pharmacy - often expressed in terms of regulatory authorities maintaining professional integrity and dignity - was a consistent theme in the Review's consultations with authorities.

Other roles

Various Acts also ask regulatory authorities to:

- Review and develop professional standards, and advising professional bodies on related matters,
- Set standards and implementing programmes for pre-registration training of pharmacy graduates;
- Commission and oversee professional education activities;
- Assist governments in the development of pharmacy policy; and
- Distribute information of an educational nature to registered pharmacists.

COSTS AND BENEFITS OF THE RESTRICTIONS

For each area of registration-related regulation there are costs and benefits in terms of the restrictions imposed on both pharmacists and pharmacy businesses. The Review needs to consider whether the benefits of these restrictions to the community as a whole outweigh their costs, and whether there are alternative approaches that would achieve the same objectives.

COSTS OF THE RESTRICTIONS

Entry to the profession

All entry restrictions and requirements for the pharmacy profession limit the numbers of people eligible to practise as a pharmacist. These restrictions carry certain personal and community costs.

Costs of training as a pharmacist

There are high entry costs both to the individual and to the taxpayer of requiring a period of three or four years of university based education followed by supervised practice. The costs to the individual include course fees, the heavy time commitment, foregone income and the requirement to spend up to 2,000 hours in pre-registration supervised practice prior to initial registration.

A cost to the community lies in funding pharmacy schools through university block grants. With their scientific, resource-intensive basis, pharmacy courses are relatively costly to provide, and on a per student basis are much costlier than a "book-based" course of study such as Arts or Law.

Because the competition for pharmacy places is so intense, the community may be missing out on the skills and enthusiasm of people who may have ideally been suited to professional life as a pharmacist and who were either unsuccessful in obtaining a university place, or were deterred by the time and cost of training.

Entry requirements for university courses are not specified in *Pharmacy Acts*. Nevertheless, given that a number of Acts and regulations specify institutions from which pharmacy qualifications are recognised, the requirements to enter those institutions are related to the registration of pharmacists and entry standards for the profession.

Overseas trained pharmacists

All States and Territories recognise qualifications from certain foreign countries, mainly the United Kingdom, New Zealand and the Republic of Ireland. Overseas-trained pharmacists without automatic recognition have to proceed through an examination process, based on Australian entry-level standards, run by APEC. A multiple-choice theoretical examination is followed, after a period of supervised practice, by a clinical examination before an overseas-trained pharmacist is entitled to apply for Australian registration.

However reasonable they may be, the requirements to meet Australian standards, and the APEC certification process, are barriers that have to be overcome by overseas-trained pharmacists to practise in Australia that apply to them and not to their Australian-trained counterparts. They have personal costs for both the individuals who might have the professional proficiency but who yet do not pass them successfully, as well as for those who need to allow for considerable time and expense to complete the well-regarded APEC process successfully.

For the wider community, they also have a broader cost in terms of losing the skills of pharmacists who may otherwise have been able to make an effective professional contribution, particularly in a time when the demand for pharmacists exceeds the supply.

Restrictions on practice

Imposing legislative restrictions on who may practise pharmacy have implications both for individual pharmacists, and for the general public.

Costs generated by regulations governing the ongoing practice of pharmacy include for pharmacists:

- Initial and re-registration fees, which impose a cost on otherwise qualified people entering or continuing practice; and
- Restrictions on their ability to practise their chosen profession or to conduct a private business as they see fit, by being made subject to regulatory frameworks and the discretion of regulatory authorities.

Costs to the public of legislation governing the ongoing practice of pharmacy may include:

- The maintenance of a comprehensive pharmacy regulatory framework that may be excessive in relation to the risk of incompetent, unsafe and unscrupulous practice by Australian-registered pharmacists;
- A reduced range of the models of pharmacy practice available (eg making it more difficult to develop innovations such as mobile pharmacies or interdisciplinary primary health facilities and team practices); and

- Potentially greater costs for pharmacy goods and services due to proprietors' needs to offer salaries sufficient to attract staff pharmacists, particularly in regional areas¹³¹, and to ensure that pharmacists and pharmacy businesses comply with regulatory requirements.

Regulatory structures

There are costs inherent in administering and running regulatory authorities that are mostly borne by the profession via registration fees, which are authorities' main source of recurrent income.

There are potential costs to the public in terms of potential conflicts between the public interest and the interests of the profession that may arise - or may be perceived to arise - because of the composition and structure of regulatory authorities, particularly those with a strong element of elected pharmacists.

Costs may also be borne by proprietors as a result of restrictions placed on pharmacy businesses by regulatory authorities, particularly as these are outlined in Chapter 2. The public may also be affected in terms of a reduced variety of services being on offer in community pharmacy as a result of such interventions, and as proprietors seek to contain and recoup their compliance costs.

Authority presidents, members, registrars and other regulatory authority officials are regulatory actors in their own right, as the activities of authorities can only be the sum of the activities of the individuals who compose them. By virtue of their positions, standing with the profession, and any professional stakeholders that they may represent, these members and officials can exert considerable influence over how *Pharmacy Acts* are interpreted and applied in the public interest as they, collectively, perceive it. This can be a cost or a benefit to the pharmacy profession and the wider community, depending on how an authority's discretion and influence are applied in practice.

BENEFITS OF THE RESTRICTIONS

Entry to the profession

Against such costs, there are also a number of clear benefits of current regulatory arrangements in terms of pharmacist registration and pharmacy practice. The benefit of restricting entry to the profession is that the public then can be guaranteed that all registered pharmacists have:

- Completed a course of study which has provided them with sufficient scientific underpinnings, specific professional knowledge and an ability to apply this theoretical knowledge in their daily practice;
- Been exposed to pharmacy practice in actual settings for a prescribed period of time under the individual supervision of an experienced pharmacist; and
- Reached an acceptable standard of proficiency that enables them to practise unsupervised in a community or clinical setting.

¹³¹ The Review heard evidence from a regional pharmacy operator that it had to offer a starting salary of \$60,000 a year to attract a recent graduate.

As a result of existing entry restrictions there is a well-trained, safe and competent pharmacy profession that conveys tangible benefits to the public such as:

- Less risk of medication misadventure due to poor or unprofessional advice;
- Reduced numbers of unnecessary visits to medical practitioners due to the effective identification of symptoms and minor ailments by pharmacists advising on available non-prescription medication;
- Better disease management by appropriate referral to medical practitioners where medical help and/or prescription medication is justified; and
- Better quality use of medicines by the Australian community, with flow-on benefits to peoples' health and the overall quality of health care levels;
- Promoting teamwork with other health professionals.

Ongoing practice as a pharmacist

The benefits of the current restrictions on pharmacy practice include:

- Low administrative costs of re-registration processes for pharmacists already on the register;
- The current system is based on a “passive” competency assurance process¹³², as lapses in safe and competent practice can be dealt with by regulatory authorities through appropriate complaints and disciplinary processes as they arise;
- Public protection is enhanced by regulations allowing authorities to compel pharmacists re-joining the profession after an extended period to undergo some re-training or continuing education; and
- Disciplinary sanctions which contribute to public safety both by removing pharmacists who have committed serious breaches and by motivating all pharmacists at least to perform to minimum standards.

Regulatory structures

Current regulatory authority structures and compositions benefit the public by providing guidance in the interpretation and enforcement of professional regulations, and in their ability to enable regulatory authorities to work with registered pharmacists to help them provide professional services of an expected high standard.

Some would argue that involvement by regulatory authorities in standard setting and the development of policy in respect of the pharmacy profession is of benefit to both the public and the profession by ensuring that standards are reasonable and that public policy is well informed on professional matters.

The ability of regulatory authorities to exercise appropriate discretion can benefit both the profession and the public by allowing common sense and professional experience to be brought to bear in individual circumstances. It also allows for flexible and organic development of legislation, regulation and administration to complement the ongoing evolution of professional and scientific trends in pharmacy knowledge and practice.

¹³² Association of Pharmacy Registering Authorities submission to the Review, page 3.

Because of their own extensive experience, regulatory authority office holders and full-time officials can also usually exercise considerable influence on good pharmacy and professional practice in their own right, and with the public interest at heart.

ALTERNATIVES TO THE RESTRICTIONS

The Review has had to consider if alternatives to the current regulations would achieve the objective of ensuring that the public is protected by ensuring that pharmacists and pharmacy practice are safe and competent. Alternatives to current arrangements appear to include:

- Deregulation of pharmacists and pharmacy practice; and
- Self-regulation by the pharmacy profession.

DEREGULATION

The profession of pharmacy could be deregulated entirely, allowing the market for pharmacy services to operate freely in this area. This could conceivably result in qualified pharmacists being able to gain a competitive advantage by advertising their qualifications and experience. Consumers similarly could exercise their preference for safety and quality in their pharmaceutical care by choosing qualified and experienced pharmacists to serve them.

Outside existing *Pharmacy Acts*, there are general legislative and common law avenues that could help to deal with incompetent and negligent conduct, and to minimise outright abuses by unqualified people attempting to practise pharmacy, including:

- Advertising sale of goods and fair trading legislation, allowing individuals to be prosecuted for falsely describing or misrepresenting their qualifications; and
- Consumers could also take legal action for damages at common law against anyone who had injured them through the incompetent or negligent practice of pharmacy.

However there are a number of factors that may suggest complete deregulation is not ideal, such as:

- Consumers would not only risk economic loss through misfeasance or malfeasance, but also their personal health and even lives;
- There may be conflicts between pharmacists' interests and the public interest;
- The costs of medication misadventures are not just borne by the individual but also by taxpayers, private health insurers and the health system generally, and these episodes – and therefore costs – could be expected to burgeon if inadequately trained and experienced practitioners provide pharmacy services; and
- There are social policy objectives in assuring the public of the safety and efficiency of the health system, which may not be fully achievable without some measure of regulatory intervention in the public interest.

SELF-REGULATION BY THE PHARMACY PROFESSION

Professional self-regulation has been seen increasingly as a “more flexible alternative to direct government regulation”¹³³. Some professions, such as accountancy, have well-

¹³³ Taskforce on Industry Self-Regulation, *Issues Paper*, October 1999.

developed self-regulation processes. Complete self-regulation in the health professions, with their abundant risks to life and limb of their unsafe and incompetent practice is, however, mostly unknown in Australia and similar countries.

Advantages of self-regulation, as outlined by the Task Force on Industry Self-Regulation¹³⁴, can be that it:

- Promotes good practice by members of the profession;
- Targets specific problems within professional practices;
- Imposes lower compliance costs on professional and businesses; and
- Offers quick, low-cost dispute and complaints resolution procedures to consumers.

The potential weaknesses of self-regulation in this area are similar to those for deregulation.

FINDINGS AND CONCLUSIONS

Having examined the restrictions relating to pharmacist registration and considered their costs and benefits to the community as a whole, the Review has made a number of findings and offers some related recommendations. These findings and recommendations are grouped in four general areas:

- General regulatory principles and regulatory measures;
- Entry to the profession and initial registration;
- Ongoing practice; and
- Disciplinary matters.

GENERAL REGULATORY PRINCIPLES

As indicated in Chapter 1, there are two basic principles on which acceptable regulation in the pharmacy profession can be based:

- Protecting the public safety; and
- Ensuring a reasonable equality of access to pharmacy services¹³⁵.

Scope of professional regulation

The prime objective of regulation in any professional area should be the safe and competent practice of that profession. Pharmacy is no exception.

It is important that the requirements of legislation governing pharmacy are kept to the minimum required to achieve those objectives, and to enforce reasonable compliance with them by practitioners. If pharmacy is going to be responsive to consumer needs and a generate a more genuine and competitive market between service providers, legislative and administrative intervention needs to be kept to the minimum necessary to protect the public from unsafe and incompetent practice.

¹³⁴ Taskforce on Industry Self-Regulation, *Issues Paper*, October 1999.

¹³⁵ See Page 19 of this report.

Additionally, the roles and responsibilities of the regulatory authorities need to be defined as clearly as possible.

The Review therefore supports a balanced model of legislative regulation of pharmacists and pharmacy services that:

- Makes regulatory authorities clearly accountable to government, and sets out clearly their constitutions and powers;
- Makes government responsible for promulgating standards and practices enforceable under *Pharmacy Acts*, and regulatory authorities responsible for administering and enforcing promulgated regulations and standards;
- Sets out clearly the professional responsibilities of pharmacists for the safe and competent provision of pharmacy services; and
- Sets out clearly complaints, disciplinary and review mechanisms, and the grounds on which these may operate.

The balance between over and under-regulation is very fine. *Pharmacy Acts*, delegated legislation and statutory instruments need to protect the public safety, and assure safe and competent practice.

Nevertheless the Acts, and those who interpret and administer them, need to ensure that the regulatory burdens that they impose on professionals and pharmacy businesses are reasonable, in the public interest, and do not stray into areas which are marginal to safe and competent professional practice. The potential for undue regulatory intrusion into wider activities, such as pecuniary interest in pharmacy businesses, is also discussed in Chapter 2 of this Report.

Setting and enforcement of professional regulation and standards

Consistent with the doctrine of government accountability to parliaments and the community for administrative action within their portfolios the Review believes that the Crown, through responsible ministers, should be the ultimate source of authority for professional regulation matters.

Governments therefore should set pharmacy regulations, with appropriate community consultation and expert professional advice. This advice may come from professional associations and other expert sources as well as regulatory authorities.

Given this, regulatory authorities should have the related role of implementing and enforcing the regulations and standards determined formally by government and incorporated in *Pharmacy Acts*, regulations or other statutory instruments.

Any standards that regulatory authorities, professional bodies or consumer organisations propose as necessary therefore should not have force until they are ratified by government action, such as the responsible minister recommending enabling regulations or statutory instruments to the Governor-in-Council for assent. This also implies a review, external to the regulatory authority, of the proposed regulations before they are promulgated, which can test the necessity and costs and benefits of their implementation individually, where required, a Regulatory Impact Statement.

Some may suggest that this is an imposition on government decision making time and that ministers and officials' lack of specialist knowledge means ultimate reliance on professional advice. The Review, instead, sees this as ensuring that governments act on a broad range of advice, and that regulatory authorities do not have a monopoly on providing it. Indeed, professional and industry boards have broader based memberships than regulatory authorities, and can call on the diverse expertise of their members.

The Review also notes that, in practice, States and Territories may and do choose to adopt (in full or part) standards and guidelines developed by pharmacy professional and industry bodies such as the Pharmaceutical Society and the Pharmacy Guild. This should continue.

Recommendation 14

The Review recommends 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.

REGULATORY AUTHORITIES

If regulations exist governing the registration of pharmacists it is necessary for these to be implemented by an appropriate regulatory authority.

Core functions of regulatory authorities

Ensuring that professional standards and procedures are effective and enforceable, and ensuring members of the profession's compliance with those standards and procedures, forms the "core business" of pharmacy regulatory authorities.

Consistent with the regulatory principles contained in Recommendation 14, the Review therefore believes that, as far as possible, *Pharmacy Acts*, regulations and statutory instruments should codify the powers of ministers and regulatory authorities, and also set out clearly provisions and define terms and concepts where it reasonably can be expected that authorities may need effective guidance as to their interpretation and application¹³⁶.

It is important that regulatory authorities' discretion to act is circumscribed to what is the minimum involvement necessary to ensure their ability to administer the safe and competent practice of pharmacy. In areas such as education and training requirements for pharmacists, standard setting and advising government, authorities should have the power to propose and suggest, but not to direct.

The Review is also concerned about provisions in a number of *Pharmacy Acts* where pharmacists are required to act on the advice or the recommendations of a regulatory

¹³⁶ For an example of the difficulties caused by imprecisely-worded provisions, see the discussion of pecuniary interest regulations in Chapter 2.

authority. A minister may take an authority's advice, but should not be mandated by legislation to act without it, or against it.

Constitution of regulatory authorities

The constitution of pharmacy regulatory authorities is highly relevant to the consideration of the competitive effects of pharmacy regulation. Being composed predominantly of pharmacists, and community pharmacists at that, these authorities are the custodians of the public interest while seeing things from largely the professional perspective of most or all of their members.

The Review believes that the first duty of regulatory authorities must always be to the Australian public, and that they should be accountable to the government of their jurisdiction as the representatives of that public. To their credit, regulatory authorities themselves emphasised in evidence to the Review their own commitment to this principle, and the Review does not question their commitment.

The Review also believes, however, that the best way of ensuring such accountability is to ensure that all regulatory authority members are appointed by the responsible minister, with the advice of professional, industry and consumer interests.

The mixture of elected and appointed members of regulatory authorities, common to a number of jurisdictions, is a step in this direction. Nevertheless, the Review believes that it is not the ideal arrangement in guaranteeing complete accountability to the community through government. Although they work well in Western Australia and in comparative countries including the United Kingdom and New Zealand, the Review believes that the day of wholly elected boards has passed.

If a wholly appointed authority is adopted, the Review believes that its membership should include:

- Persons indicative of the broad make-up of the profession – community, hospital/clinical and academic pharmacists;
- At least one, and ideally more than one, lay member capable of offering a broader community perspective to complement the outlook and expertise of the authority's professional members; and
- A legal practitioner to advise on points of law and procedure, and to participate in disciplinary proceedings.

Powers and actions of regulatory authorities

As discussed throughout this Report, *Pharmacy Acts* in all jurisdictions give considerable flexibility and discretion to the relevant regulatory authorities in terms of the interpretation of many of the provisions of those Acts. While it is important to ensure that regulatory authorities have sufficient flexibility to undertake their statutory responsibilities, it is also important that that flexibility be circumscribed in the interests of consistency and transparency in their decision-making.

A major disadvantage of regulatory authorities having an effective discretion to interpret their powers as broadly as considered necessary is that there is the potential for examining all

aspects of a pharmacy business, scrutinising not only professional activity but also the commercial judgments and activities of proprietors and their staff. This was discussed in Chapter 2 in relation to the pecuniary interest provisions of *Pharmacy Acts*, but as discussed earlier in this chapter it also relates to the regulation of professional pharmacy matters.

To maintain public confidence, and in keeping with other professions, regulatory authorities need to ensure that their operation is efficient, their professional actions positive, their decision making consistent, and their accessibility to the public and to the profession clear. To their great credit, Pharmacy Boards and the Pharmaceutical Council of Western Australia generally have worked hard to ensure such results.

Nevertheless, governments also need to monitor the activities of their regulatory authorities to satisfy themselves that the public interest is being protected and upheld by those authorities, and that authority members and staff are performing their roles in a competent and unbiased manner.

Ideally, and notwithstanding the evidence that regulatory authority members are very scrupulous in dealing with actual perceived conflicts of interest, clear conflict of interest and code of conduct guidelines for regulatory authority members and staff should be in place, and approved by the responsible minister.

Recommendation 15

The Review recommends 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.

REGISTRATION OF PHARMACISTS

Public safety is the *raison d'être* of pharmacy and pharmacist regulation. This reflects that:

- Pharmacists have a professional obligation to provide advice and promote the quality use of drugs and poisons
- Pharmacists have been trained to prepare, handle and dispense complex and potentially toxic substances and have considerably more information on their nature and therapeutic effects than most pharmacy consumers;
- In relationships of information asymmetry, consumers must place a high level of trust in pharmacists because of their general lack of specialist knowledge, and need to be able to rely on advice being in their best interests rather than being influenced by other motives; and
- If a pharmacist is incompetent, or misuses his or her professional position and/or knowledge, the health and safety of members of the public can be placed in great jeopardy.

Professional requirements for registration

State and Territory *Pharmacy Acts* and regulations on the whole operate to protect the public from unsafe and incompetent pharmacy practice, by providing for on the whole standards of training and proficiency to be implemented as necessary to gain registration as a pharmacist. They also place requirements on pharmacists and pharmacy practice that may be jurisdiction-specific and not required in other States and Territories.

The Review considers, on balance, that the legislative regulation of the profession based on registering a pharmacist as competent to a minimum level of proficiency for unsupervised practice is justifiable in the public interest.

Practice protection

The consequent restricting of the lawful practice of pharmacy to registered persons is also justifiable in the public interest.

Limited exceptions to this general rule, particularly in respect of trained medical and nurse practitioners, 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.

Title protection

Similarly, restrictions on who may use the titles of “pharmacist”, “chemist” and the like for professional purposes are also reasonable restrictions on competition. This helps to protect the public from incompetent, fraudulent and charlatan practice by non-registered persons claiming pharmacy expertise.

Personal requirements for registration

As highlighted earlier in this Chapter, each jurisdiction has its own specific personal requirements that must be satisfied by applicants for registration as a pharmacist.

In the interests of keeping professional entry requirements as simple as possible, while still maintaining the public’s confidence and trust in its pharmacists, the Review believes that only two personal requirements should be required as preconditions for registration:

- Proficiency in spoken and written English for the purposes of practice as a pharmacist; and
- Good character.

Professional membership as a prerequisite for registration

One State, Western Australia, also requires its registered pharmacists to be members of the Pharmaceutical Society of Western Australia.

To link the ability to practise pharmacy with membership of any organisation, even the appropriate professional body, is not only a restriction on competition in the profession, but an institutionalised restraint of trade. While appreciating the positive intentions of this membership requirement in Western Australia, the Review believes that no *Pharmacy Act*

should mandate membership of a professional or industrial body as a precondition for registration.

Professional requirements for registration

The protection of public safety is an important issue in determining who should be allowed to provide pharmacy services. A four-year tertiary qualification, together with supervised practical training, appears to provide a reasonable and acceptable assurance that public safety is protected. The course of study forms a valuable part of the accreditation process, particularly given the great potential for unskilled practitioners to cause harm to the public. The practical training and supervised practice provides some assurance that the knowledge and theory gained through the university course can be applied in practical situations.

In making this comment, however, the Review notes both the existing use of pre-registration examinations of applicants for initial registration by regulatory authorities based on agreed minimum competency standards, and the availability of competency-based assessment mechanisms in the form of the Australian Pharmacy Examining Council assessment process. It also notes the development Australian Pharmacy Competency Assessment Tool. This is being trialled under the supervision of the Association of Pharmacy Registering Authorities and is applied against nationally accepted professional competency standards¹³⁷.

If nationally consistent competency assessment for new registrants is found to be practical and workable it would be highly desirable, in the interests of consistency, transparency and fairness to all candidates, for *Pharmacy Acts* to move away from prescribed academic qualifications to specifying the satisfaction of appropriate minimum competency standards as the basis of eligibility for initial registration as a pharmacist.

Recommendation 16

The Review recommends 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 that membership of a professional association or society is 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.

¹³⁷ Consultations of the Review with the Association of Pharmacy Registering Authorities, 23 August 1999.

ONGOING PRACTICE AS A PHARMACIST

In order to optimise their contribution to advancing the principles of the National Medicines Policy, in particular improving health outcomes by the quality use of medicines, pharmacists need to maintain professional standards of competence once they are registered.

Presently re-registering pharmacists in most jurisdictions simply pay an annual registration fee, are subject to professional standards and guidelines operating in their jurisdictions, and are accountable to their regulatory authorities for the safe and competent performance of pharmacy services. If they are found to have breached prescribed standards, or a complaint against them is upheld, they can be subjected to disciplinary processes.

In most States and Territories, a regulatory authority can intervene if a pharmacist seeks to return to practice after a period of time, has conditions imposed on them by disciplinary action, or is incapacitated to the extent that it effects the competent performance of their duties. In these circumstances, a Board may impose conditions of restricted or supervised practice on such pharmacists before they are certified as meeting appropriate standards.

The Review sees these as reasonable restrictions on competition, as they protect the public from possible incompetent or dangerous practice.

Recommendation 17

The Review recommends 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 practise, are retained.

Demonstration of competence by practising pharmacists

Notwithstanding Recommendation 17, there is a lack of consistency between the high standards required for initial entry to the profession and the lack of regulations requiring ongoing maintenance of these standards once a pharmacist is in practice.

As pharmacy becomes increasingly more complex, and given that the link between being a registered pharmacist and a pharmacy proprietor, the assessment of practising pharmacists' ongoing competence can either be passive (that is, it is assessed when called into question by a complaint or investigation), or be active (that is, it is assessed as a regular requirement in the re-registration process, whether or not there is an immediate cause for complaint). An active approach would require mandated minimum competency standards to be set, and pharmacists' performance to be measured appropriately against such standards.

Mandated minimum standards

There has been a debate within the profession and amongst regulators for many decades regarding the need to encourage pharmacists to maintain, and update their clinical

knowledge¹³⁸. One of the most frequently cited means for achieving this has been compulsory continuing professional education (CPE).

There are a number of difficulties with a CPE-based approach including:

- Participation in CPE does not, in itself, a guarantee that a pharmacist has absorbed the information and is able to put this knowledge into practice; and
- Regulatory authorities that attempt to de-register a pharmacist on the basis of non-participation in continuing education could be successfully challenged in a court on the basis that this does not constitute reasonable proof that the pharmacist is unfit to practise.

The Review does not advocate that continuing professional education in itself be adopted as a competence assessment mechanism for registration purposes. Such measures can only be indicative: they cannot be definitive. They do not test a pharmacist's ability to apply acquired professional knowledge, but merely certify that he or she has had an opportunity to acquire it.

To penalise a registered pharmacist's professional standing, or to threaten his or her livelihood through suspension or deregistration, on the basis of non-compliance with CPE requirements would both be unfair to the individual, and would be hard to defend in court if challenged.

A more promising approach is encouraging periodic competence assessment for re-registering pharmacists against common national standards such as those in the *Statements of Competency for Australian Entry-Level Pharmacists*.

Unlike continuing education, competence testing measures the *quality* of an outcome, in this case whether a practising pharmacist continues to have the minimum skill and knowledge base required to practise competently. If these are current, a pharmacist could be expected to satisfy assessment requirements.

As discussed in relation to initial registration, there is already a national competency assessment mechanism based on these standards: the Australian Pharmacy Examining Council's (APEC) multiple-choice and clinical examinations for overseas-trained pharmacists wishing to practise in Australia. Additionally, most jurisdictions have developed their own examinations for initially registering pharmacists against national entry-level standards. More recently, a national Australian Pharmacy Competency Assessment Tool (APCAT) has been developed for administering in each jurisdiction. APCAT is currently being trialled but if it is adopted and affordable seems to promise a readily useable mechanism to measure proficiency of practising pharmacists.

The Review is also aware that at least one jurisdiction, Tasmania, is looking at linking demonstration of competence to registration procedures as part of its own review of its *Pharmacy Act*. This is an encouraging development.

¹³⁸ See the discussion of demonstrating competence and re-registration in the submission to the Review by the Association of Pharmacy Registering Authorities, pages 3-5. The Review's informal consultations suggest that the Association's positive approach to this issue might not necessarily be in accordance with professional body opinion, or with the views of many rank and file pharmacists. It would also differ to the views of some of those government officials responsible for health regulation, who would need to ensure that related regulatory changes are drafted and implemented, and who could see difficulties arising if pharmacy has competency-based registration requirements, while allied professions do not.

Regulatory significance

The Review accepts that, if jurisdictions incorporated mandatory demonstration of competence into their registration legislation, this would imply extending existing regulation rather than roll it back. To do so, in the spirit of the National Competition Policy, requires very considerable justification.

Nevertheless, such an approach would:

- Replace a diverse range of existing restrictions which can be imposed by regulatory authorities on pharmacists attempting to re-enter the profession after a period out of practice;
- Provide a mechanism which can be used to test all registered pharmacists from time to time, not only those who identify themselves to a Board as being in need of additional training and reskilling; and
- Provide the public with a greater level of protection and assurance of quality by testing competence directly.

In keeping with good regulatory design, however, the Review is concerned that any new regulation for competence testing should be:

- Superior to what is already in place;
- Efficient to administer;
- Implemented using an effective tool for determining competence;
- Transparent against consistent standards; and
- Able to ensure that competency assessment mechanisms in place are evaluated to ensure that they remain effective.

Recommendation 18

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

DISCIPLINARY PROCESSES

There are important public benefits in having legislatively-based provisions setting up professional disciplinary processes, and making practising professionals subject to complaints and disciplinary procedures is a reasonable restriction on competition, provided those processes are fair and transparent.

The Review therefore believes that any disciplinary processes should be public, open, procedurally fair and transparent and should contain mechanisms for appeal, including judicial review. Statutory-based disciplinary procedures also should ensure that there is a separation of the investigative and deliberative functions of regulatory authorities, so that those involved in investigating a complaint are not also decision-makers in that matter.

Many of these principles are contained in the model Victorian health practitioners' legislation, the exposure draft of the Tasmanian *Pharmacists Registration Bill*, and in health profession legislation developed by other jurisdictions in recent years. The Review commends such developments, and notes the importance of informing an increasingly

sophisticated and demanding consuming public about upholding standards of professional practice.

Professional misconduct and unprofessional conduct

The core of any disciplinary process is spelling out clearly and unambiguously the grounds on which complaints about a registered pharmacist's professional conduct can be held up to question or censure. This is important not only for the pharmacist who may be "accused". It is also important for the general public to know the grounds on which a reasonable complaint may be made, and upon which it will be adjudicated and reviewed.

The Review has had the opportunity to examine exposure drafts of the Tasmanian *Pharmacists Registration Bill*, as the most current review of a specific *Pharmacy Act*. The Bill sets out clearly the grounds on which complaints of professional misconduct can be made and heard. The Review sees the simple and codified grounds for professional misconduct as set out in the draft Tasmanian Bill as a good example of how professional misconduct grounds can be set out for the benefit of complainants and persons being complained about, regulatory authorities and external review agencies.

Investigation, adjudication and review of complaints

Complaints against registered pharmacists should be handled openly, and practitioners who are the subject of complaints similarly should be treated fairly and with regard to the principles of natural justice and procedural fairness. It is therefore important that the legislative frameworks for disciplinary processes reflect these imperatives.

To be consistent with community expectations of fairness and consistency, and to ensure that they are seen to be fair and transparent, the Review believes that *Pharmacy Acts*, and any disciplinary regulations and guidelines arising from them, should be consistent with the following general principles:

- Complaints may be made to the regulatory authority directly, or referred by a health complaints tribunal or, in respect of a relevant criminal conviction, by an appropriate law officer of a jurisdiction;
- Complaints are investigated by the regulatory authority or its staff, and that the pharmacist in question has the ability to respond to the substance of the complaint;
- Provision is made for the resolution of the matter by arbitration between the complainant and pharmacist if appropriate;
- If a complaint proceeds to adjudication by the regulatory authority, any members or officers of the authority involved in the investigation of the complaint should not sit as members of the adjudication panel;
- The panel should include a legal practitioner and a representative of pharmacy consumers;
- The pharmacist defending the complaint is entitled to put his or her case to the adjudication panel, with the right of legal representation if they wish;
- Decisions of the adjudication panel, including findings, penalties and orders about costs, should be subject to external review on the application of the affected pharmacist or the complainant;
- Final and timely external review of authority decisions should be the jurisdiction of a Supreme or County Court; and

- Decisions of the regulatory authority in relation to an upheld complaint should be disseminated as widely as possible.

Recommendation 19

The Review recommends 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.

NATIONAL CONSISTENCY OF PHARMACY REGULATION

The practice of pharmacy is generally uniform across Australia. The movement of registered pharmacists between jurisdictions is increasing, and the proprietorship of pharmacy businesses is also increasingly trans-jurisdictional. Given these factors, there is competitive merit in seeking to ensure that the practice and machinery of regulatory authorities is also generally consistent on a national basis.

The greatest possible consistency of appointment and composition of regulatory authorities across States and Territories would assist in promoting greater certainty and stability in pharmacy regulation nationwide. Over and above this, however, it would be desirable that the provisions of *Pharmacy Acts*, regulations and statutory instruments are standardised as far as possible across jurisdictions, perhaps by way of a model Act.

In approaching these issues, the Review considered whether there is a need for common pharmacy ownership and pharmacist registration legislation, or even a national registration body administering a single regulatory structure. It certainly is aware that the notion of a national registration body has been discussed for many years in pharmacy circles.

In making these observations, the Review notes that currently there is national regulatory interaction through the Association of Pharmacy Registering Authorities (APRA), consisting of State and Territory Pharmacy Boards, the Pharmaceutical Council of Western Australia and the Australian Pharmacy Examining Council.

There are therefore working mechanisms available to promote greater consistency between jurisdictions in areas such as pre-registration and personal requirements for pharmacists, the handling of disciplinary matters, and the nature and duration of supervised practice requirements. These can build further on cross-jurisdictional consistency in a number of existing areas of regulation, such as common entry-level standards for newly-registering pharmacists. Indeed, APRA can play a very important role in promoting greater consistency in regulatory practice across jurisdictions.

Even more importantly, the Review also notes that Queensland, Tasmania, Victoria, Western Australia, New South Wales and the Australian Capital Territory are currently or about to review or enact changes to their *Pharmacy Acts* as part of processes already in train in those jurisdictions. Given this fortuitous coincidence, there is a great opportunity for jurisdictions in general to consider standardising either their Acts as a whole, or duplicate specific principles or provisions (such as definitions of professional misconduct) in the interest of

national consistency and greater competitive certainty in the pharmacy industry and the market for pharmacy services.

This consideration could also extend to such matters as investigating whether a pharmacist needs to be registered in only one Australian jurisdiction in any one time, that jurisdiction being his or her place of principal residence. Should a person relocate in the course of the following year, at their next renewal they would be registered in their new State or Territory.

As outlined in Chapter 2, there are also areas of regulation in relation to pharmacy ownership and the commercial aspects of pharmacy practice that also could benefit from greater national consistency and complimentary legislation.

Recommendation 20

The Review recommends 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.

National Competition Policy Review of Pharmacy

PART B

REPORTS ON STATE AND TERRITORY ACTS

NEW SOUTH WALES *PHARMACY ACT 1964*

ASSESSMENT AGAINST THE REVIEW'S RECOMMENDATIONS

1. OVERVIEW

The *Pharmacy Act 1964* (the Act) has six Parts and two Schedules, plus two sets of Regulations, one of which has three Schedules. The principal objectives of the Act are to regulate the carrying on of business of a pharmacist and to authorise friendly societies to carry on pharmacy businesses.

The functions of the Pharmacy Board of New South Wales (the Board) are set out in Part 2 of the Act. These include “to generally carry out all matters relating to the practice of pharmacy authorised or required by [the Act]”.

The *Pharmacy (General) Regulation 1998* (the General Regulation) contains details relating to a relatively small number of clauses in the Act. These include requirements for work as an assistant in a pharmacy in order to qualify for registration, the prescribed form for a certificate of registration and details of the physical requirements of pharmacies. The *Pharmacy (Elections) Regulation 1998* (the Elections Regulation) set out the requirements for elections for the Board.

2. OWNERSHIP OF PHARMACIES

Ownership is dealt with in Part 5 – Control of Pharmacies. It is concerned with the registration of pharmacies and their owners, including details of business arrangements such as sale and purchase contracts and pecuniary interest. In practice the Board takes a particular interest in banner (or marketing) group agreements, all other financial arrangements and service agreements.

OWNERSHIP OF PHARMACIES BY PHARMACISTS (RECOMMENDATION 1)

DESCRIPTION

The relevant sections are 24C, 25 and 27A. These establish a Register of Pharmacies and prohibit the carrying on of the business of a pharmacist in any premises that are not approved by the Board and included in the Register.

In addition, the owner of the business must be included in the Register of Pharmacies. Section 25 specifies that only pharmacists or partnerships consisting solely of pharmacists may have an interest in pharmacists' businesses. No-one else is able to have any interest in a pharmacy, including a pecuniary interest, except where permitted in accordance with savings provisions set out in the Regulation 21 of the General Regulation.

The approach taken in the Act is quite clear, in that both pharmacists and pharmacy businesses are registered by the Board. Only registered pharmacists can have an interest in pharmacy businesses and these businesses must also be registered.

ASSESSMENT

These provisions are consistent with the Review's recommendation.

RESIDENTIAL REQUIREMENTS FOR OWNERSHIP (RECOMMENDATION 2)

DESCRIPTION

There are no residential requirements for pharmacy ownership in the Act. "Pharmacist", as used in the section 25 ownership provisions, is defined by section 3 as a person registered under the Act.

ASSESSMENT

These provisions are consistent with the Review's recommendations

OWNERSHIP STRUCTURES (RECOMMENDATION 3)

DESCRIPTION

Provisions relating to ownership structures are in Part 5 of the Act. Sub-section 25(1) specifically excludes a person who is not registered pharmacist and a corporation or an unincorporated body of persons to carry on as "owner or otherwise" the business of a pharmacist. Sub-section 25(1A) also excludes such persons and bodies from having a direct or indirect pecuniary interest in the business of a pharmacist.

A partnership consisting only of pharmacists and formed specifically to carry on, as owner or otherwise, the business of a pharmacist in a pharmacy, or for the purpose of having a direct or indirect pecuniary interest in such a business, is permitted under sub-section 25(2) .

ASSESSMENT

The Act's limitation of permitted ownership structures to sole traderships and pharmacist partnerships, and its express exclusion of bodies corporate, is very restrictive compared to a number of other jurisdictions.

While the provisions are consistent with the Review's recommendation, there may be some scope for **amending** them to include coverage of bodies corporate as outlined in the Review's recommendation.

NUMBER OF PHARMACIES OWNED BY A PHARMACIST AND PERSONAL SUPERVISION OF A PHARMACY BY A PHARMACIST (RECOMMENDATION 4)

DESCRIPTION

Sub-section 26(1) of the Act limits ownership and "direct or indirect pecuniary interest" to no more than three pharmacies. This provision applies to pharmacists either alone or in partnership. Sub-section 26(2) limits the number of partnerships of which a pharmacist may be a member to one, and this applies to carrying on the business of a pharmacist or a direct or indirect pecuniary interest.

There is a savings provision for ownership or pecuniary interest that exceeded this number on 27 November 1949. Friendly societies are also exempted from the restriction, as are interests in after-hours pharmacies.

Section 27 of the Act provides that a pharmacist is to be in charge, and personally superintend, every pharmacy and dispensary. Owners who allow this requirement to be breached, as well as the pharmacist in charge if he or she is an employee, are guilty of an offence under the Act.

ASSESSMENT

The provisions relating to the number of pharmacies a person or partnership may own or in which they may have a pecuniary interest are not consistent with the Review's recommendation and should be **removed**.

The pharmacist supervision provisions are consistent with the Review's recommendation.

PERMITTED EXCEPTIONS TO PHARMACIST OWNERSHIP (RECOMMENDATION 5)

DESCRIPTION

Section 27A of the Act exempts the conduct of a pharmacy business operated by a friendly society from certain other sections relating to the control of pharmacies. There is no actual ceiling on the number of pharmacies that can be owned by Friendly Societies.

Approval to open new pharmacies is subject to ministerial discretion under Section 27A of the Act. The approval is conditional upon the Minister being satisfied that the profits from the operation of the pharmacy are applied solely to the provision of benefits to members of the friendly society and that the operation of the pharmacy is justified in the interests of members of the friendly society or the public, or both. The approval can be subject to conditions and approval can be varied or revoked at any time. There are also restrictions on existing friendly society pharmacies relocating more than 1.6 kilometres from their present site.

In addition to the friendly societies, sub-section 26(3) provides that limitations on ownership and pecuniary interests in pharmacies do not apply to non-pharmacist owned pharmacies owned as at 27 November 1940. These provisions also permit businesses to be carried on in another pharmacy provided it is within 16 kilometres of the original pharmacy, or in the counties of Cumberland (Sydney), Northumberland (Newcastle), or the City of Greater Wollongong.

ASSESSMENT

There are 11 friendly society pharmacies currently operating in New South Wales¹. The Review understands that there has only been one new friendly society pharmacy approved in the last 50 years.

¹ Australian Friendly Societies Pharmacies Association, *Friendly Societies Pharmacies Directory*, February 2000.

The restrictions in relation to grandparented owners other than friendly societies are consistent with the Review's recommendation, although the restrictions on their relocation are somewhat excessive, and should be **removed** in the interests of consistency.

In relation to friendly societies, however, the Act's restrictions are discriminatory insofar as they impose far greater restrictions on one class of lawful pharmacy operator compared to another. Private pharmacist-owned pharmacies do not have to undergo a ministerial approval process in the same way that friendly societies are scrutinised. Similarly, private pharmacies are not constrained by State law as to where they may relocate, nor do they require ministerial approval to make what is essentially a matter of commercial and professional judgment.

These provisions should be **amended** to be consistent with the Review's recommendation.

PECUNIARY INTERESTS IN A PHARMACY BUSINESS (RECOMMENDATION 6)

DESCRIPTION

The relevant sections are 25, 25A and 25B. These prohibit persons other than pharmacists from having an interest in pharmacies, including a pecuniary interest. Section 25B authorises the Board to direct pharmacists to provide information relating to pecuniary interest in a business. There is no definition of pecuniary interest as such, although certain provisions in bills of sale are specifically prohibited in Section 25A. These include provisions relating to:

- The requirement to purchase or otherwise obtain goods or services;
- Giving power to others to control the manner in which the business is conducted;
- Giving access to books of account; and
- Providing any consideration that varies according to the profits or takings of the business.

What constitutes a direct or indirect pecuniary interest is not defined anywhere in the Act.

ASSESSMENT

Insofar as they go beyond restricting the proprietary interests in a pharmacy (that is, who may own, hold shares in or be a director of a pharmacy-operating entity), these provisions are inconsistent with the Review's recommendation.

Section 25A and other relevant provisions should be **replaced** by:

- 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. The working definition of proprietary interest in Chapter 1 of the Review's report may be of guidance in this regard; 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 the pharmacist's acting under such influence a ground for professional misconduct.

REGISTRATION OF PHARMACY PREMISES AND PHARMACY BUSINESSES (RECOMMENDATION 7)

DESCRIPTION

Registration of pharmacy businesses and owners and the approval of premises is a central feature the regulation of community pharmacy in NSW, together with requiring the provision to the Board of details of the financial arrangements of pharmacy businesses.

The Act does not specifically require the registration of businesses, but details of bills of sale and pecuniary interests as set out in Sections 25A and 25B are integral to the control of pharmacies. Section 25C of the Act requires the registration of owners of pharmacy businesses and the approval of pharmacies.

Section 12 of the General Regulation lists the standards that are to be complied with for approved pharmacy premises. These include provisions relating to:

- Direct public access;
- Secure doors, windows and roof;
- The minimum size of the dispensing area; and
- A refrigerator for the storage of biological and pharmaceutical products at appropriate temperatures.

There are other requirements relating to the provision of equipment and reference material. Section 32 allows for inspectors and other authorised persons to enter premises for the purpose of ascertaining whether the provisions of the Act are or have been complied with.

ASSESSMENT

These registration premises provisions are not consistent with the Review's recommendation and should be **removed**. Provisions relating to premises standards and powers of inspection are not affected by the recommendation.

2. REGISTRATION OF PHARMACISTS

Provisions relating to the registration of pharmacists are contained in Part 3 of the Act. The provisions describe the qualifications required for registration, including overseas qualifications. The use of qualifications and titles is included in Part 6, whilst Part 5 governs the control of pharmacies by registered pharmacists.

REGULATORY MACHINERY (RECOMMENDATIONS 14 AND 15)

DESCRIPTION

Constitution of the Board

The constitution of the Board is set out in Part 2, Section 6, of the Act. There are nine members, five of whom are elected by registered pharmacists.

The four appointed members are:

- A pharmacist nominated by the governing body of a university designated by the Minister;
- A barrister or solicitor nominated by the Minister;
- A non-pharmacist to represent the interests of consumers; and
- An officer of the Department of Health or a public health organisation.

Very detailed election procedures are set out in the Elections Regulation. The Regulation contains 26 clauses dealing with procedures for calling of elections, nominations, ballots, scrutiny of ballots and miscellaneous provisions. One of the elected members is appointed as President.

Functions of the Board

The Board has a number of specific functions and an advisory role to the Minister, as set out in Section 5 of the Act. This section sets out nine principal functions of the Board, one of which is a broad function in relation to all matters pertaining to pharmacy authorised or required by the Act. The other functions include promoting and maintaining the highest professional conduct and ethics, providing for education, consulting and advising on training and determining the length and content of training and re-training programmes.

Section 8 enables the Board to establish committees to assist it with the exercise of its functions. There is no requirement for any or all of the members of committees to also be Board members.

Staffing

Section 11 authorises the Board to appoint a registrar and other staff as may be necessary to enable the Board to exercise its functions.

ASSESSMENT

Constitution of the Board

The Review notes that the majority of Board members are appointed. Whilst this is commendable it is nevertheless inconsistent with the Recommendation and the Act should be **amended** to provide for full appointment.

Functions of the Board

On the whole the provisions regarding the functions of the Board and its operation are consistent with the Review's recommendation, but it is noted that they leave considerable discretion to the Board in areas such as professional conduct and ethics, education and training requirements.

Paragraph 5(2)(h) of the Act, relating to advising the Minister in relation to the Act should be **removed** as being inconsistent with that recommendation.

REGISTRATION OF PHARMACISTS (RECOMMENDATION 16)

DESCRIPTION

Pharmacy register

The registration of pharmacists is set out in Part 3 of the Act. Sections 12 to 19 authorise the Board to maintain a register of pharmacists and set out requirements for registration and related matters. Sections 7 and 19 of the Act authorise the payment of initial and annual fees, which are fixed by the Board.

Section 12 sets out the entries that are to be made in the Register and authorise its publication on an annual basis. Certificates of registration are issued in accordance with Section 17.

Practice protection

Section 26 prohibits a person other than a pharmacist, or a person acting under the personal supervision of a pharmacist, from dispensing or compounding any medicine prescribed by a doctor. Medical practitioners are exempted from this requirement.

Title protection

The use of registered qualifications and titles is covered in Section 30. Pharmacists are reserved the right to use certain specified titles, including “pharmacist” and synonyms. Non-pharmacists who use such titles, or who hold themselves out to be a pharmacists, are guilty of offences against the Act.

Personal requirements for registration

Personal requirements set out in Section 17 of the Act include having attained a minimum age of 18 years, satisfying the Board that they are of good character, and proving to the satisfaction of the Board that they have an adequate knowledge of English.

Professional requirements for registration

Professional requirements for registration are set out in Sections 13 to 16. These specify an approved tertiary course and practical experience in a pharmacy (for a prescribed period as set out in the General Regulation). However, Review understands that the Board also has an additional requirement for a written and oral Pharmacy Board Review to be completed prior to registration. The additional purpose of this requirement is unclear and is not included in the Act or Regulations.

ASSESSMENT

Pharmacy register

These provisions are consistent with the Review’s recommendations.

Practice protection

These provisions are consistent with the Review’s recommendations.

Title protection

These provisions are consistent with the Review's recommendations.

Personal requirements for registration

The Review notes that there are minimal personal requirements stated in the Act, but the minimum age requirement is inconsistent with the Review's recommendation and should be **removed**.

Professional requirements for registration

The current requirements, apart from the Pharmacy Board Review, are consistent with the objective of protecting public safety and are therefore a justifiable restriction on competition. Unless the role of the Pharmacy Board Review can be clarified and justified it should be **removed**.

ONGOING PRACTICE (RECOMMENDATIONS 17 AND 18)

DESCRIPTION

Re-registration

Section 17 (3) gives the Board discretion to refuse registration if a pharmacist has not been registered for more than five years, unless they pass on oral and/or written examination. There are no requirements for pharmacists re-entering practice after any length of absence if registration has been maintained. Nor are there any requirements to notify the Board of any periods of non-practice.

An annual fee is payable as determined and required by Section 19.

Competency based mechanisms

There are no requirements for competency based assessment for re-registration.

ASSESSMENT

These provisions are consistent with the Review's recommendations.

DISCIPLINARY PROCESSES (RECOMMENDATION 19)

DESCRIPTION

The disciplinary procedures are codified in Part 4 of the Act, sections 19A to 24. The procedures are set out in some detail. The Review notes that the disciplinary process is very clearly described and the rights and responsibilities of the parties in disciplinary processes are included.

Section 19F of the Act allows the Board to decide how to deal with complaints. These range from an investigation to an inquiry or referral to the Board from the Health Care Complaints Commission. The composition of disciplinary committees is set out in Section 19C and

includes a legal practitioner. Schedule 2 of the Act sets out the procedures to be followed in an inquiry by the Board or a Professional Standards Committee appointed by the Board.

The main features of the inquiry process are that it is conducted as in an open court (unless the Board decides otherwise), there is a right of defence, including legal representation, the provision of a written statement of its decision and a right of appeal to the District Court. Committee members must not have dealt with a complaint in their capacity as a Board member. Although the hearings are open to the public, in practice they are not publicly notified.

ASSESSMENT

These provisions are consistent with the Review's recommendations.

VICTORIAN *PHARMACISTS ACT 1974*

ASSESSMENT AGAINST THE REVIEW'S RECOMMENDATIONS

1. OVERVIEW

The *Pharmacists Act 1974* (the Act) has eight Parts. Regulations consolidated as the *Pharmacists Regulations 1992* (the Regulations) have seven Parts and two Schedules.

The overall objectives of the Act are to:

- Set out the functions, powers and responsibilities of the Pharmacy Board of Victoria (the Board);
- Regulate matters relating to the ownership of pharmacies and the practising of pharmacy in Victoria.

The Regulations deal with matters relating to Board elections, registration procedures, premises approval, registration and other fees, some aspects of pharmacy practice, and pharmacist education and training requirements.

In addition to the Act and Regulations, the Board publishes annually *Guidelines for Good Pharmaceutical Practice* (the Guidelines). The Board uses the Guidelines to advise pharmacists of:

- The Board's interpretation of certain parts of the Act and Regulations;
- How the Board exercises its discretion in regards to certain parts of the Act and Regulations;
- What the Board has determined to be minimum standards of good practice;
- The Board's expectations of pharmacists performance of their duties and responsibilities².

While the Guidelines do not have the status of a statutory instrument, they are approved by the Board rather than by the responsible minister or the Governor. They are more in the manner of professional directives from the Board to registered pharmacists and applicants for registration.

Where they relate to the interpretation of specific provisions of the Act or Regulations, the Guidelines will be taken into account.

2. OWNERSHIP OF PHARMACIES

Matters relating to the ownership of pharmacies generally are covered by Part 5 of the Act. The approval of pharmacy premises is covered by Part 6 of the Act.

² Pharmacy Board of Victoria, *Guidelines for Good Pharmaceutical Practice*, February 1999, para 104.

OWNERSHIP OF PHARMACIES BY PHARMACISTS (RECOMMENDATION 1)

DESCRIPTION

Sub-section 21(1) of the Act provides that a body corporate or a natural person who is not a pharmacist shall not “own or have a proprietary or pecuniary interest in a pharmacy practice”. Section 33 of the Act provides penalties for a person who is not a registered pharmacist but who holds himself or herself out to be a pharmacist or that they are carrying on the business of a pharmacist.

The only exceptions to this general requirement are recognised friendly societies “while the society is acting in accordance with this Act” (sub-section 21(4)), and pharmacy departments operated by a registered funded agency, private hospital or privately-operated hospital within the meaning of the *Health Services Act 1988* (Vic) (sub-section 21(5)).

ASSESSMENT

Insofar as they relate to community pharmacies, the provisions of the Act are consistent with the Review’s recommendation.

RESIDENTIAL REQUIREMENTS FOR OWNERSHIP (RECOMMENDATION 2)

DESCRIPTION

The Act has no requirement that a person be resident in Victoria in order to own a pharmacy in Victoria.

Section 21(1) of the Act does, however, require that a person must be a registered pharmacist to own a pharmacy in Victoria. The interpretation provisions of section 3 define a “pharmacist” or “registered pharmacist” as a person registered under the Act or its predecessors. Therefore, to be a pharmacy owner in Victoria a person must be registered in the State.

ASSESSMENT

These provisions are consistent with the Review’s recommendations.

OWNERSHIP STRUCTURES (RECOMMENDATION 3)

DESCRIPTION

Section 21 of the Act provides that a pharmacist may carry on a pharmacy practice either solely or in partnership with other pharmacists. Sub-section 22(1) of the Act requires that a copy of every partnership agreement must be lodged with the Board registrar within two months of its execution.

ASSESSMENT

These provisions are consistent with the Review’s recommendation, but could be **amended** to allow bodies corporate as composed in the Review’s recommendation.

NUMBERS OF PHARMACIES OWNED BY A PHARMACIST (RECOMMENDATION 4)

DESCRIPTION

Sub-section 21(1) provides that no pharmacist, either solely or in partnership, shall own or have a proprietary or pecuniary interest in more than three pharmacies. Sub-section 21(4) links this requirement to pharmacy premises rather than pharmacy businesses in which an interest may be held.

Other provisions in section 21 grandparent arrangements involving more than three pharmacies which may have been in place before the current provisions commenced.

ASSESSMENT

These provisions are inconsistent with the Review's recommendation and should be **removed**.

PERMITTED EXCEPTIONS TO PHARMACIST OWNERSHIP (RECOMMENDATION 5)

DESCRIPTION

Section 21 of the Act provides for two exceptions to the pharmacist only ownership requirement, these being:

- Registered societies within the meaning of the *Friendly Societies Act 1986* (Vic); and
- Registered funded agencies, private hospitals and privately-operated hospitals within the meaning of the *Health Services Act 1988* (Vic).

There are no limitations on friendly society pharmacies in terms of their numbers in the State, the numbers that may be operated by any one society and the conditions under which they are approved, established or relocated.

There are no grandparenting or other saving provisions in respect of pharmacies owned or operated by any other non-pharmacist body.

ASSESSMENT

The Act's provisions in relation to friendly society pharmacies are the simplest of any State jurisdiction. They allow friendly societies to operate pharmacies provided the societies themselves meet threshold criteria in other legislation. They assume that if a friendly society is lawfully able to operate pharmacies, then there should be no other constriction on their ability to do so. The Review notes that, notwithstanding this relatively liberal regulation, only 14 friendly societies operate in Victoria, with 47 pharmacies³.

These provisions are consistent with the Review's recommendation.

In respect of pharmacy departments in specified hospital facilities, Victoria is the only State or Territory making statutory provision for the ownership of pharmacy departments in dispensaries in private hospitals and privately-operated hospitals. The Review's reference is

³ Source: Australian Friendly Societies Pharmacies Association *Directory*, February 2000.

to consider the ownership of pharmacies, which relates to community pharmacy premises and businesses. It therefore believes that sub-section 21(5) is beyond the scope of its inquiry.

PECUNIARY INTERESTS IN A PHARMACY BUSINESS (RECOMMENDATION 6)

DESCRIPTION

As well as prohibiting non-pharmacist ownership of pharmacies, sub-section 21(1) of the Act also proscribes non-pharmacists having a “pecuniary or proprietary interest” in a pharmacy. Neither the terms “pecuniary interest” or “proprietary interest” are defined in the Act, nor is it clarified how the term “proprietary interest” differs if at all from “pecuniary interest”. The Board also does not clarify with matters of pecuniary or proprietary interest in its Guidelines.

For pharmacists, sub-section 21(3) requires that pecuniary or proprietary interests cannot be held in more than three pharmacies. Sub-section 21(7) provides that pharmacist can be required by the Board to give it information about the ownership of, pecuniary or proprietary interests in any pharmacy or pharmacy practice.

In respect of third parties providing financing or loan guarantees to a pharmacy business, sub-section 22(3) provides that no bill of sale, mortgage, lease “or in any other commercial arrangement in respect of the practice of a pharmacist” cannot 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
- The right to receive any consideration from the pharmacy business that varies according to the profits or takings by a pharmacist.

ASSESSMENT

The section 21 distinctions between “pecuniary interest” and “proprietary interest” in the Act are confusing, and hard to delineate.

Given the lack of accompanying definitions in the Act, the Board has great discretion in interpreting and applying the related provisions. The Review understands that “proprietary interest” is interpreted as relating to interests conferring the benefits of ownership, such as a shareholding or directorship in a pharmacy business, and “pecuniary interest” as particular financial or other benefits arising out of an association with a pharmacy business.

This area of Board discretion, and how the Board applies that discretion, are not clarified in its Guidelines.

The section 22 restrictions on financing and leasehold transactions are consistent with similar provisions in several jurisdictions. As they are worded, they work against pharmacy business being freely able to work with non-pharmacist individuals and firms to mutual commercial benefit. The “profit or takings” provision appears to preclude business associations such as franchise agreements involving a share of turnover or profit for the franchiser. The restrictions on terms of leaseholds also appear to make it very difficult for a pharmacy

business to co-locate effectively with a non-pharmacy business such as a supermarket or department store.

These provisions are not consistent with the Review's recommendation and should be **replaced** by:

- 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. The working definition of proprietary interest in Chapter 1 of the Review's report may be of guidance in this regard; 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.

REGISTRATION OF PHARMACY PREMISES AND PHARMACY BUSINESSES (RECOMMENDATION 7)

DESCRIPTION

Section 23 of the Act requires the Board to approve, rather than register, the premises of pharmacies and pharmacy departments before a pharmacy may be operated from those premises. Sub-section 27(1) complements this by providing that pharmacy can only be practised from approved premises, unless in specially approved circumstances.

Sub-section 24(1) provides that premises will not be approved unless they "comply with the relevant prescribed conditions", and that different parts of the premises "are properly situated and suitable for the purposes for which they are to be used". Section 27 imposes conditions on the conduct of pharmacy business from approved premises, including giving the Board the discretion to prevent any person conducting forms of business not approved by the Board.

Regulation 502 provides, that to approve premises, the Board must be satisfied that they are suitable, secure, hygienic and adequately equipped. Regulation 601 provides that the Board's approval of premises attracts a fee.

Part 6 of the Board's Guidelines, and supplementary appendixes, set out in considerable detail the Board's specifications and expectations of pharmacy premises in terms of the regulatory criteria.

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

There are no express requirements in the Act for the registration or approval of pharmacy businesses.

ASSESSMENT

While it is not described in the Act as such, premises approval as a precondition to operating a pharmacy business is de facto registration. The fact that the undertaking of the approval process attracts application fee supports this perception. The compulsory imposition of the

premises approval process is inconsistent with the Review's recommendation, and should be **removed**.

Beyond that, the setting of guidelines for a safe, secure, hygienic and suitably equipped pharmacy are not inconsistent with the Review's recommendation. This includes the Board's ability to conduct compliance inspections of premises and pharmacy records in accordance with section 19 of the Act.

The Review also suggests, however, that the conditions and specifications presently relating to approving pharmacy premises, for compliance purposes, in the Act and Guidelines should be **simplified** wherever possible. Such simplification should ensure that they concentrate solely on ensuring the safe and competent practice of pharmacy to a minimum standard, and not unduly intrude into wider commercial considerations. The Review notes, for example, that the Board's conferred discretion not to approve pharmacy premises if they are freely accessible to a non-pharmacist business (sub-section 27(2)) may be employed, in theory, to prevent co-locations with non-pharmacy businesses. The Review does understand, however, that the Board has interpreted these provisions practically and generously.

3. REGISTRATION OF PHARMACISTS

Matters relating to pharmacist regulation, pharmacy practice and disciplinary matters, and the constitution and operation of the Pharmacy Board of Victoria are found in Parts I-IV and VI of the Act, and Parts 2-4 and 6 - 7 of the Regulations.

REGULATORY MACHINERY (RECOMMENDATIONS 14 AND 15)

Part I of the Act relates to the Board, its constitution, powers and staffing. Part 7 of the regulations relates to the election of Board members.

Constitution of the Board

Section 4 of the Act provides for a Board of 10 members, five appointed by the minister and five elected by registered pharmacists. The five appointed members (sub-section 4(1)) are drawn from pharmacists in teaching or research, nominees of the Pharmacy Guild, Pharmaceutical Society, Society of Hospital Pharmacists of Australia, and the Salaried Pharmacists Association⁴. There are no lay or legal practitioner membership requirements.

Functions of the Board

Sub-section 5(1) states that the functions of the Board "shall be to initiate and coordinate policy in regard to the training registration and practice of pharmacists in Victoria and to develop pharmaceutical science with a view to achieving the highest possible standards of human health".

The sub-section provides a list of specific Board functions pursuant to this general objective, effectively covering a broad range of professional activity, including that it may:

- Consult with appropriate bodies on pharmacist training;
- Determine the length and content of training and retraining programmes under the Act;

⁴ Now the Association of Professional of Professional Engineers, Scientists and Managers, Australia (Pharmacists Branch).

- Determine the contents of pharmacy examinations and to direct examinations;
- Providing for the registration and renewal of registration of persons qualified to practise as pharmacists in Victoria;
- Ensuring the highest standards of professional conduct and ethics are maintained in the pharmacy profession;
- Advising the community on the proper use and administration of drugs and medicines; and
- Carrying out “all matters relating to the practice of pharmacists authorised or required by this Act”.

Sub-section 4(2) provides that the Board president be appointed by the Governor in Council from the elected Board members. Sub-section 4(4) provides for three-year renewable terms for Board members. Sub-section 5(2) enables the Board to establish advisory committees and to co-opt any person or persons as members of those committees.

Staffing

Section 6 of the Act provides that the Board may appoint and remove a registrar, inspectors and such other officers as are required for the purposes of the Act, and make by-laws in relation to their powers, duties, functions and remuneration.

ASSESSMENT

Functions of the Board

The listed functions of the Board are wide in relation to the practice of pharmacy and the regulation of pharmacists in Victoria. Its Guidelines are also very comprehensive, and cover aspects of pharmacist conduct and pharmacy practices in minute detail. The Board has the ability, and indeed the statutory responsibility, to oversee all aspects of professional education and training, practice, and professional development. It undertakes these responsibilities with a membership composed entirely of registered pharmacists.

To its credit, the Board has exercised its remit carefully, prudently and responsibly. There is no question of the Board not acting in the public interest as it perceives that interest. There are questions, however, about the breadth of its remit, and its ability to intervene and set standards for all aspects of pharmacy practice.

The Review therefore has reservations about the scope of the Board’s powers and functions under section 5. It believes that a number of the listed functions, such as the control of the practice of pharmacy by registered pharmacists, and setting training and registration standards, should actually be determined by government through wide professional consultation followed by regulation-setting process, and implemented and enforced by the Board. Again that is not to say that the Board itself does not act improperly or without consultation, but rather that this is not its appropriate role.

The Review certainly believes that the Board’s annual Guidelines, which are an admirable consolidation of its expectations and requirements in administering the Act, raise questions of fine interpretation of the Act and Regulations that may need to be endorsed by government from time to time.

In respect of the Guidelines, it may therefore be desirable to make them a statutory instrument, endorsed annually by the Governor in Council, with amendments made during the year approved by the minister. Alternately, detailed specific requirements (for example, for the fitting out of pharmacy premises) should perhaps be incorporated in the Regulations themselves. The Review does not believe that arrangements of this type would hamper unduly the flexibility of regulations or prevent their easy amendment to keep them up to date. To a considerable extent, therefore, the Act, Regulations and Guidelines need to be **revised** to be consistent with the regulatory principles in Recommendation 14.

Constitution of the Board

The Review notes that, under the Act, all members of the Board must be registered pharmacists. In a time of increasing health consumer awareness of their rights, and in the interests of public accountability, this lack of direct community involvement in Board activities is out of kilter with community expectations and with regulatory developments in Victoria and elsewhere.

The present constitution of the Board, including the election of half its members, is inconsistent with the Review's Recommendation 19, and should be **replaced**.

Victorian model legislation

In considering the Act in this regard, the Review had reference to the relevant parts of other Victorian Acts to which that State's template legislation for health professionals has been applied⁵. That model contains provisions relating to the constitution of Boards that:

- Ensure that members are all appointed by the Minister;
- Provide for the appointment of lay and legal practitioner members;
- Provide for the disclosure of interests by Board members in matters before the Board.

In the Review's opinion, the Victorian model health practitioner disciplinary provisions are more consistent with these recommendations than those of the existing Act, and should be considered in any review or replacement of the Board-specific provisions of the *Pharmacists Act*.

REGISTRATION OF PHARMACISTS (RECOMMENDATION 16)

Pharmacy register

Part II of the Act relates to the Pharmacists Register of Victoria, listing all pharmacists qualified for registration in the State. Section 11 of the Act provides that the register may be inspected by any person, and details extracted from it. Schedule 2 to the Regulations requires that the Register record a pharmacist's name and address, and qualifications.

Practice protection

Paragraph 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. Given that section 3 of the Act defines "practice of a pharmacist" as including "the supplying

⁵ The Review used as its main model the *Osteopaths Act 1996* (Vic).

compounding and dispensing of drugs and medicines on an order or prescription”, this seems to prevent the lawful dispensing of a prescription medicine by a medical practitioner or allied health professional such as a nurse practitioner.

Title protection

Paragraph 33(1)(b) of the Act prohibits persons who are not registered pharmacists from using the titles of pharmacist, pharmaceutical chemist and other synonyms, or any title, sign or symbol which may be construed as being able to be construed as implying that they are qualified to practise pharmacy. Similarly, such a person cannot designate premises to be a pharmacy or similar title (paragraph 33(1)(c)).

Personal requirements for registration

In addition to paying the prescribed annual fee and possessing prescribed qualifications and experience, sub-section 12(1) of the Act requires that a candidate is entitled to be registered if “upon personal attendance at the Board’s office he satisfies the Board that he is of good character”. In practice, this is understood principally to involve an interview with the Board’s registrar.

Detailed requirements for registration are contained in the Guidelines (Guidelines 210-209), and vary for Victorian graduates, persons being restored to the register, applicants from other Australian jurisdictions and New Zealand, applicants from the British Isles and other overseas pharmacists.

All applicants are expected to supply the Board with personal details including full name, date of birth place of residence, preferred mailing address, contact telephone number and any languages spoken in addition to English. In addition to good character, Victorian and “other” overseas pharmacists are expected to have a Level 2 Basic First Aid certificate or comparable evidence of first aid proficiency. Victorian graduates are also expected to have evidence of the successful completion of an approved management course.

Guideline 320 provides that pharmacist trainees who are candidates for the Board’s final examination must demonstrate their fluency in spoken and written English.

Professional requirements for registration

Section 12 of the Act empowers the Board to register a person as a pharmacist if they:

- Have completed a prescribed course of practical training for a minimum number of hours;
- Have completed study at the Victorian College of Pharmacy or other prescribed institution; and
- Have passed entrance examinations approved by the Board, including a final examination under the auspices of the Board (section 14), or holds a certificate of competency from a body recognised by the Board and “substantially equivalent to the training and required examination required for registration in Victoria”.

Section 13 authorises the Board to determine the education requirements for a person seeking to study pharmacy, the courses of study leading to annual and final examinations. It also enables the Board to consult with the Dean of the Victorian College of Pharmacy and equivalent persons in other schools of pharmacy in relation to course content.

Some details of education and training requirements are set out in Part 3 of the Regulations, including topics to be included in a course of practical training (Regulation 301), the setting of 2,280 hours as the prescribed period for practical training (Regulation 302), subjects for study at the Victorian College of Pharmacy (Regulation 303) and subjects for the Board's final examination (Regulation 304). Part 3 of the Guidelines sets out further detail again, including requirements specific for overseas-trained pharmacists, and for persons seeking restoration to the Register.

ASSESSMENT

Pharmacy register

These provisions are consistent with the Review's recommendation.

Practice protection

These provisions are consistent with the Review's recommendation, but there is some uncertainty in relation to dispensing when necessary by medical practitioners and other health professionals. Although it is understood that in practice paragraph 33(1)(a) of the Act has not been applied to the supply of medicines by such persons, a strict interpretation of the term "practice of a pharmacist" as defined elsewhere in the Act could result in the paragraph 33(1)(a) offence being applied to them. It may therefore be prudent to **amend** the Act to eliminate any doubt.

Title protection

These provisions are consistent with the Review's recommendation.

Personal qualifications

The Review notes 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.

Notwithstanding this, the Guidelines' requirement for certain pharmacists to have first aid qualifications is not consistent with the Review's recommendation, and should be **removed**.

Professional qualifications

The Review notes 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.

These provisions are, notwithstanding this observation, consistent with the Review's recommendation.

ONGOING PRACTICE (RECOMMENDATIONS 17 AND 18)

DESCRIPTION

The Act stipulates no other requirements for renewed registration as a pharmacist than payment of the prescribed fee (section 15). Regulation 30, however, enables the Board to require to undertake prescribed training for an applicant for restoration to the register if a person:

- Does not apply for registration within two years of otherwise being eligible to apply and has not practised as a pharmacist in that time; or
- Has not practised as a pharmacist for more than two years.

ASSESSMENT

These provisions are consistent with the Review's Recommendation 17. While it falls short of mandatory competence for renewing pharmacists in terms of Recommendation 18, the Act's statutory provision for the Board to impose competency training and assessment requirements on "lapsed" pharmacists wishing to return to practice is consistent with the public's interest in ensuring the safe and competent practice of pharmacy.

DISCIPLINARY PROCESSES (RECOMMENDATION 19)

Part IV of the Act relates to the conduct of inquiries and investigations by the Board. Section 17 establishes that the Board's proceedings are subject to the State's *Evidence Act 1958*. Section 17A for a quorum on a disciplinary panel of three members, with additional members able to be co-opted if Board members are unavailable because of a declared interest in the matter, or because specific expertise is needed.

Grounds for disciplinary action

Section 18 provides that the Board may inquire into and punish discreditable conduct by a pharmacist, acting wither on a complaint or its own volition. Sub-section 18(3) states a pharmacist may be penalised if he or she:

- Has been convicted of an indictable offence in Victoria or elsewhere;
- Is physically or mentally unfit to practise as a pharmacist;
- Is drug or alcohol dependent;
- Has been convicted by a court of an offence against the Act, the *Drugs, Poisons and Controlled Substances Act 1981* or their Regulations;
- Is advertising in a prohibited or discreditable manner; or
- Is guilty of "any other conduct discreditable to a pharmacist or which renders him unfit to be registered as a pharmacist".

Findings and review of decisions

Sub-section 18(3) provides penalties ranging from admonishment to the striking of a pharmacist from the Register, and enables the Board to make orders as to the costs of proceedings.

Section 18 also provides for the review, on appeal to the Supreme Court of Victoria, of Board disciplinary decisions. As a procedural measure, Section 18A of the Act provides that a pharmacist's registration may be suspended by the Board pending the outcome of an inquiry, including any appeals.

The Board's Guidelines do not elaborate on disciplinary proceedings and related matters, and there are no specific regulations covering disciplinary matters. This is not to say that the Board's activities in this area of responsibility are not careful, rigorous and consistent, and the Review understands that internal guidelines assist the Board in undertaking its disciplinary responsibilities.

ASSESSMENT

As they stand, the disciplinary provisions of the Act provide a bare bones structure for the conduct of disciplinary proceedings. They imply mechanisms for receiving and investigating complaints, and for conducting disciplinary inquiries and hearings if these are required. They also provide an avenue of appeal from Board decisions.

What is relatively lacking is both detail and relevance to current administrative law practice and procedures in Victoria. While it is sound on most aspects of ground for investigating a pharmacist, the Act is silent on what constitutes "other conduct discreditable to a pharmacist"⁶.

On balance, the Review believes that the Act's existing provisions are not entirely consistent with its recommendation, and should be **replaced**.

In considering the existing provisions, the Review had reference to the disciplinary parts of other Victorian Acts to which that State's template legislation for health professionals has been applied⁷. That model contains a highly detailed and clearly-explained machinery for the handling of complaints and disciplinary matters. Just as importantly, as in section 3 of the *Osteopaths Act 1996* (Vic), the model defines in detail what may constitute "unprofessional conduct", including professional misconduct. Professional conduct itself is, however, not defined.

In the Review's opinion, the Victorian model health practitioner disciplinary provisions on the whole go considerably beyond those of the present Act to meeting its preference for arrangements that are more accessible, public, transparent and open to external review. The model provisions would, therefore, generally be consistent with its recommendation.

As a broad observation, the Review notes that the Act and the model health practitioner legislation are both silent on the matter of awarding costs arising from a disciplinary investigation and hearing by a Board.

It would nevertheless be reasonable, as both a penalty and as a deterrent against incurring conduct disciplinary penalties, for a party found at fault to be liable for the costs of the

⁶ Although the Review understands that this was judicially considered by the Supreme Court of Victoria in *Mercer v The Pharmacy Board of Victoria*, [1968] VR 72, per Pape J, and the *Mercer* judgement is used and guidance by the Board.

⁷ The Review used as its main model the *Osteopaths Act 1996* (Vic).

process, and an order for costs against them made accordingly. Should the Act be **amended** to allow for such a possibility, this amendment would be justifiable in the public interest.

QUEENSLAND *PHARMACY ACT 1976*

ASSESSMENT AGAINST THE REVIEW'S RECOMMENDATIONS

1. OVERVIEW

The *Pharmacy Act 1976* (the Act) consists of five Parts. The Act is supplemented by the *Pharmacy By-Law 1985* (the By-Law), which is made by the Pharmacy Board of Queensland (the Board) under section 40 of the Act. Regulations made by the Governor in Council pursuant to section 41A of the Act are contained in the *Pharmacy Regulation 1997* (the Regulation)

The Long Title of the Act identifies its objectives as being:

- Setting out requirements for the qualifications and registration of pharmacists; and
- The regulation of pharmacy practice.

The Terms of Reference for the Review require that only matters in relation to Part 4 of the Act be examined.

As a point of observation, the Act and subordinate legislation are minimal in their specific coverage as aspects of pharmacy ownership and the commercial conduct of pharmacy businesses. The Review understands that forthcoming amendments to Queensland health practitioners legislation may be making substantial changes to the legislation including the *Pharmacy Act*, and its comments here are made anticipating any amendments.

2. OWNERSHIP OF PHARMACIES

Part 4 of the Act deals with pharmacy ownership and related commercial matters, including limitations on ownership and pecuniary interests in pharmacy practices. The By-Law or Regulation do not deal with pharmacy ownership or related matters.

OWNERSHIP OF PHARMACIES (RECOMMENDATION 1)

DESCRIPTION

Sub-section 30(1) of the Act, with limited specified exceptions, restricts the ownership of pharmacy practices to pharmacists.

Section 5 of the Act defines a “pharmacist” as a person currently registered under the Act.

ASSESSMENT

These provisions are consistent with the Review’s recommendation.

RESIDENTIAL REQUIREMENTS FOR OWNERSHIP (RECOMMENDATION 2)

DESCRIPTION

There are no residential requirements for pharmacy ownership in the Act. The Act effectively requires, however, that a pharmacist owning a pharmacy in Queensland must be registered there.

ASSESSMENT

These provisions are consistent with the Review's recommendation.

OWNERSHIP STRUCTURES (RECOMMENDATION 3)

DESCRIPTION

Sub-section 30(1) of the Act precludes persons who are non-pharmacists from carrying on as an owner of a pharmacy, or otherwise having a direct or indirect pecuniary interest in a pharmacy.

ASSESSMENT

It is understood that sub-section 31(1) has been interpreted in the State as not preventing sole trading pharmacists and pharmacist partnerships but precluding corporations, whether or not there are wholly composed of pharmacist shareholders and directors. The Review notes this, but is still not certain whether such bodies corporate would be precluded by the provision as worded, as the natural persons constituting the body corporate would all be registered pharmacists.

These provisions, with this qualification, are consistent with the Review's recommendation. They could be **amended**, however, to allow definitively for bodies corporate as composed in the Review's recommendation.

NUMBER OF PHARMACIES OWNED BY A PHARMACIST AND PHARMACIST SUPERVISION OF A PHARMACY (RECOMMENDATION 4)

DESCRIPTION

Section 30 (2) of the Act specifies that a pharmacist can own, or have a pecuniary interest in, up to four pharmacies.

There is a savings provision in Section 30 (3B), which allows individuals or associations of persons with ownership or pecuniary interest in four or more pharmacies at the date of commencement of the Act to retain, but not increase, the number of pharmacies they hold.

Sub-section 32(3) makes it an offence for the proprietor of a pharmacy not to have a pharmacy practice carried on under the personal supervision and management of a pharmacist. This ensures that any one pharmacy is always operated under personal pharmacist supervision and direction.

ASSESSMENT

The provisions relating to the number of pharmacies a person or association may own or in which they may have a pecuniary interest are not consistent with the Review's recommendation and should be **removed**.

The provision relating to the direct supervision of a pharmacy by a pharmacist is consistent with the Review's recommendation.

PERMITTED EXCEPTIONS TO PHARMACIST OWNERSHIP (RECOMMENDATION 5)

DESCRIPTION

Paragraph 30(3)(a) of the Act exempts friendly society pharmacies in existence at the date of the commencement of the Act from its general restrictions on ownership of and pecuniary interest in a pharmacy.

Friendly societies carrying on business when the Act commenced may continue to operate on their sites at that time. Such pharmacies may only relocate to a site "within the locality" if approved by the minister on the recommendation of the Board.

Sub-section 30(7) of the Act provides that the establishment of a new pharmacy by a friendly is only possible if the Board advises the minister that it is appropriate, on the basis of:

- An established need for the establishment of a pharmacy; and
- The composition and membership of the society satisfies prescribed statutory requirements. Paragraph 40(1A)(n) of the Act gives the Board the ability to make by-laws to prescribe "the composition and membership of friendly societies by which the establishment of a pharmacy practice may be approved by the Board".

Other permitted exceptions are limited to those non-pharmacists persons and companies owning and operating pharmacies at the time of commencement of the Act (sub-section 30(3)(a)). As with friendly society pharmacies operating at the time of the Act's commencement, their locations are circumscribed and limited relocations require ministerial approval on Board advice.

ASSESSMENT

There are 24 friendly society pharmacies currently operating in Queensland⁸. The Review understands that there is one grandparented non-pharmacist non-friendly society owner of a pharmacy in the State. It also understands that there have only been a handful of new friendly society pharmacies approved since the Act commenced in 1976.

The restrictions in relation to grandparented owners other than friendly societies are consistent with the Review's recommendation, although the restrictions on their location and relocation are excessive, and should be **removed** in the interests of consistency.

In relation to friendly societies, however, the Act's restrictions are discriminatory insofar as they impose far greater restrictions on one class of lawful pharmacy operator compared to

⁸ Australian Friendly Societies Pharmacies Association, *Friendly Societies Pharmacies Directory*, February 2000.

another. Private pharmacist-owned pharmacies do not have to undergo a ministerial approval process, and Board scrutiny, in the same way that friendly societies are scrutinised. Similarly, private pharmacies are not constrained by State law as to where they may relocate, nor do they require ministerial approval to make what is essentially a matter of commercial and professional judgment.

The Review is particularly concerned by the Act's requirement that a Minister may only decide in respect of a friendly society pharmacy only on the advice and recommendation of the Board. This gives the Board a disproportionate say on specific matters and essentially a right of veto over current or proposed pharmacies not owned by pharmacists.

Of equal concern is the perception that this power could be perceived as being exercised in a partial manner. The Board itself submitted to the Review that "the public is best served by a professional environment in which the ownership and control of pharmacies and the responsibility for the activities within are vested solely in registered pharmacists"⁹. Such statements do not suggest a predetermined approach by the Board when applied to its statutory responsibility to advise ministers on any proposal involving a friendly society pharmacy.

These provisions should be **amended** to be consistent with the Review's recommendation.

PECUNIARY INTERESTS IN A PHARMACY BUSINESS (RECOMMENDATION 6)

DESCRIPTION

Sub-section 30(1) of the Act provides that a non-pharmacist shall not own a pharmacy or have a "pecuniary interest, direct or indirect, in a practice of pharmacy". What constitutes a direct or indirect pecuniary interest beyond ownership is not defined in either section 30 or section 5 of the Act.

Sub-section 30(5) provides that the pecuniary rights of pharmacy employees, and of the grantees of bills of sale in respect of a pharmacy practice, are not affected by sub-section 30(1).

Sub-section 30(6) provides that provisions in commercial arrangements such as bills of sale, mortgages, franchises and agencies are void if they:

- Require goods or services to be obtained from a specific person or body;
- Give a person "other than the person lawfully carrying on the practice" the right to control in whole or part the manner of the practice, to inspect the practice's books (except for the purposes of ensuring compliance with the relevant document); and
- Give other persons rights to a consideration that varies according to the profits or takings of the pharmacy practice.

ASSESSMENT

Insofar as they go beyond restricting the proprietary interests in a pharmacy (that is, who may own, hold shares in or be a director of a pharmacy-operating entity), these provisions are inconsistent with the Review's recommendation.

⁹ Pharmacy Board of Queensland, submission to the Review, page 2.

They could be **replaced** by:

- 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. The working definition of proprietary interest in Chapter 1 of the Review's report may be of guidance in this regard; 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 the a pharmacist's acting under such influence a ground for professional misconduct.

REGISTRATION OF PHARMACY PREMISES AND PHARMACY BUSINESSES (RECOMMENDATION 7)

DESCRIPTION

There are no requirements in the Act for the registration of premises or businesses.

WESTERN AUSTRALIAN *PHARMACY ACT 1964*

ASSESSMENT AGAINST THE REVIEW'S RECOMMENDATIONS

1. OVERVIEW

The *Pharmacy Act 1964* (the Act) has six Parts and three Schedules. Regulations consolidated as the *Pharmacy Act Regulations 1976* (the Regulations), made pursuant to the Act, have nine Parts.

The overall objectives of the Act are to:

- Set out the constitution, administration and operation of the Pharmaceutical Council of Western Australia (the Council) insofar as these relate to the oversight and administration of professional pharmacy activity in the State; and
- Set out matters, including disciplinary matters, relating to registration and practising as a pharmacist in Western Australia, what entities may carry on business as chemists, advertising, title protection and miscellaneous provisions.

The Regulations spell out detailed constitutional matters of the Council (including rules for the election of Council members and the appointment of a Registrar), examinations and practical training for pharmacists, licences to practise, the registration of pharmacies, and miscellaneous provisions.

The Western Australian Government presently is undertaking a systematic review of its health practitioners legislation, with a view to maximising consistency of regulatory practice across relevant professions, including pharmacy. The Review understands that those restrictions contained in the Act, outside the Terms of Reference for this Review, will be considered later in 2000 as part of this systematic process.

2. OWNERSHIP OF PHARMACIES

Matters related to pharmacy ownership generally are covered in Part V (Miscellaneous Provisions) of the Act.

OWNERSHIP OF PHARMACIES BY PHARMACISTS (RECOMMENDATION 1)

DESCRIPTION

The Act expresses ownership in terms of describing “persons entitled to carry on business as chemists”. Sub-section 36(1) of the Act provides that the practice of a pharmaceutical chemist may only be carried on by:

- A pharmaceutical chemist (defined by section 5 of the Act as a person registered under the Act or its predecessors)¹⁰; and
- A company or friendly society, provided that the practice of pharmacy is under the immediate supervision of a licensed pharmaceutical chemist.

¹⁰ For ease of reading, this assessment report shortens “pharmaceutical chemist” to pharmacists, which is itself a synonym recognised under the title protection provisions of section 37 of the Act.

Sub-section 36(2) restricts the ownership privilege for companies and friendly societies to those who had it at the time of the Act's commencement, thus grandparenting those entities and restricting the establishment of new pharmacy business to registered pharmacists.

Section 5 of the Act defines “the practice of a pharmaceutical chemist” as:

- The professional dispensing of drugs and medicines; and, where appropriate; and
- The sale of goods and the provision of services in association with the professional dispensing of medicines and drugs.

ASSESSMENT

These provisions are consistent with the Review's recommendation.

RESIDENTIAL REQUIREMENTS FOR OWNERSHIP (RECOMMENDATION 2)

DESCRIPTION

Section 26 of the Act requires practising pharmacists to have a licence to practise in Western Australia issued by the Council in addition to being registered.

While section 26 does not prescribe that the holder of a licence has to be a resident of Western Australia, sub-section 26(1) provides that to practise as a pharmaceutical chemist in the State a pharmacist proprietor or employed pharmacist must also be a resident of Western Australia.

ASSESSMENT

Sub-section 26(1) prevents an interstate resident owning or operating a pharmacy in Western Australia. This is the only such restriction in any State or Territory *Pharmacy Act*.

Effectively, it imposes a restraint of trade on non-domiciled persons who otherwise would be eligible to operate a pharmacy in the State, and it appears to be a de facto restraint on interstate commerce. As a residence-based restriction, this provision protects the business of Western Australian pharmacists against interstate-based competition, even though Western Australian pharmacists can establish themselves in pharmacy businesses in any other of the States or Territories.

To the extent that it specified a residence requirement, sub-section 26(1) of the Act is contrary to the Review's recommendation, and the domiciliary requirement should be **removed**. There is further comment on the licensing requirement generally later in this assessment report.

OWNERSHIP STRUCTURES (RECOMMENDATION 3)

DESCRIPTION

Sub-section 36(1) of the Act, by specifying that a pharmaceutical chemist may carry on a pharmacy business, effectively permits pharmacists to operate as sole traders. Paragraph 36(2)(d), in dealing with the ownership privileges of friendly societies and companies,

specifies that there is nothing to prevent two or more pharmacists forming a partnership operating not more than two pharmacies.

ASSESSMENT

These provisions are consistent with the Review's recommendation, but could be **amended** to allow for the coverage of bodies corporate as composed in the Review's recommendation.

NUMBER OF PHARMACIES OWNED BY A PHARMACIST AND PERSONAL SUPERVISION OF A PHARMACY BY A PHARMACIST (RECOMMENDATION 4)

Sub-section 28(1) of the Act provides that a pharmacist who, either on their own behalf or "as the agent, employee, partner or other associate of another person or body" carries on the business of, or has a pecuniary interest in, more than two pharmacies, commits an offence under the Act.

Sub-section 38(1) of the Act requires that the practice of a pharmaceutical chemist must be carried on under the personal supervision of the pharmacist or by an assistant who is a pharmacist.

ASSESSMENT

In evidence to the Review, the Pharmaceutical Council of Western Australia advised that restricting holdings to two pharmacies recognises that, ideally, while personal supervision of a pharmacy by a proprietor suggests one pharmacy per pharmacist, giving proprietors a source of ongoing income should they wish to close or sell a pharmacy ensures continuity for the pharmacy business ¹¹.

The Review understands that the two pharmacy rule long predates the present Act. It is the smallest number of owned pharmacies permitted under any of the comparable provisions in other States.

This provision, nevertheless, is inconsistent with the Review's recommendation, and should be **removed**.

The pharmacist supervision requirements are consistent with the Review's recommendation.

PERMITTED EXCEPTIONS TO PHARMACIST OWNERSHIP (RECOMMENDATION 5)

DESCRIPTION

Sub-section 36(1)(b) of the Act provides that a company or friendly society may carry on the business of a pharmaceutical chemist, provided that this is done under the immediate supervision of a pharmacist.

Sub-section 36(2) limits this entitlement to practices being carried on at the time of the Act's commencement, effectively grandparenting the pharmacy holdings of the friendly society or pharmacy to those held at that time. Section 36(2)(b) goes further to restrict these pharmacies

¹¹ Consultations of the Review with the Pharmaceutical Council of Western Australia, 25 August 1999.

to the sites they occupied at the commencement of the Act, unless the Minister decides that it is necessary to move the pharmacy to another location “in the immediate vicinity”.

Section 37 provides that after 1977 amendments to the Act, the pharmacy practices of amalgamating friendly societies could also be amalgamated, subject to the limitations of section 36.

The Act does not enable friendly society or grandparented companies to acquire new pharmacies to replace those that they sell or close.

ASSESSMENT

The Act allows both friendly societies and companies to operate pharmacies, but the terms of its provisions are more restrictive than in several other jurisdictions. While the grandparenting of company-owned pharmacies is consistent with other jurisdictions, the similar grandparenting of friendly societies is not. In practice, the Review is advised that there is one company-owned pharmacy still operating in Western Australia, and one friendly society pharmacy¹².

Sub-section 36(2) is not inconsistent with the Review’s recommendation in relation to the grandparenting of existing friendly societies operating pharmacies.

Paragraph 26(2)(b), in fixing the location of a “grandparented” pharmacy, and only allowing it to move within the immediate vicinity and then only with ministerial approval is, however, a restriction that discriminates against the operator vis a vis private pharmacy providers. This is inconsistent with other parts of the Review’s recommendation, and should be **removed**.

Sub-section 36(2), insofar as it relates to grandparenting company-owned pharmacies, is consistent with the Review’s recommendation.

PECUNIARY INTERESTS IN A PHARMACY BUSINESS (RECOMMENDATION 6)

DESCRIPTION

The Act contains a number of provisions relating to pecuniary interests in a pharmacy business.

Sub-section 23(5), relating to the registration of pharmacies, requires the applicant for registration to make a full disclosure of the persons or bodies having an interest in the business or portion of the business, and the extent of such interest.

Sub-section 28 (1) provides that no pharmacist may have a pecuniary interest “whether direct or indirect” in more than two pharmacies. Sub-section 28(2) has a saving provision for pharmacies held under arrangements in place before the commencement of the *Pharmacy Act Amendment Act 1975*.

Sub-section 28(3) provides that any provisions in “a document purporting to have effect in relation to the practice of a pharmaceutical chemist”; a leasehold, licensing or occupancy

¹² Advice from the Pharmaceutical Council of Western Australia, 11 January 2000.

agreement; or a bill of sale associated with a pharmacy business or pharmacy shall be void if they:

- Purport to enable any person than a licensed pharmacist to control the operation of a pharmacy business;
- Enable such persons to receive any consideration from that business that varies according to profit or takings;
- Requires the purchase of goods or services from a specific supplier; or
- Enables access to a pharmacy business's records or documents for purposes other than determining "whether or not the grantor of a bill of sale is complying with the conditions of that bill of sale".

Regulation 56(h) provides that the Council shall not register a pharmacy until it is satisfied that the applicant has made a full disclosure of the persons and bodies having an interest in the business applying to operate the pharmacy.

The Act does not define what may or may not constitute direct or indirect pecuniary interest. The relevant provisions appear to assume that pecuniary interest relates to ownership of, or benefiting from the management decisions relating to, a pharmacy practice. The collective purpose of the provisions appears to be to reinforce the basic premise of pharmacist ownership and control of pharmacy businesses.

ASSESSMENT

While they may be intended to protect the integrity of pharmacist proprietorship of pharmacy businesses, the set of provisions in the Act and Regulations are considerably broad in their range. To be implemented, and to determine in some cases what may constitute a direct or indirect pecuniary interest, regulatory and reviewing authorities necessarily have to apply broad discretion in administering these provisions.

Consistent with the Review's recommendations on the pecuniary interest issue, the existing pecuniary interest provisions in the Act could be **replaced** by:

- 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. The working definition of proprietary interest in Chapter 1 of the Review's report may be of guidance in this regard; 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 the a pharmacist's acting under such influence a ground for professional misconduct.

Section 28(3) should be **removed** and not replaced in new legislation. Regulation 56(h) should also be **replaced** with a provision reflecting the above points.

REGISTRATION OF PHARMACY PREMISES AND PHARMACY BUSINESSES (RECOMMENDATION 7)

DESCRIPTION

Pharmacy premises

The registration of pharmacy premises is governed by section 23 of the Act and Part VI of the Regulations (Regulations 54-61A).

Section 23 provides that:

- No pharmacy business can be carried out in a pharmacy that is not registered with the Council (23(1));
- Applications for registration of premises may be made to by a pharmacist, company or friendly society, and the Council may withhold registration until prescribed conditions are prescribed with (23(2));
- Registration of premises is annual, remaining in force until 30 June each year, and may be certified by the Council on payment of a prescribed fee (23(3));
- Council decisions relating to registration of premises are appealable to a judge of the Supreme Court of Western Australia (23(4)); and
- Applicants for registration of premises can be required to make a “full disclosure” of the nature and extent of other persons or bodies interests in the business (23(5)).

Section 24 provides that fees for the registration of a pharmacy, as determined by regulation, shall be paid to the Council for the registration to be effective.

Regulation 56(1) sets out the conditions that must be satisfied before the Council registers a pharmacy. These include that:

- Pharmacy premises are “walled, floored and ceiled”, and have a separate entrance from a street or public thoroughfare;
- The premises are well lit and adequately ventilated;
- Fittings and equipment used in the handling and storing of drugs are maintained, clean and in good repair;
- The premises shall not be used in relation to receiving, handling or storing clothing for dry cleaning, laundering or repair;
- The dispensary has a minimum floor space, plumbing services, specified apparatus and reference books;
- Proper and adequate provision is made for the full recording and maintaining of all prescriptions and repeat prescriptions dispensed in the pharmacy; and
- Disclosure of interests in the pharmacy.

Regulation 57 provides discretion for the Council to register a pharmacy “subject to such conditions as it may determine” where either circumstances exist that the requirements of Regulation 56 cannot be complied with immediately, or if in the Council’s opinion it is not in the public interest to require such compliance.

Regulation 58 requires the Council’s approval of structural, layout or floor area alterations of a pharmacy before they are carried out. The Council may withhold approval only if these

plans would, if carried out, mean the pharmacy would cease to comply with any requirements of Regulation 56.

Regulation 71 provides that officers of the Council may inspect the pharmacy or any other premises to which the Act applies.

Pharmacy businesses

The Act does not provide for the registration of pharmacy businesses. As described above, however, the disclosure of details of the pharmacy business, and interests in that business, is a precondition to registering a pharmacy under the Act.

ASSESSMENT

The Act provides for, and the Regulations set out, a series of guidelines and specifications for the fitting out and operation of a safe and effective pharmacy. Provided that they are relevant to the minimum standards needed for the safe and competent contemporary practice of pharmacy, do not interfere unduly in the overall operation of the pharmacy as a commercial business and continue to be approved by the Government, provisions and specifications of this nature are consistent with the Review's recommendation.

It is also noted that the powers of inspection for the Council and its officers could be exercised without the pharmacy premises formally being registered.

Provisions of the Act and Regulations requiring or presuming that a pharmacy be registered by the Council as a precondition to its operation are inconsistent with the Review's recommendation, and should be **removed** to the extent of that requirement or presumption.

Regulations relating to the use of pharmacy premises for non-pharmacy premises, such as the handling of clothing for dry cleaning and similar purposes, need to be examined very carefully to ensure that they do not unduly intrude on the commercial operation of the pharmacy business as a whole, and that they do not relate to activity already regulated elsewhere (eg under public health regulations). If their ongoing presence cannot be justified as central to ensuring the safe and competent practice of pharmacy on the premises, such regulations should be **removed**.

3. REGISTRATION OF PHARMACISTS

Matters relating to pharmacist regulation, pharmacy practice and disciplinary matters, and the Pharmaceutical Council of Western Australia are found in Parts II-V of the Act, and II-VI and VII-IX of the Regulations.

REGULATORY MACHINERY (RECOMMENDATIONS 14 AND 15)

DESCRIPTION

Section 6 of the Act establishes the Pharmaceutical Society of Western Australia, and requires all registered pharmacists in the State to be members of the Society. Section 7 establishes a seven-member Pharmaceutical Council of Western Australia "for the purposes of this Act and the management of the Society".

Part II of the Act deals with matters relating to the constitution and administration of the Council. The key provision is section 10, which provides for both the election of members of the Council by members of the Society, and for the elected Council members to elect their president and deputy president.

Part II of the Regulations (Regulations 5-38) also relate to the constitution of the Council. It sets out procedures for conducting Council elections, conducting Council meetings, and the management of Council funds.

Section 15 of the Act provides for the appointment of a Council registrar and such other officers and examiners as the Council considers necessary for the administration of the Act. Regulations 32 and 33 make a very general description of the registrar's duties in terms of the Act and the Council's determination. Regulation 32 states clearly that the registrar is subject at all times to the Council's direction. Regulation 33 obliges the registrar to consult with the president or deputy president on out of session matters, and follow any instructions that they may give.

ASSESSMENT

The Pharmaceutical Council of Western Australia is unique among Australian jurisdictions as being both the executive body of pharmacists' professional association, as well as being the State's pharmacy regulatory authority under statutory charter. In this regard it has a similar role to Pharmaceutical Societies in the United Kingdom, Ireland and New Zealand.

It is also unique in that it is the only fully elected pharmacy regulatory authority in Australia.

The Council has a long tradition of professional involvement in the administration and regulation of pharmacy in Western Australia. In consultations and discussions with the Review, it stressed consistently that it is committed to protecting the public interest, has the highest objective standards of its members, and is impartial and unbiased in its operation. The Review has no reason to doubt this.

The question for the Review, however, is not simply whether the existing regulatory arrangements work well. It is also to ask whether these arrangements effectively promote the open conduct of professional regulation by ensuring that regulatory machinery and processes are open, fair and accountable to the community, and do not unduly hamper professional or commercial activity.

On these points, the Review believes that the Pharmaceutical Council structure is no longer the ideal way to administer pharmacy legislation in Western Australia. This is because:

- A fully elected Council is directly accountable only to its electors, the registered pharmacists of Western Australia;
- The Council has very wide discretion to act as it sees appropriate on a considerable range of professional matters in the Act and regulations; and
- As the State's peak pharmacy body as well as its regulatory authority, and even with the best intentions of its members, the fully elected Council structure has the potential for conflicts of judgment between the interests of the profession and those of the wider community.

While it commends the Council and its members for their commitment and efforts, the Review must conclude that current provisions regarding the Council and its operation are not consistent with its recommendation. It also concludes that the regulatory machinery should be **reformed** when the Act is reviewed by the jurisdiction in the near future. Such reforms could include:

- The reconstitution of the Council as a Pharmacy Board or like body comparable to those in other States and Territories;
- The appointment of ideally all and at least a significant proportion of the members of the new body by the responsible minister;
- Ensuring that members of the body include representatives of the general community and a legal practitioner;
- A clear setting out of the new body's role, powers (including limitations on its discretion) and responsibilities in the Act and regulations; and
- Ensuring that regulations, by-laws, guidelines and procedural statements that may be proposed by the new body are not effective until they are approved by the Governor-in-Council as statutory instruments.

REGISTRATION OF PHARMACISTS (RECOMMENDATION 16)

DESCRIPTION

Pharmacy register

Section 20 of the Act requires that the Council keeps “The Pharmaceutical Register of Western Australia” and that the Council registers an eligible applicant, his or her residential or business address, qualifications and date of registration.

The Council may refuse registration under section 22 of the Act. If this occurs, the applicant may appeal against the refusal to a judge of the Supreme Court of Western Australia.

Practice protection

Section 39 of the Act provides that no person shall dispense any medicine or drug if they are not:

- A pharmacist;
- A person who carries out such dispensing under the immediate personal supervision of a pharmacist;
- A medical practitioner; or
- A dentist or veterinary surgeon acting in the course of their profession.

Sub-section 38(2) of the Act makes it an offence, except in an emergency, for a person to accept a prescription other than at a pharmacy where a medicine shall be prepared and supplied.

Title protection

Sub-section 37(1) prohibits a person other than a registered pharmacist assuming or using the title pharmaceutical chemist or other recognised synonyms, or to display any title, term or sign that conveys the impression that a person is a registered pharmacist.

Some of the titles listed in the sub-section, such as druggist, homoeopathic chemist, chemist and druggist are dated and obsolete.

Personal requirements for registration

In addition to paying the prescribed annual registration fee and possessing prescribed qualifications and experience, sub-section 22(1) of the Act requires that an applicant be:

- Aged 18 or over; and
- Able to speak, read and write intelligibly in English.

Sub-section 6(2) provides that every registered pharmacist shall be a member of the Pharmaceutical Society of Western Australia.

Professional requirements for registration

Section 21 of the Act sets out the profession requirements expected of a registered pharmacist. Paragraph 21(1)(a) provides that the general requirements are:

- Completion of at least 2,000 hours practical training in accordance with such conditions prescribed by and in such premises that are approved by the Council;
- Passing examinations prescribed by the Council; and
- Passing a First Aid examination approved by the Council.

The prescribed examination and practical training requirements are set out in Regulations 41-43.

For pharmacists qualified outside Western Australia section 21(d) of the Act provides that they may be recognised for registration in Western Australia if they have been recognised as a pharmacist by “any society, college or board of pharmacy prescribed by the regulations and remain in good standing with that authority. Interstate and New Zealand applicants may be required to demonstrate post-qualification employment experience of at least one year, and all have to sign a statutory declaration that they have study Western Australian law governing the practice and sale of poisons.

Section 21 also contains provision for Council discretion in special circumstances and apprenticeship training predating university pharmacy courses.

Regulation 45 sets out the regulatory authorities whose certification of pharmacists is recognised. They are the Pharmacy Boards of the States and the Pharmaceutical Societies of the United Kingdom, Ireland, Northern Ireland, and New Zealand. The Pharmacy Boards of the Australian Capital Territory and the Northern Territory are not included in the list.

ASSESSMENT

Pharmacist registration

These provisions are consistent with the Review's recommendations.

Practice protection

These provisions provide for classes of health and allied professionals other than pharmacists to dispense drugs and medicines as well as registered pharmacists. In practice these exceptions are limited, but it is noted that they do not include nurse practitioners as is suggested by the Review.

These provisions are therefore consistent with the Review's recommendation.

Title protection

These provisions are consistent with the Review's recommendation. There may be merit, however, to specifying only two titles in the Act consistent with modern usage: pharmacist and (pharmaceutical) chemist, and **removing** other synonyms.

Personal requirements for registration

The English language provision is consistent with the Review's recommendation. The minimum age requirement, however, is not consistent, and arguably is unnecessary. It should be **removed**.

Professional requirements for registration

With the exception of the first aid requirement, these provisions are consistent with the Review's recommendation.

While it is desirable and commendable to ensure a pharmacist has first aid training, having that training is not essential to the safe and competent practice of pharmacy. As a requirement for registration, this provision should be **removed**.

The Review notes the Act's confining of recognised pharmacists to those certified by specified jurisdictions. This potentially discriminates against skills and qualifications certified in other jurisdictions, and therefore an effective barrier to competition for those affected pharmacists.

As indicated in its Report, the Review supports moving to a more competitive registration approach based on certifying an applicant's competency to practise without reference to where he or she was trained or certified.

While specific recognition arrangements are in place, however, the omission of the Pharmacy Boards of the Australian Capital Territory and the Northern Territory discriminates, however inadvertently, against pharmacists registered in those jurisdictions, and is contrary to the spirit of the Mutual Recognition Principles. It is not clear why this is the case, and may be an oversight. Regulation 45 should therefore be **amended** to include the Territory Boards.

ONGOING PRACTICE (RECOMMENDATIONS 17 AND 18)

DESCRIPTION

Licensing of pharmacists for practice

In addition to registration as a pharmacist, section 26 of the Act requires that a registered pharmacist must also be licensed by the Council in order to practise or carry on business as a pharmacist. Sub-section 26(2) gives the Council the discretion to impose such conditions on the granting of a licence as it considers advisable or necessary in the public interest. No such conditions are set out in the Regulations: they are determined directly by the Council.

A practising pharmacist's licence is renewed annually (sub-section 26(4)). Should a pharmacist wish to return, after an extended absence, to practise as a pharmaceutical chemist, in the sense that practice is defined in section 5 of the Act, they would therefore need apply for a new licence, and thus satisfy the prescribed requirements for the licence.

ASSESSMENT

The licensing requirement additional to registration as a pharmacist is a requirement unique to Western Australia. It was put to the Review that this double requirement for practising pharmacists acts to assure the public of the high quality and competence of their pharmacy care¹³. The licensing requirement also recognises that some pharmacists need the status of registration but do not practise on a day-to-day basis. Such pharmacists would include those in academia or research, in government and industry, or who have retired but otherwise would be ineligible to own pharmacies under the Act.

While commending the good intentions of the Act in this regard, the Review notes that it creates an effective double jeopardy for pharmacists wishing to practise in Western Australia. Not only do they need to satisfy basic registration requirements, they also need to satisfy a "higher" set of licensing requirements. This runs counter to the Review's recommendation that regulated professional requirements only be the minimum needed to ensure the safe and competent practice of pharmacy. Requirements for registration as a pharmacist should be sufficient for this regulatory purpose.

The Act's licensing provisions are therefore inconsistent with the Review's recommendation 17 but may remain valid if, as part of reviewing the Act, Western Australia introduces mandatory demonstrations of competence for re-registering pharmacists along the lines of Recommendation 18. If this does not happen, however, these provisions should be **removed**.

DISCIPLINARY PROCESSES (RECOMMENDATION 19)

DESCRIPTION

Sections 32-34 of the Act deal with disciplinary proceedings and decisions against registered pharmacists, and against friendly societies and companies permitted to operate a pharmacy. Section 32 sets out disciplinary procedures, and the following sections deal with appeals and actions arising from disciplinary decisions.

¹³ Consultations of the Review with the Pharmaceutical Council of Western Australia, 25 August 1999.

There are no specific regulations relating to conducting disciplinary processes, although it is understood that the Council has its own procedural guidelines to complement the Act.

Handling complaints

The Act is silent on procedures for receiving and investigating a complaint. Section 32's coverage commences only at the point where a party is summonsed to show cause that they should not be dealt with on specified grounds (sub-section 32(3)). Matters relating to the receipt, initial handling and investigation of complaints, and of referred matters such as a criminal conviction of a pharmacist, effectively are at the discretion of the Council and based on established practice rather than set guidelines or standing orders.

Grounds for disciplinary action

The grounds for a summonsed party to show cause are listed in sub-section 36(6). They are that the party:

- Has been convicted of an offence that the Council believes renders them to be unfit to continue to carry on the practice of a pharmacist;
- Is a pharmacist unfit to continue to practise by reason of physical or mental capacity, alcohol or drug addiction;
- Is guilty of carelessness, incompetence, impropriety, misconduct or infamous conduct as a pharmacist;
- Has breached an undertaking given in respect of a previous disciplinary proceeding; or
- Has breached advertising regulations.

Hearing of matters and decisions of the Council

The Act is silent on how disciplinary matters are dealt with by the Council, other than to provide guidance on the treatment of documents and exhibits tendered as evidence, and the protection of witnesses.

The Council itself therefore has considerable discretion in taking action short of formal disciplinary processes, including conciliation of complaints and counselling of pharmacists. In discussions with the Review, the Council highlighted that they seek as a body to work sensitively and appropriately to resolve a matter including, for example, providing informal advice and support to pharmacists dealing with substance abuse. Appearance before a formal hearing as is seen as a last resort¹⁴.

Sub-section 32(7) sets out the penalty options if a party is found liable to be disciplined. These are:

- Erasure from the register;
- Suspension from carrying on practice as a pharmacist for up to three years;
- Imposing fines not exceeding \$500; or
- Censure.

Paragraph 32(7)(c) enables the Council to make costs orders against a party, to impose conditions of a party's licence or registration, or to seek specific undertakings from the party.

¹⁴ Discussions between the Review and the Pharmaceutical Council of Western Australia, 28 November 1999.

Appeals from disciplinary matters

Section 27 of the Act provides for appeals from decisions of the Council, including disciplinary matters, to a Judge of the Supreme Court of Western Australia, whose adjudication is final.

ASSESSMENT

The disciplinary provisions of the Act are a bare framework for a fair, open and accountable disciplinary process. It is not, however, a comprehensive guide to the Council, complainants, parties complained against, or the general public about how the disciplinary system works and how it works effectively to protect the public interest.

The Review accepts, however, that the Council, in developing and applying its own discretion and procedures to supplement the Act, has been and is acting with the public interest in mind, and with professional zeal and integrity. It has sought to fill the gaps in the legislation as practically as possible.

In the Review's opinion, the disciplinary provisions of the Act therefore are inconsistent with its recommendation about the acceptable principles of relevant regulation, and should be **amended** when the Act is reviewed by the State in the near future.

Areas to which attention could be given include:

- Who may make complaints, referral of matters by courts and other bodies, and the manner in which complaints and referrals are made;
- Specific grounds for complaint, including setting out in reasonable detail what may constitute professional misconduct;
- Investigating complaints;
- Conciliating complaints and dealing with matters short of a hearing;
- Dealing with complaints by way of formal and informal hearings, and procedures for those hearings, including dealing with conflicts of interest for Council members and ensuring that persons investigating a complaint do not adjudicate on the matter;
- The setting of penalties, including appropriate periods of suspension and adequate financial penalties;
- Dissemination of disciplinary decisions; and
- Grounds for appeals against by the regulatory authority and the hearing of such appeals.

At minimum, any guidelines or standing orders used by the Council to investigate, hear and adjudicate on disciplinary matters should be statutory instruments. These should cover all stages of a complaints process, including receiving and investigating complaints.

SOUTH AUSTRALIA *PHARMACISTS ACT 1991*

ASSESSMENT AGAINST THE REVIEW'S RECOMMENDATIONS

1. OVERVIEW

The *Pharmacists Act 1991* (the Act) contains six Parts and two Schedules. The Pharmacists Regulations 1991 (the Regulations) four Divisions and two Schedules.

The principal objectives of the Act are:

- Providing for the registration of pharmacists;
- Constituting the Pharmacy Board of South Australia (the Board) and setting out its composition, functions and powers; and
- Regulating the practice of pharmacy, including pharmacy ownership and related matters, and complaints and disciplinary matters relating to registered pharmacists.

The Regulations include provisions relating to pharmacist registration, prescribed standards for pharmacy premises, prescription and dispensing requirements and restrictions on pharmacists advertising.

2. OWNERSHIP OF PHARMACIES

Pharmacy ownership and related matters are covered in Part 3 of the Act.

OWNERSHIP OF PHARMACIES BY PHARMACISTS (RECOMMENDATION 1)

DESCRIPTION

The Act deals with which natural persons or companies can own a pharmacy through prescribing who may practise pharmacy. Section 4 of the Act defines “pharmacy” as “the supply of a drug or medicine on the prescription of a...person authorised to prescribe the drug or medicine”. By prohibiting non-pharmacists from this supplying role, the Act determines indirectly that only registered pharmacists may operate a business involving the supply to the public of prescribed drugs or medicines.

Sub-section 18(1) specifies the basic qualifications of a person eligible for a registration as a pharmacist¹⁵. Under sub-section 18(2), a company may be registered as a pharmacist if it satisfies the Board that its memorandum and articles of association satisfy certain requirements. This will be considered further in relation to permitted ownership structures.

Sub-section 26(1) of the Act specifies that only registered pharmacists may practise pharmacy. Sub-section 26(2) contains limited exceptions, including two specified friendly societies.

¹⁵ Registration requirements for individuals are discussed further below in the context of pharmacist registration and related matters.

ASSESSMENT

While they are indirect rather than express in relation to determining who may own a pharmacy, these provisions are consistent with the Review's recommendation.

RESIDENTIAL REQUIREMENTS FOR OWNERSHIP (RECOMMENDATION 2)

DESCRIPTION

There are no residential requirements for pharmacy ownership in the Act. A natural person or company does, however, have to be registered under the Act to practise pharmacy in the State.

ASSESSMENT

These provisions are consistent with the Review's recommendation.

OWNERSHIP STRUCTURES (RECOMMENDATION 3)

DESCRIPTION

Provisions relating to ownership and grandparented pharmacies are set out particularly in Sections 18 and 26. In addition, there are number of special obligations for registered pharmacy companies contained in Sections 35 to 39. These include matters such as gaining approval from the Board prior to altering articles of association and that partnerships cannot be entered into without Board approval.

Sub-section 18(2) requires a company registered as a pharmacist to have satisfied 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.

The Act does not make specific provision for sole trading pharmacist or partnerships of registered pharmacists. Given that such arrangements are not in breach of section 18 requirements on who may practise pharmacy, there is effectively no restriction on these combinations of persons registered under the Act.

ASSESSMENT

South Australia's registration of companies as "pharmacists" is unique among State and Territory *Pharmacy Acts*. The provision for prescribed relatives to have shares and non-voting directorships in the company is also unique.

While they do not require all the shares of the registered company to be owned by a pharmacist or pharmacists, the requirements of the Act provide for the effective pharmacist ownership of the company through pharmacists' effective and undisputed control of voting rights. This is consistent with the Review's definition of pharmacy ownership by pharmacists.

These provisions are consistent with the Review's recommendation.

NUMBER OF PHARMACIES OWNED BY A PHARMACIST AND PERSONAL SUPERVISION OF A PHARMACY BY A PHARMACIST (RECOMMENDATION 4)

DESCRIPTION

Sub-section 34 (1) limits a person from carrying on a business of pharmacy at more than four places of business. Eligible friendly societies are restricted to owning a maximum of thirty-one pharmacies. Holdings of more than four pharmacies in place at the time of the Act's commencement are grandparented.

Section 33 of the Act provides that any place open to the public and involving the carrying on pharmacy as defined in the Act must be under the "direct and constant" personal supervision of a registered pharmacist.

ASSESSMENT

The pharmacy holdings provisions are not consistent with the Review's recommendation and should be **removed**.

The pharmacist supervision provision is consistent with the Review's recommendation.

PERMITTED EXCEPTIONS TO PHARMACIST OWNERSHIP (RECOMMENDATION 5)

DESCRIPTION

Sub-section 26(2) provides that, other than registered pharmacist persons and companies, the following excepted entities may practise pharmacy:

- Non-pharmacist natural persons or companies carrying on a pharmacy business before present restrictions commenced in 1972 and 1942 respectively;
- The Mount Gambier United Friendly Societies Dispensary Incorporated; and
- The Friendly Societies Medical Association Incorporated.

Sub-section 34(3) provides that the Friendly Societies Medical Association, a group of friendly societies that trades under the name of National Pharmacies, may carry on a pharmacy business at maximum of 31 sites.

ASSESSMENT

These provisions generally are consistent with the Review's recommendations. In relation to the Review's comments about regulating friendly society pharmacies, however, the Act could perhaps be **amended** to:

- Remove the references to specific friendly societies and express eligibility in terms of friendly societies as that are recognised under recent changes to the Corporations Law; and
- Removing the specific limitation on the number of pharmacies held by a particular friendly society group.

PECUNIARY INTERESTS IN A PHARMACY BUSINESS (RECOMMENDATION 6)

DESCRIPTION

Pecuniary interest is not defined for the purposes of the Act, and there are no prohibitions on non-proprietary pecuniary associations with a pharmacy business.

Regulation 18 is, however, indirectly concerned with supervising pecuniary interest matters. It requires the approval of the Board to carry on business other than the practice of pharmacy at registered premises. A business commonly associated with the practice of pharmacy is possible with the Board's permission, although there is no definition of a commonly associated business. This appears to be left to the Board's interpretation and discretion.

ASSESSMENT

Because of its treatment of who may be registered as a pharmacist, and the requirements imposed on registered pharmacy companies, the Act is quite clear on who may hold a proprietary interest in a pharmacy. Further definition as suggested in the Review's recommendation is not necessary.

The Act's general lack of regulation of pecuniary interests in a pharmacy business is consistent with the Review's recommendation. It may be desirable, however, to **amend** the Act along the lines of the recommendation to include:

- 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. The working definition of proprietary interest in Chapter 1 of the Review's report may be of guidance in this regard; 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 acting under such influence a ground for professional misconduct.

REGISTRATION OF PHARMACY PREMISES AND PHARMACY BUSINESSES (RECOMMENDATION 7)

DESCRIPTION

The registration of pharmacy premises is required by section 32 of the Act. Sub-section 32(2) provides that the Board may register premises if it is satisfied that they are suitable for the purpose of carrying on the business of pharmacy and the annual fee has been paid. Sub-section 32(4) provides for a registration application fee to be paid, and sub-section 32(6) that the registration of premises be renewed annually.

Section 40 gives the Board the power to inspect registered premises, if it has reasonable grounds to suspect proper cause for disciplinary action against a registered pharmacist, that a registered pharmacist is physically or mentally incapacitated, or a person other than a registered pharmacist is guilty of an offence under the Act. Sub-section 40(2) gives Board inspectors the power to enter registered and unregistered premises if he or she reasonably suspects that pharmacy is being practised on those premises.

Regulations 14 to 18 specify prescribed requirements for premises to be registered as suitable. These include the physical characteristics, the display of contact details for a pharmacist with access to the premises, and reference works to be kept at the premises.

There are no requirements for pharmacy businesses to be registered, although this is blurred by the Act's requirement that eligible corporations be registered as pharmacists.

ASSESSMENT

The ability of the Act and Regulations to prescribe standards for pharmacy premises, and to give the Board rights of access and inspection to those premises, are reasonable in protecting the public interest, and are consistent with the Review's recommendation.

The requirement that the premises be registered as a precondition to their operation as pharmacies, however, is not consistent with the Review's recommendation and should be **removed**.

The Review sees the Act's requirement for eligible companies to register as pharmacists as being distinct from this recommendation. They relate to defining a corporate entity that may practise pharmacy, and only indirectly to an individual registered pharmacist. Should the Act or Regulations have required individual registered pharmacists to disclose and register their relevant business interests, this would have been inconsistent with the Review's recommendation.

2. REGISTRATION OF PHARMACISTS

Part II of the Act related to the Pharmacy Board of South Australia as the responsible regulatory authority. The registration of pharmacists and related matters are mainly set out in Part III of the Act. Part IV deals with investigations and inquiries (including disciplinary matters) and Parts V and VI with appeals of decisions and offences under the Act and related matters. Part 2 and Schedule 1 of the Regulations deal with eligibility for registration, including acceptable qualifications.

REGULATORY MACHINERY (RECOMMENDATIONS 14 AND 15)

DESCRIPTION

The Act

The Act sets out the role, functions and powers of the Board as the regulatory authority. Section 60 of the Act confers regulatory making powers on the Governor in relation to matters including pharmacy practice standards and record keeping, pharmacy premises, professional conduct, and advertising. The Governor's regulatory power relating to fees and charges under the Act may be delegated to the Board.

Constitution of the Board

The constitution of and administrative arrangements for the Board are set out in Part 2, Sections 5 to 14.

Section 6 provides that the Governor appoints all eight Board members. The prescribed membership a legal practitioner, a consumer representative, and nominees of the South Australian branches of the Pharmacy Guild of Australia, the Pharmaceutical Society of Australia, and the Society of Hospital Pharmacists of Australia. Two other members are nominated by the head of the pharmacy school of the University of South Australia and the Friendly Societies Medical Association Incorporated, and the final member is a registered pharmacist "at large". The Minister appoints a registered pharmacist member as president of the Board under sub-section 6(2).

Section 11 gives the Board the power to establish committees and to co-opt persons to those committees who are not Board members. Section 14 requires the Board to appoint a registrar and gives it discretion to employ such other staff as are necessary for the administration of the Act.

Functions of the Board

Section 15 prescribes the functions of the Board as being:

- The registration and professional discipline of pharmacists;
- Overseeing pharmacy practice standards;
- Keeping under review the law relating to pharmacy and advising the Minister with respect to that law;
- Monitoring pharmacist pre-service and in-service training; and
- Exercising other functions under the Act.

ASSESSMENT

In general, the Act gives the Board very broad responsibilities with relatively little guidance as to how it discharges these. This arrangement places an obligation on the Board with to exercise, with the public's best interests in mind, a considerable degree of discretion in its administration and interpretation of the Act and Regulations.

The advisory role incorporated into the section 15 statement of functions also gives the Board considerable influence in both developing pharmacy policy and in setting as well as administering the rules governing the practice of pharmacy in South Australia.

The Act

Generally, the Act is consistent with principles set out in the Review's Recommendation 14. The distinction between the regulation and standard setting role of the executive government, and the implementation role of the Board is noted. Nevertheless, the Review notes that the powers of the Board to advise the Minister on matters pharmacy law gives the Board a certain degree of specific and direct involvement in the decision making process that goes beyond this separation of responsibilities.

Constitution of the Board

These provisions are consistent with the Review's recommendation.

Functions of the Board

These are consistent with the Review's recommendation, with the exception of paragraph 15(1)(c) of the Act relating to reviewing and advising on pharmacy-related law. This paragraph should be **removed**, as giving the Board a statutory role in executive decision making processes.

REGISTRATION OF PHARMACISTS (RECOMMENDATION 16)

DESCRIPTION

Pharmacy register

Sub-section 24(1) of the Act requires that the Board registrar keep a registrar of pharmacists. Under section 20, the Board must register a person as a pharmacist if it is satisfied that the applicant is eligible for registration, that is, they have satisfied the prescribed education and training requirements and paid the prescribed registration fee. Section 20 allows for provisional registration, and section 21 enables the Board to impose conditions on a pharmacist's registration.

Practice protection

Section 26 of the Act provides that only persons registered as pharmacists (as discussed in Section 2 above) may practise pharmacy in the State. It also makes the practising of pharmacy by a non-registered person an offence. The Act does not make provision for the emergency dispensing of drugs and medicines by prescribers, including medical practitioners.

Title protection

Section 28 restricts certain titles to registered pharmacists, including companies registered as pharmacists. These titles include "pharmacist", "pharmaceutical chemist", "pharmaceutist" and "dispensing druggist".

Personal requirements for registration

Sub-section a natural person is eligible for registration as a pharmacist if he or she:

- Is 18 years old or over;
- Is a fit and proper person;
- Has prescribed qualifications and experience in pharmacy; and
- Fulfils all other requirements prescribed by the Regulations.

Regulation 5(c)(iii) provides that where an applicant's qualifications have been obtained in a non-English speaking country, the Board must be satisfied that he or she has a sufficient knowledge of English to practise pharmacy.

Applicants for registration are also required to complete an approved first aid course.

Professional requirements for registration

Regulation 5 sets out four sets of professional requirements for registration as a pharmacist:

- An Australian or New Zealand degree or diploma in pharmacy, plus up to one year's practical experience;
- Unconditional registration as a pharmacist in another State or Territory, or New Zealand; or
- A degree or diploma in pharmacy conferred by British and Irish institutions listed in Schedule 1 of the Regulations, unconditional British or Irish registration and at least four weeks supervised practice under an approved pharmacist (defined as a South Australian registered pharmacist or an unconditionally registered pharmacist of another State, Territory or New Zealand); and
- Certification by the Australian Pharmacy Examining Council (APEC) that a person has the necessary qualifications to practise in the State, plus completion of at least the APEC requirements for supervised practice.

In addition to academic and practical training requirements, applicants for registration are required by regulation 5 to satisfactorily have passed a forensic examination conducted by the Board on State law relating to the sale and supply of drugs and poisons.

ASSESSMENT

Pharmacy register

These provisions are consistent with the Review's recommendation.

Practice protection

These provisions are consistent with the Review's recommendation. It may, however, be desirable to **amend** them to ensure that there are no inadvertent obstacles to dispensing being carried out in limited circumstances (that is, where a registered pharmacist may not be readily accessible) by approved prescribers such as medical practitioners.

Title protection

These provisions are consistent with the Review's recommendation, although the retention of prohibitions on specific titles that are obsolete could be reconsidered.

Personal requirements for registration

The first aid course requirement and the minimum aged requirement are not consistent with the Review's recommendation, and should be **removed**.

Professional requirements for registration

These provisions are consistent with the Review's recommendation.

ONGOING PRACTICE (RECOMMENDATIONS 17 AND 18)

DESCRIPTION

Section 22 provides for renewal of pharmacists' registration from 31 December to 31 December each year. Sub-section 22(3) provides that applications for renewals of registration must be delivered to the Board registrar not earlier than 1 October and not later than 30 November for the following registration period, but the Board can also decide whether to accept an application made outside this period.

Sub-section 22(4) requires renewal of registration to take place if the application follows these requirements and the prescribed fee is paid.

Particular provisions apply to pharmacists returning after a lapse of registration. Section 29 provides that a person who has not personally practised pharmacy for three or more years cannot himself or herself commence practising pharmacy without the Board's approval. Sub-section 29(2) enables the Board to require such pharmacists to undertake a refresher course or obtain specified qualifications and experience.

The Board also has the ability to impose conditional registration on a pharmacist under section 21 of the Act.

ASSESSMENT

These provisions are consistent with the Review's recommendations. While they fall short of mandatory demonstration of competence for renewing pharmacists, the ability to impose retraining and other requirements on pharmacists returning to personal practice go to the public's interest in ensuring the safe and competent practice of pharmacy.

DISCIPLINARY PROCESSES (RECOMMENDATION 19)

DESCRIPTION

Investigative and disciplinary procedures are codified in Sections 40 to 59 of the Act. The procedures are set out in some detail and cover pharmacy inspections, incapacity, procedures for inquiries, powers of the Board, costs, appeals and penalties.

Section 40 provides that an investigation may be initiated by the Board if it has reasonable cause to suspect that:

- There is proper cause for disciplinary action against a pharmacist;
- A registered pharmacist may be physically or mentally unfit to practise pharmacy; or
- A person other than a registered pharmacist has committed an offence against the Act.

In respect of the first two points, sub-section 44(1) provides that the Board may act on its own initiative or on receiving a complaint. Sub-section 45(6) defines proper cause for disciplinary action as being:

- Improperly obtained registration;
- Conviction or guilt of offence against the Act, an offence involving dishonesty or an offence punishable by imprisonment for one year or more; and/or
- Guilt of unprofessional conduct, which is not defined.

Section 45 of the Act sets out basic procedures for a disciplinary inquiry, including the giving of written notice to both the complainant and the person being complained about; the right of the person being complained about to have legal representation; and that the accused practitioner has a reasonable opportunity call or give evidence, to examine and cross-examine witnesses and to make submissions to the Board. Section 45 also enables the Board to determine its own inquiry procedures, and requires it to act “according to equity, good conscience and the substantial merits of the case” (sub-section 45(5)).

Sub-section 44(4) provides that the Board, if it is satisfied that there is proper cause for disciplinary action against a registered pharmacist, may impose one of a series of penalties ranging from reprimand to cancellation of registration.

Section 46 sets out the Board’s powers in relation to an inquiry, including powers of summons, swearing of witnesses and requiring answers from witnesses, and recording proceedings.

Section 49 gives right of appeal to the Supreme Court of South Australia against any decision or order of the Board made pursuant to the Act.

ASSESSMENT

These provisions are only broadly consistent with the Review’s recommendations in that they allow for separate investigative and hearing processes for disciplinary matters, provide for accused pharmacists’ rights of response, and include rights of external review of Board decisions.

The Review is concerned that what may constitute professional misconduct effectively is left to the Board’s discretion. While it is important that the public is protected from the unsafe and incompetent practice of pharmacy, it is also important that the powers to determine what may constitute professional misconduct are relatively codified and objective. The Review notes that other jurisdictions, notably Tasmania, have sought to refine similar provisions by setting out grounds for professional misconduct in greater detail.

It is also of some concern that the procedural requirements in the Act are bare bones provisions, and are not as sufficiently comprehensive and open for the public and accused

persons to be assured that complaints are handled consistently and fairly by the Board as an investigating and adjudicating body.

This, however, goes both ways. It is also important that the Board, its members and its staff know what is required of them in disciplinary and professional competence matters. Then the Board can act, and be seen to act, confidently, fairly and consistently in the interests of the persons most directly affected by a given matter, and in the interests of the South Australian community as a whole. This better protects the Board its members and its officers.

Although the Act dates back only to 1991, much work has been undertaken in other States in recent years to revise and overhaul legislation relating to complaints against health practitioners and dealing with disciplinary and professional competence matters openly, consistently and fairly. On balance, the Review believes that while the Act's existing provisions are broadly consistent with the principles of its recommendation, they should be **amended** to make them as fully consistent with these principles as possible, with reference to recent developments in other professions and jurisdictions.

TASMANIAN PHARMACY ACT 1908

ASSESSMENT AGAINST THE REVIEW'S RECOMMENDATIONS

1. OVERVIEW

The Long Title of the *Pharmacy Act 1908* (the Act), describes its objective as being “to establish a board of pharmacy in Tasmania, and to make provision for the registration of pharmaceutical chemists”.

The Act has three Parts and two Schedules. Since 31 December 1998 there have been no regulations under the Act, as the then current regulations lapsed pending the replacement of the present Act with new legislation. The Review notes that the administration of the profession has been carried on as if they were still in place.

The Tasmanian Government currently is developing a *Pharmacists Registration Bill* (the draft Bill), which has been released publicly for comment in exposure draft form. Where awareness of the provisions of the draft Bill has assisted the Review's consideration of existing provisions, passing references may be made to relevant provisions of the draft Bill in the following sections.

The Review particularly commends the direction being taken in the draft Bill in terms of developing clear and detailed provisions about the operation and powers of the Pharmacy Board of Tasmania (the Board). It notes especially the draft Bill's codifying of matters relating to complaints about the professional conduct of pharmacists, its setting out of clear and relevant disciplinary procedures and practices, and its clear setting out of the grounds on which regulations may be made under the Act.

The Review's Terms of Reference exclude the consideration of Tasmanian legislation about the registration of pharmacists and related matters. The following comments on the present Act, therefore, relate only to the ownership of pharmacies against the framework of the Review's recommendations in Chapter 2 of its Final Report.

2. OWNERSHIP OF PHARMACIES

Matters relating to pharmacy ownership generally are covered in Part III of the Act.

OWNERSHIP OF PHARMACIES BY PHARMACISTS (RECOMMENDATION 1)

DESCRIPTION

Section 30 of the Act provides that, other than registered pharmacists, partnerships composed entirely of registered pharmacists, and recognised friendly societies, no natural person or body corporate may carry on a pharmaceutical business (as owner or otherwise). It also provides that such excluded persons or bodies corporate cannot hold an interest in a pharmacy or the business carried on in a pharmacy.

Sub-section 30(3) provides that a pharmacist whose registration is suspended may retain an interest in a pharmacy or pharmacies during that suspension, if the Board makes an order to that effect under sub-section 17A(8C).

Paragraph 29(1)(d) makes it an offence for a person other than a registered pharmacist to carry on business as a pharmacist or to open a shop or place of business for pharmacy practice.

ASSESSMENT

These provisions are consistent with the Review's recommendation.

RESIDENTIAL REQUIREMENTS FOR OWNERSHIP (RECOMMENDATION 2)

DESCRIPTION

The Act has no express residential requirements for pharmacy ownership. Section 30A requires, however, that a pharmacy must be owned by a registered pharmacist, and section 2 of the Act defines a "registered pharmaceutical chemist" as someone who has a Tasmanian certificate of registration. Therefore, a pharmacist with an interest in a Tasmanian pharmacy must be registered in Tasmania.

ASSESSMENT

This provision is consistent with the Review's recommendation.

OWNERSHIP STRUCTURES (RECOMMENDATION 3)

DESCRIPTION

Section 30 of the Act makes it an offence for a natural person or body corporate to carry on a pharmacy business unless the person or body corporate is:

- A registered pharmacist (ie as a sole trader);
- A partnership in which all the partners are pharmacists; or
- A recognised friendly society.

ASSESSMENT

The Review notes that the draft Bill would modify these provisions to allow for individual pharmacist proprietors and bodies corporate of whom each member is a registered pharmacist, and the supervision of the pharmacy practice and business is vested in a registered pharmacist. This broader wording would make possible different corporate structures, including incorporated companies, provided all the shareholders are registered pharmacists.

The present provisions are consistent with the Review's recommendation, and the draft Bills provisions would effectively incorporate the Reviews recommendations on bodies corporate.

NUMBERS OF PHARMACIES OWNED BY A PHARMACIST (RECOMMENDATION 4) AND PERSONAL SUPERVISION OF A PHARMACY BY A PHARMACIST

DESCRIPTION

Section 30A of the Act provides that no registered pharmacist shall at any one time either carry on a pharmacy business, or have a direct or indirect interest, in any more than two “ordinary” pharmacies. Section 2 defines an ordinary pharmacy as a pharmacy other than an after hours pharmacy.

After-hours pharmacies are treated differently. Section 2 of the Act requires an after hours pharmacy to be carried on by a partnership consisting of at least five registered pharmacists. Sub-section 30A(2) allows a pharmacist to carry on business or to hold an interest in two after-hours pharmacies, over and above the limitation on owning ordinary pharmacies.

Pharmacy holdings inconsistent with the present rules, but in place when they commenced, are grandparented by sub-section 30(3), until such time as the person gives up their interest in the affected pharmacies, or the pharmacy relocates. The Review understands that this provision is now all but redundant.

Section 31 provides that a pharmacist must ensure that a pharmacy must be supervised by either that pharmacist or another registered pharmacist, or to permit anyone other than a registered pharmacist to vend medicines, or to compound and dispense prescriptions.

ASSESSMENT

The Review is unsure about the necessity for a distinction between ownership privileges for ordinary and after hours pharmacies. It notes, however, that the distinction is expected to disappear in the new legislation, although the present Act’s limitation of holdings to two pharmacies is expected to continue.

In terms of the numerical requirement, however, the provisions are not consistent with the Review’s recommendation, and should be **removed and not replaced** in the new legislation.

The provisions requiring personal pharmacist supervision of a pharmacy are consistent with the Review’s recommendation.

PERMITTED EXCEPTIONS TO PHARMACIST OWNERSHIP (RECOMMENDATION 5)

DESCRIPTION

Sub-section 30(2) permits a pharmacy business to be carried on by a friendly society that is recognised by the *Friendly Societies (Tasmania) Code*. Sub-section 30(1) prohibits incorporated and unincorporated associations from owning pharmacies. There are no grandparented provisions in Tasmania.

The Act appears to be worded so that there is no limitation on the number of pharmacies that may be owned by a friendly society, but the Review understands that in practice the two groups operating pharmacies under the Act have two pharmacies each.

ASSESSMENT

The Review understands that friendly societies legislation in Tasmania has been amended to reflect the coverage of friendly societies under the Corporations Law. These provisions are taken as being consistent with the Review's recommendation.

The Review understands that a body similar to a friendly society but a non-pharmacist owned body corporate, the Queenstown Medical Union, was prescribed as eligible to operate pharmacies under the lapsed regulations to the Act. Given that the Union is not a friendly society, its continued operation appears to be inconsistent with the provision for role. If so, its continued pharmacy role would need special provision.

PECUNIARY INTERESTS IN A PHARMACY BUSINESS (RECOMMENDATION 6)

In dealing with permitted ownership structures, sub-section 30(1) of the Act also provides that no ineligible person or association "shall carry on a pharmaceutical business (whether as owner or otherwise) or hold an interest in a pharmacy or in the business carried on in the pharmacy". Paragraph 29(1)(d) makes it an offence for a person other than a registered pharmacist to carry on the business of a pharmacist.

Section 30D provides that bills of sale, loan documents, leasehold agreements cannot contain terms that:

- Require goods or services necessary for the carrying on the pharmacy business to be bought or otherwise obtained from a specified person;
- Give any party to the agreement, other than the registered pharmacist the power to control the conduct of the business, or access to the accounts of that business; and
- Allow that any party to the instrument receives any consideration from the business that varies according to the business's profits or takings.

ASSESSMENT

The Act does not offer a definition of what constitutes a direct or indirect interest in a pharmacy.

Contextual reading of the relevant sections, however, suggests that these terms that "direct interest" appears to relate to a shareholding in a pharmacy owning entity. "Indirect interest" appears to relate to a non-owning party's ability to influence the direction of a pharmacy business, to derive a share of the business's revenue other than by a contract of supply or service, or both. This would seem to rule out the acceptability of a franchise agreement based on share of turnover or profit.

On this reading, it appears that the sub-section 30(1) reference to "business carried on in a pharmacy" would appear to apply against arrangements such as a full franchise, where a franchise agreement may expect conformity with group practice in terms of matters such as layout, or confer on the franchisor elements of stock management or purchasing. It would not prohibit banner group arrangements where services are provided for a flat fee, and nominally at least participating pharmacist can take or leave elements of the banner package as they see fit.

The Review believes that existing provisions are too vague and go further than is necessary to protect the principle of pharmacist ownership and control of pharmacies and pharmacy businesses. It suggests that the draft bill could **replace** existing pecuniary interest provisions by including:

- A clear statement that no ineligible person or corporation should have a proprietary interest (ie a direct shareholding or directorship) in a pharmacy business;
- If necessary, a definition of proprietary interest to simplify and make consistent the interpretation and administration of relevant provisions of the Act; and
- A provision making it an offence under the Act for any person or corporation to apply improper or inappropriate influence on the professional conduct of a pharmacist, and making the a pharmacist acting under such influence a ground for professional misconduct.

The new Act should also ensure that section 30D of the present Act is **removed**, and not replaced with comparable provisions.

REGISTRATION OF PHARMACY PREMISES AND PHARMACY BUSINESSES (RECOMMENDATION 7)

DESCRIPTION

Pharmacy premises

Section 30B of the Act provides that a pharmacy business can only be carried out in a currently registered pharmacy. Sub-section 30B(3) provides that the Board may register or refuse to register a pharmacy, or it may withhold registration until an applicant complies with such conditions as may be prescribed. Decisions by the Board may be appealed to a magistrate.

Section 30C provides that a pharmacy business can only be carried on in a pharmacy that complies with “the prescribed requirements”, which may include requirements in relation to the pharmacy’s construction, ventilation, lighting, cleanliness, sanitation and fittings.

Section 45 gives inspectors appointed by the Board powers, for the purposes of compliance with the Act, to enter and inspect any premises in an inspector has reasonable grounds for believing that a pharmacy practice or business is being carried on.

Regulations may be made by the Governor under sub-section 38(5) of the Act in respect of the registration of pharmacies and the requirements with which registered pharmacies are to comply. Currently no such regulations are in force.

Pharmacy businesses

There is no requirement under the Act to register a pharmacy business.

ASSESSMENT

The pharmacy provisions of the Act are broad, vague and at the present time unsupported by regulations setting out precisely what conditions or specifications a registered pharmacy must satisfy. While it is understood that the reason for this situation is that regulations lapsed

pending imminent passage of a new Act, the Review is concerned that a prolonged gap in coverage may leave the Board enforcing standards that no longer have statutory force. Regulations of the nature specified in the Act would be justifiable restrictions on competition in interests of public safety, as they would contribute to the safe and competent practice of pharmacy.

The requirement for the registration of pharmacies is, however, inconsistent with the Review's recommendation, and should be **removed**.

The Review notes that, if enacted, the draft Bill would discontinue the present requirement for pharmacies to be registered. The draft Bill does, however, allow the Governor to make regulations in relation to the prescribed requirements for pharmacy premises. It also would retain powers of inspection for the Board, and enable the Board to make by-laws consistent with the new legislation, including in relation to pharmacy premises.

AUSTRALIAN CAPITAL TERRITORY *PHARMACY ACT 1931*

ASSESSMENT AGAINST THE REVIEWS' RECOMMENDATIONS

1. OVERVIEW

The *Pharmacy Act 1931* (the Act) has six Parts. There are no Regulations. The main provisions of the Act are the qualifications and registration of pharmacists and the conduct of business by pharmacists. In addition, and the constitution of the Pharmacy Board (the Board) is set out at Section 2 and specifies that the Board is charged with the general administration of pharmacy in the Territory.

2. OWNERSHIP OF PHARMACIES

OWNERSHIP OF PHARMACIES BY PHARMACISTS (RECOMMENDATION 1)

DESCRIPTION

The Act has no express requirement on the ownership of pharmacies. Sub-section 2(4) of the Act defines people who practice pharmacy as those who do so personally on their own account, or as a member of a firm, or those who employ pharmacists. The last provision appears to imply that non-pharmacists, including non-pharmacist companies, can own pharmacies and that they are subject to the Act in relation to the practice of pharmacy.

There is a requirement in sub-section 45(1) for owners of pharmacy business to display the name of the pharmacist in charge at the premises. Sub-section 45(2) contains the penalties that apply to companies and in other cases for contravention of sub-section (1).

ASSESSMENT

The Act appears to make a distinction between the ownership of businesses and the practice or conduct of the business of pharmacy. This view is supported by the provision in Section 45 for the separate concept of a pharmacist in charge as distinct from the owner of a business.

The Review understands that legal opinion obtained by the Board regarding these provisions indicates that there could be some doubt about the ability of non-pharmacists to own a pharmacy business. This advice argues that although a company can own a pharmacy, it cannot be registered as a pharmacist under Section 9 as a company could not meet the requirements of passing an examination and undertaking practical experience. Also, it appears that there would be difficulties in meeting the requirements of the Territories *Drugs of Dependence Act 1989* by a corporate entity or a pharmacy controlled by non-pharmacists. Owning or controlling certain prohibited substances is an offence under this Act, although pharmacists are exempted from these provisions.

On balance, the Review believes that the provisions on the Act cannot be held to rule out the ownership of pharmacies by persons other than pharmacists. If that is so, the current provisions are not wholly consistent with the Review's recommendation but, because they fall *within* and not *outside* the scope of the Review's conclusion on the boundaries of

justifiable regulation of who owns pharmacies¹⁶, any adjustments to current statutory requirements are a matter for the Territory.

RESIDENTIAL REQUIREMENTS FOR OWNERSHIP (RECOMMENDATION 2)

DESCRIPTION

There are no residential requirements for ownership or registration as a pharmacist under the Act. Section 21 lists the details that are to be included in the Register of Pharmacists and includes the person's place of residence, whether within or outside the Territory.

ASSESSMENT

As the Act is silent on these points, it is not inconsistent with the Review's recommendations.

OWNERSHIP STRUCTURES (RECOMMENDATION 3)

DESCRIPTION

There are no provisions in the Act relating to ownership structures. Section 43 of the Act authorises the administration of the estate of deceased pharmacists for six months, or more if the Board agrees, provided that the practice of pharmacy in the business is carried on by a registered pharmacist.

ASSESSMENT

The Act does not preclude or prohibit any ownership structures for, or shareholding arrangements in, pharmacy businesses. Generally, this is consistent with the Review's recommendation, but any implied ability for persons and corporations who are not registered pharmacists to be shareholders in a for-profit pharmacy business would be inconsistent with the Review's recommendation.

NUMBER OF PHARMACIES OWNED BY A PHARMACIST AND PERSONAL SUPERVISION OF A PHARMACY BY A PHARMACIST (RECOMMENDATION 4)

DESCRIPTION

The Act contains no references to pharmacy ownership or the numbers of pharmacies that may be owned by any person, persons or entities.

Paragraph 48(c) of the Act provides that a pharmacist shall not carry on business except under the supervision of that pharmacist or another registered pharmacist.

ASSESSMENT

The Act currently is interpreted as having no limitation on the number of pharmacies that a pharmacist may own. This is consistent with the Review's recommendations.

The pharmacist supervision provisions are consistent with the Review's recommendation.

¹⁶ See also Chapter 1 of Part A of this Report.

PERMITTED EXCEPTIONS TO PHARMACIST OWNERSHIP (RECOMMENDATION 5)

DESCRIPTION

The Act contains no references to friendly societies or other ownership structures or arrangements and therefore contains no grandparenting provisions or other exemptions.

PECUNIARY INTERESTS IN A PHARMACY BUSINESS (RECOMMENDATION 6)

DESCRIPTION

There are no provisions in the Act concerning pecuniary interest.

ASSESSMENT

Unless the Act was amended to clarify its coverage of pharmacy ownership, pecuniary interest provisions are not required. Should such amendments be made, however, they could include:

- 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. The working definition of proprietary interest in Chapter 1 of the Review's report may be of guidance in this regard; 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 the acting of a pharmacist under such influence a ground for professional misconduct.

REGISTRATION OF PHARMACY PREMISES AND PHARMACY BUSINESSES (RECOMMENDATION 7)

DESCRIPTION

The Act has no provisions relating to the registration of pharmacy premises or businesses, although a number of sections provide for the setting and enforcement of pharmacy practice and dispensary standards, and for reasonable inspection of premises.

ASSESSMENT

The Act is consistent with the Review's recommendations.

3. REGISTRATION OF PHARMACISTS

Part 3 of the Act deals with pharmacist registration, and part 4 is concerned with the conduct of pharmacy business, including provisions for the cancellation of registration. Essentially, the two parts provide the Board with the authority to register pharmacists, limit the practice of pharmacy to registered pharmacists, and to determine the professional and personal requirements for registration.

The latter power includes an ability to cancel or suspend registration if a person has engaged in any improper or unethical behaviour, or is not competent to practise pharmacy. The Board also has a discretionary power to impose conditions on registration at Section 22 of the Act. These conditions can include the duration of registration, limitations on practice and conditions relating to any other matters the Board considers appropriate.

REGULATORY MACHINERY (RECOMMENDATIONS 14 AND 15)

DESCRIPTION

Constitution of the Board

The constitution of and administrative arrangements for the Board are set out in Part 2, Sections 5 to 7. The Board consists of a Chairperson, three other members, all of whom are registered pharmacists and appointed in accordance with the *Health Professions Boards (Procedures) Act 1981* and three who are elected in accordance with the *Health Professions Boards (Elections) Act 1980*, which requires that all candidates be registered pharmacists. The Act is silent in relation to all other aspects of the administration and conduct of the Board, including disciplinary procedures.

Functions of the Board

The Board has a broad role outlined at Section 5, which is the “general administration” of the Act. In practice, the Act requires that the Board and has discretion in a number of areas regarding registration. For example, Section 14 permits the Board to refuse registration to persons convicted of an offence that renders them “unfit in the public interest to practice”. There are also a number of specific powers and functions that the Board is required to perform. These mostly relate to the actual registration and re-registration of pharmacists and generally confine the role of the Board to registration and the practice of pharmacy.

Staffing

There are no provisions relating to staffing apart from Section 7, which provides the ability to create and maintain one or more offices which have duties including the performance of the function of an inspector.

ASSESSMENT

Constitution of the Board

The lack of wider community and legal practitioner representation in Board membership, and the fact that half its members are elected, are inconsistent with the Review’s recommendations, and the existing provisions should be **amended**.

Functions of the Board

Current provisions regarding the Board and its operation are not consistent with the Review’s recommendations and the regulatory machinery should be **revised** to make the provisions more consistent with the principles outlined in Recommendation 14.

REGISTRATION OF PHARMACISTS (RECOMMENDATION 16)

DESCRIPTION

Pharmacy register

The registration of pharmacists is dealt with in Part 3 of the Act. The Board is required to keep a Register of Pharmacists in accordance with Section 23, whilst the details to be included in the Register are listed in Section 24. Notification of changes of address, alterations to the Register and the publication of entries in the Register are included in Sections 32 to 34. Certificates of Registration are issued and authorised in Section 31.

Practice protection

Section 42 of the Act makes it an offence for persons other than registered pharmacists to carry on the business of a pharmacist. Section 49 allows dentists, medical practitioners and veterinary surgeons to dispense medicines without becoming registered pharmacists.

Title protection

Prohibition on the use of descriptions or titles by persons other than registered pharmacists in respect of the practice of pharmacy is also included in Section 42.

Personal requirements for registration

There are a number of personal requirements in the Act. These include, conviction of an offence, deregistration outside the Territory, competence and good character (sections 13-16). Additionally, Section 18 requires that application is to be made on the prescribed form and accompanied by the determined fee.

Professional requirements for registration

The qualifications required for registration are covered at Section 9. The requirements specify a tertiary course accredited by the Board, passing an examination conducted by or on behalf of the Board and practical experience or training in practising pharmacy for up to twelve months. There are mutual recognition discretionary provisions at Sections 10 and 11 respectively. The latter permits the board to grant registration for teaching or research positions for people who possess qualifications that the Board considers appropriate.

ASSESSMENT

Pharmacy register

These provisions are consistent with the Review's recommendations.

Practice protection

These provisions are consistent with the Review's recommendations.

Title protection

These provisions are consistent with the Review's recommendations.

Personal requirements for registration

Requirements excess to good character and English language proficiency are inconsistent with the Review recommendations and should be **removed**.

Professional requirements for registration

These provisions are consistent with the Review's recommendations.

ONGOING PRACTICE (RECOMMENDATIONS 17 AND 18)

DESCRIPTION

Re-registration

The only re-registration requirement is at Section 28 of the Act, which requires the payment of the determined fee by 31 October each year. There are no requirements to notify the Board of any periods of non-practice nor any other matter. This means that registration can be maintained unless it is cancelled by the Board in accordance with other provisions in the Act relating to registration. These are dealt with in the section on disciplinary processes below.

ASSESSMENT

These provisions are consistent with the Review's recommendations.

DISCIPLINARY PROCESSES (RECOMMENDATION 19)

DESCRIPTION

The grounds for the cancellation or suspension of registration and the procedures to be followed by the Board are contained in Part 4 of the Act, Sections 35 to 53, which are concerned with the conduct of business as a pharmacist. The Board has both specific and broad powers to cancel registration. These range from withdrawal of the pharmaceutical qualification to habitual drunkenness and improper conduct and incompetence.

The Board can also caution, reprimand and impose fines on pharmacists. The cancellation or suspension of registration can only be imposed following an inquiry, which is required in accordance with Section 41. This Section also applies in cases where pharmacists are cautioned, reprimanded, ordered to undergo medical or psychiatric treatment or counselling or have conditions imposed on their practice.

There are no requirements for the conduct of inquiries and the publication of their findings is at the discretion of the Board (section 44). There are no provisions for the public to make complaints and for them to be investigated, nor is it specified how an inquiry should be instigated or conducted. Appeal rights to the Administrative Appeals Tribunal set out at Section 54, with written notification of Board decisions specified at section 55.

ASSESSMENT

The Act does not provide a comprehensive framework for pharmacist disciplinary system works and how it protects the public interest. The disciplinary provisions of the Act are therefore inconsistent with the Review's recommendation and should be **amended**.

Areas to which attention could be given include:

- Who may make complaints, referral of matters by courts and other bodies, and the manner in which complaints and referrals are made;
- Specific grounds for complaint, including setting out in reasonable detail what may constitute professional misconduct;
- Investigating complaints;
- Conciliating complaints and dealing with matters short of a hearing;
- Dealing with complaints by way of formal and informal hearings, and procedures for those hearings including dealing with conflicts of interest for Board members and ensuring that persons investigating a complaint do not adjudicate on the matter;
- The setting of penalties, including appropriate periods of suspension and adequate financial penalties; and
- Dissemination of disciplinary decisions.

At minimum, any guidelines or standing orders used by the Board to investigate, hear and adjudicate on disciplinary matters should be statutory instruments. These should cover all stages of a complaints process, including receiving and investigating complaints.

NORTHERN TERRITORY *PHARMACY ACT 1996*

ASSESSMENT AGAINST THE REVIEW'S RECOMMENDATIONS

1. OVERVIEW

The *Pharmacy Act 1996* (the Act) has five Parts. There are currently four Pharmacy Regulations.

The purpose of the Act is to register pharmacists and control the practice of pharmacy in the Northern Territory. The main provisions of the Act relate to the administration of the Pharmacy Board of the Northern Territory (the Board), registration requirements for, and the qualifications of, pharmacists, and the conducting of pharmacy businesses. The Regulations relate to meetings of the Board, details to be included in the Register of Pharmacists and the issue of certificates of registration.

By way of a general observation, pharmacy regulation in the Territory is notable for its relative lack of express regulation. While this promotes a professional practice environment, this in itself puts a particular pressure on the Board, which has to use its discretion and interpretative skills to administer the Act. The Act's relatively patchy coverage of key matters, such as pharmacy ownership and disciplinary and professional conduct matters, is noted.

It may be that it is timely for thorough revision of the Act. If this possibility is taken up by the Territory, the Review commends the principles of pharmacy legislation outlined in Recommendation 14 of this Report.

2. OWNERSHIP OF PHARMACIES

OWNERSHIP OF PHARMACIES (RECOMMENDATION 1)

It appears that the Act is concerned with who can practise the profession of pharmacy, rather than ownership of a pharmacy business as such. It is ambiguous in the way it approaches the matter of who can own a pharmacy. Some provisions imply that pharmacists can own pharmacies, and others simply provide that a pharmacy business must be under the management of a registered pharmacist.

Section 39 requires that only pharmacists can carry on business as a pharmacist and that dispensaries are to be constantly under the control of a pharmacist when open for business. Section 32 prohibits anyone other than a registered pharmacist from carrying on the business of a pharmacist. Also contained in Section 32 is a clause regarding the arrangements to be put in place when a pharmacist dies and specifies a transitional time limit of two months before which a registered pharmacist must conduct the business. These provisions could be read as implying only pharmacists are presumed to legally be capable of owning pharmacies.

On the other hand section 34, which relates to the management of a pharmacy, requires the "manager of a pharmacy" to display their name in front of the pharmacy, advise that Board of the pharmacy's location and that he or she is its manager, advise the Board of his or her continuous absence for more than three days, and "who will act as manager of the pharmacy during the absence".

Read in conjunction with sections 32 and 39, however, section 34 seems to imply very strongly that the Act's only interest is that a pharmacy is under the management of a professional pharmacist, and not necessarily that the manager is also the proprietor of the business.

The interpretation section of the Act provides no definition of terms such as "carry on the business of a pharmacist", as "manager of a pharmacy".

ASSESSMENT

The question whether the Act prohibits pharmacies to be owned by persons other than pharmacists is ambiguous at best.

Legal opinion obtained by the Pharmacy Board of the Northern Territory regarding these provisions indicates that it can be strongly argued that the Act implies that a pharmacy must be owned by a pharmacist¹⁷. The opinion canvassed the effects of sections 32 and 39, but notably overlooked the contrary implication of section 34.

Nevertheless, the contention that the Act has an implied assumption that only pharmacists may own pharmacies has some basis on a reading of the Act. Sub-section 32(2), containing transitional provisions for pharmacy businesses on the death of a pharmacist, could be taken to suggest that there was an intent shown by Parliament that only pharmacists can own pharmacies, otherwise this provision would not be needed. It could also be, however, that this sub-section relates only to those businesses that are owned and operated by pharmacists, and not to all pharmacy businesses in the Territory.

But when the pharmacy manager provisions of section 34 are taken into account, the Act can be construed as requiring simply that pharmacies are managed and supervised by registered pharmacists. That a pharmacist also owns a pharmacy is not essential to ensuring the supervision of pharmacy services by a registered pharmacist.

The phrase "carrying on the business of a pharmacist" as used in sub-section 32(1), is also ambiguous. Similar phrases in State *Pharmacy Acts* appear to relate to proprietorship, and in others to the day to day operation of a pharmacy and the provision of professional pharmacy services by pharmacists.

Without clear guidance from the Act itself, it may be that the only ways that this question is resolved definitively are by amendment to clarify the Territory's intentions, or by judicial interpretation if a non-pharmacist proprietor seeks to establish a pharmacy business in the Territory and is challenged by the Board as another party.

On balance, the Review believes that the provisions in the Act cannot be held to rule out the ownership of pharmacies by persons other than pharmacists. If that is so, the current provisions are not wholly consistent with the Review's recommendation but, because they fall *within* and not *outside* the scope of the Review's conclusion on the boundaries of justifiable regulation of who owns pharmacies¹⁸, any adjustments to current statutory requirements are a matter for the Territory.

¹⁷ This legal advice was conveyed to the Review in a letter from the Board dated 16 December 1999.

¹⁸ See also Chapter 1 of Part A of this Report.

RESIDENTIAL REQUIREMENTS FOR OWNERSHIP (RECOMMENDATION 2)

DESCRIPTION

The Act is silent on both whether a pharmacist has to be resident in the Territory to own a pharmacy, and on whether a pharmacist must be registered in the Territory to own a pharmacy.

ASSESSMENT

As the Act is silent on these points, it is not inconsistent with the Review's recommendation.

OWNERSHIP STRUCTURES (RECOMMENDATION 3)

DESCRIPTION

Over and above its unclear provisions on whom may own pharmacies, the Act makes no comment about permitted ownership structures and arrangements for pharmacy businesses.

ASSESSMENT

Because of its silence, the Act does not preclude or prohibit any ownership structures for, or shareholding arrangements in, pharmacy businesses. Generally, this is consistent with the Review's recommendation, but any implied ability for persons and corporations who are not registered pharmacists to be shareholders in a for-profit pharmacy business is inconsistent with the Review's recommendation.

NUMBERED OF PHARMACIES OWNED BY A PHARMACIST AND PERSONAL SUPERVISION OF A PHARMACY BY A PHARMACIST (RECOMMENDATION 4)

DESCRIPTION

The Act is silent on how many pharmacies a pharmacist may own in the Territory, and in which he or she may have a pecuniary interest.

Paragraph 39(c) of the Act provides that a pharmacist shall not carry on business except under the supervision of that pharmacist or another registered pharmacist.

ASSESSMENT

The Act currently is interpreted as making no limitation on the number of pharmacies that a pharmacist may own. This is consistent with the Review's recommendation.

The pharmacist supervision requirement is consistent with the Review's recommendation.

PERMITTED EXCEPTIONS TO PHARMACIST OWNERSHIP (RECOMMENDATIONS 5)

DESCRIPTION

Further to its ambiguity on who may own pharmacies, and the permissible ownership structures for those pharmacies, the Act is silent on who besides registered pharmacists may be the proprietors of a pharmacy. There are no references to friendly societies or any other potential non-pharmacist proprietors in, apart from Section 36 that prohibits persons other than registered pharmacists from holding appointments as pharmacists to a number of agencies, including friendly societies.

ASSESSMENT

In light of the Review's interpretation of other provisions of the Act as not precluding non-pharmacist owned pharmacies, it follows that friendly societies, and non-pharmacist individuals and companies, are not prevented from owning pharmacies in the Territory as the legislation stands.

In practice, it is understood that all community pharmacies in the Territory are currently owned by pharmacists and the issue has not needed to be resolved.

The Act, therefore, is not in itself inconsistent with the Review's recommendation, in the sense that leaves unregulated matters considered by that recommendation.

PECUNIARY INTERESTS IN A PHARMACY BUSINESS (RECOMMENDATION 6)

DESCRIPTION

The Act is silent in this area. This implies that any natural person or body corporate may have lawful pecuniary interest in a pharmacy or pharmacy business.

ASSESSMENT

Unless the Act is amended to clarify its intentions on pharmacy ownership, pecuniary interest provisions are not required. If it is so amended, however, it could include:

- 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. The working definition of proprietary interest in Chapter 1 of the Review's report may be of guidance in this regard; 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 the acting of a pharmacist under such influence a ground for professional misconduct.

REGISTRATION OF PHARMACY PREMISES AND PHARMACY BUSINESSES (RECOMMENDATION 7)

DESCRIPTION

The Act has no provisions relating to the registration of pharmacies or pharmacy businesses.

Section 17, however, provides for persons authorised by the Chairman of the Board to enter and examine premises where any pharmacist is carrying on business. Regulation 3 requires the “Professional Address” of pharmacists to be included in a Register of Pharmacists but there is no definition of what constitutes such an address.

Section 34 requires the display of the name of the pharmacy manager. A description of a dispensary is included at Section 39(2), which defines one as a place within a shop where certain drugs or substances are stored. These drugs and substances are defined in other Acts.

ASSESSMENT

These provisions are consistent with the Review’s recommendation.

3. REGISTRATION OF PHARMACISTS

Part 2 of the Act deals with Board matters, Part 3 deals with the registration of pharmacists, whilst part 4 is concerned with the conduct of pharmacy businesses and professional practices, and includes provisions for the cancellation of registration. Essentially, the Act parts provide the Board with the authority to register pharmacists, to limit the practice of pharmacy to registered pharmacists, and to determine the professional and personal requirements for registration.

REGULATORY MACHINERY (RECOMMENDATIONS 14 AND 15)

DESCRIPTION

The constitution of, and administrative arrangements for, the Board are set out in Part 2, Sections 6 to 8A. The Board consists of a Chairman and five registered pharmacists. No members are elected, with the Chairman being the Chief Health Officer, or his or her nominee and five registered pharmacists appointed by the Minister. There are no requirements regarding potential conflict of interest in disciplinary and other matters before the Board.

The role of the Board is not actually codified in the Act. Specific functions are found throughout the Act, the principal ones being the registration of pharmacists (section 21), cancellation of registration, (section 29), and powers to undertake investigations (Sections 9 to 14).

ASSESSMENT

The full appointment of Board members is consistent with the Review’s recommendation.

On the whole, however, provisions regarding the Board and its operation are not consistent with the Review’s recommendation, and indeed with practice either adopted or being

considered for pharmacy regulatory authorities in other States and Territories. The regulatory machinery in the Act should be **amended**. Such amendments could include:

- A clear setting out of the Board's (or new body's) role, powers (including limitations on its discretion) and responsibilities in the Act and regulations; and
- Ensuring that regulations, by-laws and guidelines that may be proposed by the Board or new body are not effective until they are approved by the Administrator-in-Council as statutory instruments.

REGISTRATION OF PHARMACISTS (RECOMMENDATION 16)

DESCRIPTION

Initial Registration

The Board maintains a register of pharmacists, the requirements for which are set out in Section 18 and Sections 26 - 30.

Section 19 describes how a person is registered. The qualifications required for registration are at section 21, and require a candidate passing the examinations prescribed by the Board in any State or by overseas colleges or boards of pharmacy recognised by the Board. Mutual recognition of registration in other States and Territories is provided for in section 20. There is no fee for registration, but one is payable for the issue of a certificate of registration.

Practice Protection

Section 32 makes it an offence to for persons other than registered pharmacists to carry on business as a pharmacist. Retailers of patient or proprietary medicines, defined in section 32(2), are not deemed to be carrying on the business of a pharmacist. Similarly, medical practitioners and veterinary surgeons may dispense medicines and do not need to be registered pharmacists.

Title Protection

The use of certain descriptions or titles, and words of similar meaning, by persons other than registered pharmacists is included in Section 32the Act at section 32.

Personal requirements

Section 21 requires that they be of "good fame and character". Other than this, there are no other personal requirements for initial registration.

ASSESSMENT

Initial Registration

These requirements are consistent with the Review's recommendation.

Practice Protection

These requirements are consistent with the Review's recommendation.

Title Protection

These requirements are consistent with the Review's recommendation.

Personal requirements

These requirements are consistent with the Review's recommendation.

ONGOING PRACTICE (RECOMMENDATIONS 17 AND 18)

DESCRIPTION

The Act contains no re-registration requirements of any kind. This means that a pharmacist's registration continues unless and until it is cancelled by the Board in accordance with the Act. In section 29(1) of the Act grounds for cancellation are set out. These include situations where the original registration was obtained by fraud or misrepresentation, being found guilty of an offence, habitual drunkenness or improper conduct that the Board considers renders a person unfit to practise.

ASSESSMENT

These requirements are consistent with the Reviews recommendations.

DISCIPLINARY PROCESSES (RECOMMENDATION 19)

DESCRIPTION

Disciplinary procedures are codified in Part 2 of the Act, Sections 9-14. These provisions outline the powers of the Board and the procedures it is to adopt in gathering and assessing evidence. Section 29 lists the grounds for cancelling the registration of a pharmacist, whilst Section 30 requires that the Board conduct an inquiry prior to cancellation of registration.

Certificates of registration are to be returned to the Board for cancellation. The grounds for cancellation are outlined above. Persons who appear before the Board are entitled to representation and have the right to examine witnesses. The Board can summon people to give evidence and require them to provide a range of records in their custody or control.

There are no other guidelines for the conduct of inquiries or public notification or the right of the public to attend. Nor are there any appeal rights in the Act, other than a right of appeal against the board's refusal to register a pharmacist. There are no specific grounds or procedures for the public to make complaints to the Board.

ASSESSMENT

The Act does not provide detailed requirements for the making and investigation of complaints. In fact, it does not specify any grounds for the public to make complaints. Nor does it provide a comprehensive guide about how the disciplinary system actually works and how it protects the public interest.

This is not to say that complaints are not dealt with in a rigorous and professional manner by the Board. However, the disciplinary provisions of the Act are inconsistent with the Review's recommendation, and should be **amended**.

Areas to which attention could be given include:

- Who may make complaints, referral of matters by courts and other bodies, and the manner in which complaints and referrals are made;
- Specific grounds for complaint, including setting out in reasonable detail what may constitute professional misconduct;
- Investigating complaints;
- Conciliating complaints and dealing with matters short of a hearing;
- Dealing with complaints by way of formal and informal hearings, and procedures for those hearings including dealing with conflicts of interest for Board members and ensuring that persons investigating a complaint do not adjudicate on the matter;
- The setting of penalties, including appropriate periods of suspension and adequate financial penalties; and
- The dissemination of disciplinary decisions.

At minimum, any guidelines or standing orders used by the Board to investigate, hear and adjudicate on disciplinary matters should be statutory instruments. Regulation making power in relation to “the control of registered pharmacists and the practice of the profession” is already conferred on the Administrator by Section 48 of the Act.

Appendix 1

THE REVIEW'S TERMS OF REFERENCE

Introduction

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

BACKGROUND

On 13 May 1997 the Prime Minister, in his role as Chairman of the Council of Australian Governments (COAG), wrote to State Premiers and Territory Chief Ministers, seeking their agreement to a national competition review of pharmacy regulation. On 1 May 1998, the Prime Minister advised Premiers and Chief Ministers that all Governments had agreed to the review.

LEGISLATION TO BE REVIEWED

The specific items of legislation to be reviewed are listed at Attachment A.

In summary, they include:

- in relation to State and Territory responsibilities, legislation concerning pharmacy ownership and the registration of pharmacists; and
- in relation to Commonwealth responsibilities, section 99L of the National Health Act insofar as it relates to the regulation of the location of premises from which pharmacists may dispense pharmaceutical benefits.

OBJECTIVES AND SCOPE OF THE REVIEW

Clarify the objectives of the legislation listed at [Attachment A](#).

Identify the nature of any restrictions on competition arising from that legislation.

Analyse the likely effects of those restrictions on competition and on the economy generally.

Assess and balance the costs and benefits of the restrictions, and assess whether the objectives of the legislation can be achieved only by restricting competition.

Consider alternative means for achieving the objectives, including non-legislative approaches.

The review will have regard to the relevant sections of the Competition Principles Agreement, the COAG Guidelines and Principles for National Standard Setting and

In the case of Tasmania and Queensland, the review will not cover the registration of pharmacists as this legislation has already been reviewed.

Regulatory Action, the COAG Guidelines for Review of Professional Regulation and make use of material contained in guidelines published by Commonwealth and State governments on regulatory impact statements and on conducting National Competition Policy legislation reviews. If practicable, the review should also have regard to the outcome of related reviews such as the national competition review of drugs and poisons regulation.

The review should also assess the net public benefit of the legislation having regard to the public benefit criteria set out in clause 1(3) of the Competition Principles Agreement (see Attachment B).

REVIEW ADMINISTRATION

Chair and Steering Committee

The review will be conducted by an independent Chair who will be supported by a small secretariat. The Chair will be advised by a Steering Committee specifically established for that purpose.

The Chair should have familiarity with economic principles and the pharmacy industry. He/she will be selected from a short-list of nominees prepared by the Commonwealth Department of Health and Aged Care in consultation with State and Territory health departments.

Nominations for membership of the Steering Committee will be obtained through consultation involving Commonwealth, State and Territory Departments of Health and the Committee for Regulatory Reform of COAG. A key criterion for the Steering Committee is that it comprises one representative from each jurisdiction and that that person is able to represent the government agency whose legislation is subject to the review.

Resources

The Commonwealth will fund half the costs of the review, excluding Steering Committee participation costs, which are to be met separately by each participating government. The remaining costs of the review will be shared proportionately according to the population of each State and Territory. If considered appropriate, any participating government may offer to second an officer to the review Secretariat as part of its contribution.

Costs to be taken account of in developing a budget for this review include:

- staffing and office costs for secretariat;
- payment to an independent Chair;
- payment to any consultants contracted;
- costs of producing the report;
- costs associated with consultations, advertising for submissions etc; and
- associated travel costs.

The total cost of the review could be expected to be in the vicinity of \$500,000.

The Commonwealth Department of Health and Aged Care will provide the base for the Secretariat functions and significant staff support for the Review Secretariat itself. Final

details of staffing, including the appropriate level and mix of skills, can be resolved through the Steering Committee.

Conduct of the review

The Chair should seek submissions from the public through advertisements in the national press and other mechanisms considered appropriate. The Chair should also consult directly with key stakeholders on the issues covered by the review.

The review is to commence as soon as possible. The Chair should provide governments and key stakeholders with an interim report within 4 months of the commencement of the review to assist in their consideration of issues relating to pharmacy ownership, the registration of pharmacists and the location of pharmacies, and to provide an indication of the review's likely findings. The Chair should provide COAG with a final report on the review not more than 6 months after its commencement.

Legislation to be Reviewed**1. State and Territory legislation**

The relevant instruments relating to pharmacy ownership and registration of pharmacists for the States and Territories are as follows:

Western Australia, *Pharmacy Act 1964*

New South Wales, *Pharmacy Act 1964*

Victoria, *Pharmacists Act 1974*

South Australia, *Pharmacists Act 1991*

Queensland, *Pharmacy Act 1976*, Part 4

Tasmania, *Pharmacy Act 1908*, (not including those parts relating to the registration of pharmacists)

Northern Territory, *Pharmacy Act 1996*

Australian Capital Territory *Pharmacy Act 1931*

2. Commonwealth Legislation

There is one instrument involved:

Commonwealth Ministerial Determination under section 99L (1) of the *National Health Act 1953*: that part relating to “Approval to Supply Pharmaceutical Benefits”.

ATTACHMENT B**PUBLIC BENEFIT TEST**

Competition Principles Agreement, Clause 1(3) states:

“Without limiting the matters that may be taken into account, where this Agreement calls:

- (a) for the benefits of a particular policy or course of action to be balanced against the costs of the policy or course of action; or*
- (b) for the merits or appropriateness of a particular policy or course of action to be determined; or*
- (c) for an assessment of the most effective means of achieving a policy objective;*
- (d) the following matters shall, where relevant, be taken into account:*
- (e) government legislation and policies relating to ecologically sustainable development;*
- (f) social welfare and equity considerations, including community service obligations;*
- (g) government legislation and policies relating to matters such as occupational health and safety, industrial relations and access and equity;*
- (h) economic and regional development, including employment and investment growth;*
- (i) the interests of consumers generally or of a class of consumers;*
- (j) the competitiveness of Australian businesses; and*
- (k) the efficient allocation of resources”.*

Appendix 2

THE NATIONAL COMPETITION POLICY

INTRODUCTION

In 1995 the Council of Australian Governments (COAG) agreed to implement the National Competition Policy (NCP) based on the recommendation of the National Competition Policy Review Committee chaired by Professor Fred Hilmer AO.

NCP represents a commitment by all Australian governments to a consistent approach to fostering greater economic efficiency and improving the overall competitiveness of the Australian economy.

HOW NCP IS GIVEN EFFECT

NCP is being given effect through the implementation of three intergovernmental agreements signed by COAG in April 1995:

- The *Conduct Code Agreement*, which committed Governments to the application of uniform competition laws;
- The *Competition Principles Agreement*, which established consistent principles governing pro-competitive reform of government business enterprise and government regulation;
- The *Agreement to Implement National Competition Policy and Related Reforms*, which incorporated a timetable for reform and a commitment by the Commonwealth to make additional general purpose payments to the States conditional upon compliance with the agreed reform agenda and timetable.

COMPETITION PRINCIPLES AGREEMENT

As part of the *Competition Principles Agreement*, all governments agreed to adopt the following guiding legislative principle:

Legislation should not restrict competition unless 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.

To give effect to this principle, governments have agreed to:

- Review, and where appropriate, reform all existing legislative restrictions on competition against the guiding legislative principle; and
- Ensure that all new legislative proposals are assessed against this principle.

The *Competition Principles Agreement* provides that in assessing the costs and benefits of a restriction on competition, the following matters, where relevant, are taken into account:

- Government legislation and policies relating to ecologically sustainable development;
- Social welfare and equity considerations, including community service obligations;

- Government legislation and policies relating to matters such as occupational health and safety, industrial relations and access and equity;
- Economic and regional development, including employment and investment growth;
- The interests of consumers generally or of a class of consumers;
- The competitiveness of Australian businesses; and
- The efficient allocation of resources.

The *Competition Principles Agreement* also requires that a legislation review should consider the following:

- Clarify the objectives of the legislation;
- Identify the nature of the restriction on competition;
- Analyse the likely effect of the restriction on competition and on the economy generally;
- Assess and balance the costs and benefits of the restriction; and
- Consider alternative means for achieving the same result, including non-legislative approaches.

NCP PURPOSE AND PHILOSOPHY

The purpose of the guiding legislative principle is to critically assess whether restrictions on competition are necessary to achieve the objectives of the legislation in which they appear. As stated in the Victorian Government's *Guidelines for the Review of Legislative Restrictions on Competition*:

These [restrictions] typically evolved to serve wider public policy objectives, including protection of the consumer, the environment or the wider public from unscrupulous, unsafe or environmentally destructive practices, processes or products. The guiding legislative principle established under the Competition Principles Agreement does not imply that competition objectives should take precedence over these important policy objectives. However, the form which regulation takes often creates unwarranted barriers to entry to relevant markets, limiting consumer choice, stifling innovation and generating monopoly rents for existing producers which result in higher prices to consumers.

Application of the Policy's guiding legislative principle therefore is intended to establish whether particular restrictions on competition remain necessary to the achievement of specific public policy objectives through a rigorous assessment of the benefits to the public of each restriction compared with the costs involved, and assessment of non-regulatory alternatives.

The general proposition underlying these reviews is that open and unrestricted competition in markets is generally the most efficient method of allocating the community's resources, and that the benefits of a restriction on competition will generally only outweigh the costs in situations of 'market failure'. Therefore, intervention should generally be restricted to those situations.

This Appendix is an extract from the Victorian Department of Human Services' November 1998 discussion paper for the Review of Victorian Health Act 1958. It is adapted with permission.

Appendix 3

THE PHARMACEUTICAL BENEFITS SCHEME AND PHARMACIST REMUNERATION

The purpose of the Pharmaceutical Benefits Scheme (PBS) is to provide timely, reliable and affordable access for the Australian community to necessary and cost effective medicines.

The PBS has been in operation for more than 50 years. It has evolved into a scheme which from 1 February 1999 covers 559 drug substances (generic drugs), available in 1,354 forms and strengths (items) and marketed as 1,992 different drug products (brands). The list of benefits is comprehensive, providing suitable therapy for most medical conditions in which medicine is an accepted form of treatment and diagnosis by a medical practitioner is appropriate.

Eligibility is restricted to Australian residents and visitors from those countries with which Australia has a Reciprocal Health Care Agreement. Currently, those countries are the UK (including Northern Ireland), Ireland, New Zealand, Malta, Italy, Sweden, the Netherlands and Finland.

The PBS is complemented by the Repatriation Pharmaceutical Benefits Scheme (RPBS), which provides access to some additional pharmaceutical items to persons with entitlements under the *Veterans' Entitlements Act 1986*.

Decisions on what drugs are included, or "listed" under the PBS, are based upon the recommendations of an expert body of medical practitioners and pharmacists, the Pharmaceutical Benefits Advisory Committee. Over recent years, increasing emphasis has been placed on manufacturers having to demonstrate the cost effectiveness of the drugs they are seeking to have listed on the Schedule of Pharmaceutical Benefits.

PBS listed products must be:

- Prescribed by a registered medical practitioner or, for certain drugs, by a registered dental practitioner; and
- Dispensed by an approved pharmacist or, in limited cases where a pharmaceutical service is not available, by an approved medical practitioner.

The Commonwealth Government reduces the cost of pharmaceuticals to patients by:

- Negotiating an agreed price for the medicine with the supplier of the product;
- Controlling the mark-ups applied by wholesalers and dispensers;
- Remunerating dispensers an amount determined by the Pharmaceutical Benefits Remuneration Tribunal; and
- Subsidising the cost of the product to patients with the level of subsidy linked to the welfare needs of the patient.

In negotiating prices with manufacturers, which are used to establish prices paid to pharmacists, the Commonwealth Government has significant market power because only products listed on the PBS are subsidised and doctors tend to confine their prescribing to the

PBS list. As a result of this monopsony power, the pharmaceutical industry claims that Australian prices are significantly lower than most other comparable overseas countries.

Under the PBS, the current maximum cost to consumers for drugs listed under the PBS is \$20.30 for General Beneficiaries (who are members of the general public and do not have concession cards) and \$3.20 for Concessional beneficiaries (who are holders of Pensioner Concession, Commonwealth Seniors Health Cards and Health Care Cards), except where a special patient contribution, a brand premium, or a therapeutic group premium applies.

So, for example, if a person required treatment for multiple sclerosis with Interferon Beta-1b (*Betaferon*), the cost of a set of injections is \$1264.34, but a General Beneficiary would pay \$20.30 and a Concessional beneficiary \$3.20, with the Commonwealth meeting the balance of the cost.

COST OF THE PBS TO GOVERNMENT

In 1997/98, the PBS dealt with over 125 million benefit prescriptions. For that year, the cost to the Commonwealth of the PBS was \$2.541 billion and the patient contribution was \$571 million, making the total cost of the Scheme \$3.112 billion.

Of this total, the amount paid to pharmacists for dispensing the drugs was \$773 million, representing around 25 per cent of the total cost of the Scheme.

It took 40 years for the cost of the PBS to reach \$1 billion and only a further six years to double to nearly \$2 billion in 1994/95. Since then, the cost to the Government of pharmaceutical benefits has grown at an average annual rate of 9.7 per cent in real terms over the last 4 years. PBS costs are expected to grow at an average rate of 8.0 per cent real per annum over the next 5 years. The total cost to the Government of the PBS can be expected to double again in the next 11 to 12 years.

Government expenditure on the PBS represents 5.9 per cent of total health services expenditure; the PBS average annual expenditure growth rate of 9.7 per cent per annum compares with an average annual growth rate of around 4.8 per cent in total health services expenditure.

As in the case of other medical technologies, newer medicines tend to be more expensive than older ones and prescribers tend to favour the newer and more expensive medicines. So, for example, in 1997/98 there were over 6 million PBS prescriptions for cholesterol-lowering drugs, at an average price of \$50.78 and at a total cost to Government of some \$274 million. Antacids and drugs for treating peptic ulcers accounted for over 8 million PBS prescriptions, at an average price of \$46.58 and at a total cost to Government of over \$322 million.

The majority of expenditure on PBS prescriptions continues to be directed towards those least able to afford the cost of medicines, with Government expenditure on pharmaceuticals for Concessional beneficiaries representing around 80 per cent of total PBS expenditure in 1997/98. The remaining 20 per cent was spent on subsidising the price of drugs prescribed to General beneficiaries.

PHARMACIST REMUNERATION

The current Australian Community Pharmacy Agreement between the Commonwealth and the Pharmacy Guild of Australia provides for payments to approved pharmacists for the dispensing of PBS listed medicines. This agreement expires on 30 June 2000 and is currently being re-negotiated.

The amount paid to pharmacists consists of:

- A mark-up of 10 per cent on the Government agreed price to the pharmacist, up to \$180, or \$18.00 on the price to pharmacists above \$180 up to \$360, or 5 per cent on the price to pharmacists above \$360,
- **Plus** a Government composite fee of \$4.34 for ready prepared items or \$6.20 for extemporaneously prepared items,
- **Plus** a range of miscellaneous fees and allowances where applicable, such as:
 - the Isolated Pharmacy Allowance and Remote Pharmacy Allowance;
 - fees for accredited pharmacists undertaking medication reviews in nursing homes; and
 - additional charges for PBS medicines below the general patient copayment (of \$20.30)

Payments to suppliers (including manufacturers) are 90 per cent of the pharmacist price, whilst wholesalers receive 10 per cent of the pharmacist price.

This material was prepared by the Commonwealth Department of Health and Aged Care and is adapted with acknowledgment.

Appendix 4

POSSIBLE CORPORATE STRUCTURE MODEL

Please Note: This appendix is accessible on as a separate PDF document at www.health.gov.au/haf/pharmrev/final.htm

Appendix 5

ALTERNATIVES TO EXISTING REGULATION FOR NEW AND RELOCATED PHARMACIES

Further to Recommendations 9-13 in Chapter 3, the Review has considered how transitional arrangements may apply for regulations related to locating pharmacies to dispense Pharmaceutical Benefits Scheme (PBS) benefits. This Appendix assumes that relocated pharmacy restrictions would be phased out after the transition period, and that new pharmacy approval restrictions will in time be replaced with other measures.

NEW PHARMACY APPROVALS

For the transitional period, the existing rules for new pharmacy approvals would continue, and the ACPA's determining role would continue. The criteria applied would, however, be revised to make them more efficient, relevant and equitable, particularly to make them as "rural friendly" as possible.

Subject to negotiation and consultation, including with affected communities themselves, adjusted criteria could be more flexible, and take such factors into account as:

- Local population health characteristics (eg aged persons, persons with chronic illnesses, people with serious disabilities, numbers of children under 10) rather than disadvantaged social groups;
- The proximity of the nearest pharmacy and nearest hospital;
- The local community's ability to support the pharmacy business;
- A general practitioner being within a reasonable travelling time of the locality (of say 30 minutes) rather than present in a town full- or part-time; and
- Changing the population definition to reflect a locality's year-round profile, including temporary residents in peak periods (for example, in a holiday locality where a high transient population may be present for several months) rather than simply count the number of permanent residents.

RELOCATED PHARMACY APPROVALS

From the 1 July 2001 commencement date suggested in Chapter 3, the existing distance-based relocation rules would continue for a agreed time, with modifications to make their operation more effective and practical, and better to reflect contemporary and evolving trends in health care delivery in and beyond pharmacy.

"Long distance" relocations

Interim adjustments to the long distance relocation criteria could include:

- Shortening the new site relocation distance from 2 kilometres to 1.5 kilometres. This would continue the trend of the Second Agreement from the First in shortening the radius from 5 to 2 kilometres; and

- Changing the current route definition of the “shortest lawful distance door to door” to the “shortest reasonable access route”. This would not eliminate the potential for administrative or judicial review of distance-based decisions. It would, however, mean that they would be based on more practical considerations such as the degree of difficulty for an old, ill or infirm person, or a parent with young children, in reaching their nearest pharmacy.

Local relocations

For short distance relocations of an established pharmacy to a nearby site:

- The present 1 kilometre route measure for short distance relocations would be extended to 1.5 kilometres by the shortest reasonable access route;
- The period in one site before a short distance relocation could be sought would be reduced from 2 years to 1 year; and
- The need for Australian Community Pharmacy Authority (ACPA) approval of short relocations would be abolished, although the new premises would still need to satisfy any local State or Territory requirements.

Shopping centre relocations

For shopping centre relocations, existing distance-exempt provisions would continue, but:

- The present distinction between service and retail shops would be abolished, and the total number of shops in the complex would be the eligibility criterion;
- The ratio of pharmacies to shops in any one complex would not necessarily change (ie 1:30; 2:100; 3:200);
- The definition of an eligible shopping centre would be clarified along the lines of “*a discrete collection of shops, including a food store, supermarket or department store, within one exclusive pedestrian and car parking precinct*”; and
- The Secretary of the Department of Health and Aged Care (the Secretary) would have the discretion to approve a pharmacy in a community shopping precinct of less than 30 shops and less than 1.5 kilometres from the nearest pharmacy if:
 - (a) The existing pharmacy would be difficult for residents without private transport to reach easily (for example, due to topographical features or lack of access to existing public transport routes);
 - (b) A general practitioner is or will be co-located in the precinct.

SPECIFIC APPROVALS

Recognising that certain care facilities have special pharmacy needs, the Secretary could consider also new and relocated approvals for pharmacies in:

- Medical centres;
- Private hospitals with inpatient services (without a minimum bed requirement); and
- Aged care facilities (single or multi-complex) with sufficient residents and community-based clients to justify an in-house pharmacy service.

The distance criteria for relocations would not apply, although safeguard criteria and definitions of eligible facilities may be put in place to protect the public interest.

RURAL LOCALITIES

In limited circumstances, the Secretary may issue a PBS approval to a designated rural or isolated locality if that locality satisfies the revised definite community need criteria of the nature outlined above, and applies for the issue of a location specific PBS approval under these proposed arrangements.

In these circumstances:

- The PBS approval would be tied to that locality;
- The ACPA may not necessarily have a role in recommending locality-based applications;
- The approval could not be relocated with a pharmacy from the designated locality to another place;
- The local community may use the approval to attract a pharmacy business to that locality, and may be involved in selecting pharmacy proprietors applying for access to the approval; and
- The ongoing need for an approval specific to a given locality would be reviewed periodically by the Commonwealth Department of Health and Aged Care.

PERIOD OF OPERATION OF THE SUGGESTED MEASURES

These arrangements would commence on 1 July 2001, giving pharmacists and pharmacy proprietors reasonable notice of the changes coming into effect. Effectively, the starting date would be one year into the next Australian Community Pharmacy Agreement.

Once commenced, the measures outlined above would apply for a three to five year transitional period. At the end of that period:

- The pharmacy relocation restrictions would be abolished altogether; and
- The new approval restrictions would be abolished if different remunerative arrangements are put in place as discussed in Chapter 3.

Savings arrangements

PBS dispensing approval applications for new and relocated pharmacies commencing trading after 1 July 2001 would be considered under present rules in respect of pharmacies for which (a) deeds of sale or purchase have been executed, (b) leases have been signed, and (c) applications for PBS dispensing approvals have been lodged, before 30 June 2001.

THE AUSTRALIAN COMMUNITY PHARMACY AUTHORITY

For any transition period, there is a case for restructuring the composition and functions of the ACPA to ensure that it, and whatever rules it administers, are as responsive as possible to the needs of the community as a whole.

Under the transitional approach the ACPA would be retained but would:

- Be recognised by all parties as having its first duty to the Australian community rather than to the Commonwealth or to the community pharmacy industry and profession;

- Be composed of persons appointed by the Commonwealth Minister in consultation with the Pharmacy Guild of Australia, the Pharmaceutical Society of Australia, and consumer interests;
- Be chaired by a person with personal experience of community pharmacy but not a current proprietor, and include in its membership a legal practitioner and a lay member, neither of whom should also be a registered pharmacist; and
- Interpret the Determination rules fairly and consistently on the basis of clear guidelines and established precedent. The ACPA in doing so could exercise approved limited discretion on matters such as distance from the nearest pharmacy, and matters relating to community shopping precincts described above. The limits of such discretion, and procedures for dealing with any ACPA member's conflicts of interest in dealing with applications, should be set out in published guidelines approved by the Minister.

