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APPENDIXES

National Competition Policy Review of Pharmacy

MDP 93
GPO Box 9848
CANBERRA ACT 2611

Telephone: 02 6289 8665
Facsimile: 02 6289 8665

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The Hon John Howard MP
Prime Minister
Parliament House
CANBERRA ACT 2600

Dear Prime Minister

Pursuant to its Terms of Reference, I am pleased to present to the Council of Australian Governments the Preliminary Report of the National Competition Policy Review of Pharmacy.

The Review was given the task under the National Competition Policy to examine collectively specified Commonwealth, State and Territory legislation. It was asked particularly to assess effects of that legislation on competition in the regulatory areas of the ownership of pharmacies, the location of pharmacies for the purposes of the Commonwealth Pharmaceutical Benefits Scheme, and the registration of pharmacists.

The Review has made a number of findings and recommendations, some of which will be elaborated further in its Final Report. I commend these recommendations to Commonwealth, State and Territory jurisdictions for their consideration.

Yours sincerely

Warwick J. Wilkinson AM
Reviewer

EXECUTIVE SUMMARY

The National Competition Policy Review of Pharmacy was announced in June 1999. It was charged, on behalf of Commonwealth, State and Territory governments to examine specified Acts and regulations to determine, in accordance with the framework of the National Competition Policy, whether they impose restrictions on competition and, if so, whether they should be removed.

The Review's Terms of Reference asked it to look specifically at provisions of State and Territory *Pharmacy* and *Pharmacists Acts*, and a ministerial determination made under section 99L of the Commonwealth *National Health Act 1953*, to examine the restrictions that they may impose on the:

- Ownership of pharmacies;
- Location of pharmacies to dispense benefits under the Commonwealth Pharmaceutical Benefits Scheme; and
- Registration of pharmacists.

Both pharmacy as a profession and community pharmacy as an industry have enjoyed a long history of protection from the full forces of competition. Practices in both the pharmacy profession and the community pharmacy industry have been entrenched with a highly protective regulatory framework to support them. As a general observation, the Review concluded that there are definite and pronounced restrictions of competition in all three areas that it examined.

The full effects of these regulatory restrictions, however, could not be evaluated fully without taking into account factors in the professional and industry environments largely outside the scope of the Review's Terms of Reference, including drugs and poisons legislation. In fact, drugs and poisons legislation is the subject of a separate National Competition Policy review.

Most important of these other external factors is the Australian Community Pharmacy Agreement between the Commonwealth Government and the Pharmacy Guild of Australia, which sets the terms and conditions for the remuneration of pharmacies for the dispensing of PBS items, and related concessions and allowances to pharmacies and pharmacists. The Review's location head of inquiry is the only direct connection with the Agreement in its inquiries.

The PBS accounts for nearly two-thirds of pharmacies' average turnover, and the Commonwealth through the PBS pays most of the cost of 95 per cent of prescription medicines dispensed in Australia. The Agreement, supported by the *National Health Act*, influences how the PBS links to the national network of community pharmacies that supply the subsidised medicines to the public. In turn this affects the rules of the competitive game in retail pharmacy.

OWNERSHIP OF PHARMACIES

Under each State Act, with the specified exceptions of friendly societies and some "grandparented" proprietors, only registered pharmacists may own pharmacies. The Australian Capital Territory and Northern Territory *Pharmacy Acts* only require that a pharmacy be managed by a pharmacist.

The Review concludes that while it is a major restriction on who may enter and compete in the community pharmacy industry, the restriction of ownership almost exclusively to registered pharmacists is a net benefit to the community as a whole. Community pharmacy is an unusual hybrid of a traditional professional practice and shopfront-based retail business. Through pharmacist proprietorship, there is a reasonable assurance for the public that the principal purpose of a community pharmacy is to provide

safe and competent professional pharmacy services. These arrangements also provide that pharmacist proprietors ensure that the pharmacies under their control strive to provide the quality of services that Australians are entitled to expect, and that they can be held professionally accountable for their pharmacy's professional services.

The Review also recommends that existing exceptions to the general pharmacist ownership principle, friendly societies and grandparented non-pharmacist owned pharmacies are retained, subject to some further examination of relevant industry factors.

Beyond the professional provision of pharmacy services, the overall operations of pharmacy businesses do not need to be regulated closely by *Pharmacy Acts*. Yet there is a raft of provisions in these Acts, supported by interpretations by Pharmacy Boards and the courts, that allow regulators to intrude into aspects of pharmacy businesses that are well beyond what is needed to ensure safe and competent professional practice. These include rules relating to the numbers of pharmacies held by a proprietor and what constitutes a third party pecuniary interest in a pharmacy.

The Review has concluded that regulations of this nature are not justifiable restrictions on competition, and should be removed wherever possible to ensure that pharmacy businesses can make their own commercial judgments without undue interference from professional regulatory authorities.

LOCATION OF PHARMACIES

To supply medicines subsidised by the Pharmaceutical Benefits Scheme, a pharmacy must be approved by the Commonwealth on the recommendation of the Australian Community Pharmacy Authority. Under the terms of the Australian Community Pharmacy Agreement, embodied in the *National Health Act* determination referred to the Review, there are strict controls imposed on approving a new pharmacy, and on relocating existing pharmacies, for PBS purposes.

Given that PBS sales and dispensing remuneration are by far the greater part of a pharmacy's overall turnover, an indirect effect of these controls is that they effectively can determine who can operate a financially viable pharmacy, and where a viable pharmacy can operate.

The Review concludes that these existing requirements restrict free and effective competition in the community pharmacy industry. It also concludes that there may be mechanisms other than the current new approval controls that could achieve the outcome of managing the overall numbers of pharmacies to a level the community can afford in terms of outlays on PBS and other services. It also concludes that the restrictions on relocation are serving little purpose since a major rationalisation of pharmacy outlets was completed in the early 1990s, and should be removed.

Ideally, the current restrictions could go at the conclusion of the Australian Community Pharmacy Agreement, but if not they could be phased out over a reasonable transitional period. In the event there is a phased rather than immediate abolition, the Review supports the criteria for both new approvals and relocations being revised considerably to make them more efficient, transparent and equitable.

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

REGISTRATION OF PHARMACISTS

The purpose of regulating who may practise pharmacy, and how it is practised, is to assure the Australian public that their pharmacists are competent and the professional services they provide are safe.

Under this guiding principle, and taking into account that there is an information asymmetry between pharmacists and consumers, it is reasonable to regulate the practice of pharmacy and its practitioners. The Review therefore concludes that the registration of pharmacists, and specifying entry standards based on a minimum level of proficiency to practise unsupervised, are justifiable restrictions on competition.

Consistent with its recommendations on pharmacy ownership, the Review also concludes that regulation of pharmacists and pharmacy practice should be confined to enforcing practice standards, and not intrude unduly on other 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, and implemented by regulatory authorities such as Pharmacy Boards.

The Review has given considerable thought to the minimal requirements in State and Territory *Pharmacy Acts* relating to pharmacists renewing their registration. Generally, this occurs with the payment of an 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, it may be appropriate to introduce appropriate and defendable competency assurance benchmarks as part of re-registration processes, just as these now apply to initial pharmacist registration.

There are some complicated issues behind what are appropriate quality and competency assurance mechanisms for professionals generally, and how they can be applied practically and equitably. The Review believes that there is some merit in expecting already registered pharmacists to demonstrate their competence from time to time, by way of appropriate and valid assessment mechanisms, and that limited new regulation to support this can be justified in the public interest.

As part of examining the effects of registration restrictions on competition in pharmacy, the Review also believes that the constitution, powers and membership of regulatory authorities needs to be taken into account. It concludes that authorities should be accountable to the community for monitoring professional pharmacists' compliance with standards set by Government, and to deal fairly with breaches of those standards and of discipline.

CHAPTER 1: OVERVIEW

Before addressing the specific regulatory areas of pharmacy ownership, location of pharmacies for Pharmaceutical Benefits Scheme 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 may be acceptable regulation, consideration of these questions also assists in identifying whether the elements of the Public Benefit Test of the Competition Principles Agreement[1] 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 are two principal streams of practice. These are clinical (or hospital) pharmacy, and community pharmacy.

Clinical pharmacy

The first stream is clinical pharmacy, which is the specialised 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.

Clinical pharmacists are often assisted by technician staff who perform a range of administrative and para-professional tasks under a pharmacist's direction. A recent 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 research[2].

Community pharmacy

The second stream is community pharmacy. These are the 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 employ almost 80 per cent of employed pharmacists[3] as well as many non-professional staff.

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

[1] See attachment B to the Review's Terms of Reference, Appendix 2, page 70 of this report..
[2] Australian Institute of Health and Welfare, *Pharmacy Labour Force 1994*, December 1996, page 3.
[3] Ibid.

THE FUNCTIONS OF CONTEMPORARY PHARMACY

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

- Supply prescriptions for medicines, including the minimisation of the risk of adverse consequences for the patient;
- Supervise the proper sale and distribution to the public 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" advice, and the pharmacist derives his or her income from the medicines dispensed 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 and others, photographic services and so on. Indeed, many larger pharmacies have evolved to look very similar to niche and sometimes even general retailers.

OTHER ENVIRONMENTAL FACTORS SHAPING PHARMACY PRACTICE IN AUSTRALIA

Pharmacy in Australia is practised in a highly regulated environment. State, Territory and Commonwealth legislation control virtually every aspect of pharmacy, from who is able to provide pharmacy services, to where they can be provided and, for the vast majority of prescription medicines, the cost at which they can be sold.

The Terms of Reference for the Review have three specific areas of inquiry – ownership, location and registration. However, these areas of regulation 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. These 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.

In relation to Commonwealth regulation, for example, the Review's Terms of Reference include only that part of the regulatory framework relating to the location of pharmacies. Whilst this is very significant, it represents only a portion of the competitive effects that Commonwealth programmes have

in relation to pharmacy. Indeed, the location controls form only one of a number of elements in the Australian Community Pharmacy Agreement between the Commonwealth and the Pharmacy Guild of Australia for the provision of medicines under the Pharmaceutical Benefits Scheme, most of which are beyond the direct scope of the Review's inquiries.

Drugs and Poisons Legislation

Australia has obligations under international conventions to protect the public from the uncontrolled availability of potentially dangerous products, including the potential for the diversion of drugs to the illicit market.

The added complexity and costs associated with these provisions, particularly in relation to accountability, handling, storage and transport, have a significant impact on the practice of pharmacy. These special requirements need to be kept in mind when assessing and considering changes in the pharmacy industry.

Drugs and poisons legislation also provides for the scheduling of drugs, medicines and other dangerous substances to regulate who may store, handle and sell these items. Schedules 2 and 3, with minor variations between jurisdictions, 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, mostly dispensed by pharmacists.

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 make-up 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 in the analysis. The legislation is, however, being examined by a separate National Competition Policy review, due to report in mid 2000.

Pharmaceutical Benefits Scheme (PBS)

The objective of the PBS is to provide timely, reliable and affordable access for the Australian community to necessary and cost effective medicines[4]. A variety of mechanisms are in place to administer the PBS, including the approval of new medicines in the PBS and their cost. Access to medicines under the PBS is provided through the community pharmacy network. A fuller explanation of how the PBS works is included at Appendix 4.

The PBS accounts for 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. Of the $3,112 million total cost of PBS, $773 million was spent on dispensing remuneration to pharmacists[5]. The remainder represented reimbursement for the retail and wholesale costs of the listed medicines supplied.

[4] Commonwealth submission to the Review, para 2.18.
[5] Ibid, paras 2.26 – 2.27.

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

Through the scale of its PBS subsidies, the Commonwealth effectively purchases such a volume of medicines by way of the PBS 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.

It is this leverage, coupled with its ability to approve which pharmacies can supply PBS items, that gives the Commonwealth such influence in the community pharmacy market.

The presence of the PBS, therefore distorts the operation of that market. If the Commonwealth took its PBS bat and ball and went home, most pharmaceutical products would be beyond the financial reach of ordinary Australians, and the community pharmacy industry would be markedly different. But, on the other hand, the Commonwealth cannot ensure the distribution of PBS medicines without the community pharmacy industry. Community pharmacy needs the Commonwealth, and vice versa, which has been the basis of an uneasy relationship since the PBS was introduced in 1948. In recent years, however, this relationship has been codified through the Australian Community Pharmacy Agreement.

The Australian Community Pharmacy Agreement

The Agreement is the embodiment of the understanding 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 methodology for calculating the prices paid to pharmacists to dispense drugs under the Pharmaceutical Benefits Scheme and conditions relating to the approval of new pharmacies and the relocation of existing pharmacies. Details are of current remuneration arrangements are set out at Appendix 4.

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, an objective necessarily is to achieve the best possible remunerative and related outcomes for its members, representing most pharmacist proprietors and over 4,700 pharmacies.

The Agreement itself saves the Commonwealth from having to negotiate individual contracts with each pharmacy business for PBS services. In return the Pharmacy Guild has worked cooperatively with the Commonwealth in areas such as industry restructuring, developing new modes of delivery for pharmacy services, and in ensuring that pharmacy services are available to all Australians.

Relationship of the Agreement to the Terms of Reference

The Terms of Reference for the Review do not include all parts of the Agreement, even though a number of aspects of the Agreement affect issues of direct relevance to this inquiry. This necessarily constrains the Review's ability to comment directly on Agreement matters which may be relevant (such as pharmacist remuneration for PBS dispensing), yet are outside the scope of its Terms of Reference.

In particular, the Agreement's fixed formulae for calculating remuneration paid to pharmacists for the purchase and supply of PBS medicines effectively prohibit or marginalise price competition in the core

area of community pharmacy turnover-generating activity. In return, pharmacists receive direct and indirect relief from additional competition in their catchment areas by the Agreement's imposed restrictions on both new pharmacy PBS licensing and on relocating PBS-approved pharmacies from one site to another.

By eschewing price competition, and basing remuneration to pharmacists on highly restrictive foundations, the PBS and the Agreement both hamper the development of price and service competition in the community pharmacy industry. They are both, however, highly relevant for the ownership question as well as for location because:

- The retail privileges of the PBS are almost entirely exclusive to community pharmacies;
- Without PBS rights a pharmacy business is all but unsustainable and the remuneration per dispensed item helps make many pharmacy businesses highly profitable; and
- It is largely this exclusive PBS market that makes pharmacies attractive as a new opportunity for resourceful non-pharmacist retailers such as supermarkets and department stores, as well as making them highly desirable for pharmacist proprietors themselves.

Relationship between pharmaceutical wholesalers and distributors and retail pharmacy

Over decades a very close, indeed interdependent, relationship has evolved between wholesalers and retailers in the pharmacy industry.

Pharmacies across Australia appear to be 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 timely access to essential medicines.

The major wholesalers depend very heavily on a diffuse community pharmacy network placing constant orders for the products they supply, and work hard to protect their considerable investment and exposed risk by working to nurture strong relationships with individual pharmacy businesses. Activities in which wholesalers interact with community pharmacies 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 formally tied to the wholesaler; and
- Developing positive arrangements with young and growing pharmacy businesses by standing as guarantors for pharmacy business improvement and start-up loans[6].

Clearly, any changes in the make-up and operation of the community pharmacy industry, including changes that may emerge from this Report, would have major implications for pharmacy wholesalers. If, for example, a large non-pharmacist retailer owned pharmacies, or a large-scale pharmacy franchise or other business could use their own distribution network, the operating environment of pharmaceutical wholesalers could change.

[6] A pharmacy broker indicated to the Review that this guarantee arrangement made pharmacy business proposals very attractive to banks as lenders.

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 outweigh the costs; and
(b) the objects of the legislation can only be achieved by restricting competition[7]*.*

With the Guiding Principle in mind the Review needs to ask, about the legislative instruments within its Terms of Reference:

- What are the restrictions on competition that they impose;
- 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.

SCOPE OF DESIRABLE REGULATION

In examining the legislative restrictions on competition, and their costs and benefits to the community as a whole within the scope of its Terms of Reference, there needs to be a preliminary judgment about what should be the scope of regulation in the pharmacy profession and community pharmacy industry. The Review believes that the principal points of justifiable regulation are:

- 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 competently-delivered and efficient pharmacy services.

If these are the starting points, it follows that:

- Persons practising as pharmacists are competent to practise as pharmacists, and that they practise competently.
- Any standards of practice that are laid down need only to be to a level sufficient to sustain safe and competent pharmacy practice;
- Pharmacy services provided by a pharmacy business must be provided in a professional manner and under appropriate professional supervision; and
- Equality of access to pharmacy services may be assisted by regulatory intervention in some circumstances.

To assist it in its analysis, especially given that *Pharmacy and Pharmacists Acts*[8] definitions of pharmacy business, practice and services are so variable, the Review has adopted for this Report a working definition of "pharmacy services" based on current and evolving trends in pharmacy practice.

[7] *Competition Principles Agreement 1995*, Clause 5(1).
[8] Hereinafter cited collectively as *Pharmacy Acts.*

That definition is:

Pharmacy services means 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, 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.

APPROACH OF THE REVIEW

The Review has taken the approach that, consistent with the points of principle identified earlier, its task is to recommend the removal of regulatory provisions marginal or irrelevant to the provision of safe and competent pharmacy services, and to ensure reasonable public access to those services.

In its analysis, the Review is assuming that the principal purpose of State and Territory pharmacy regulation is to ensure safe and competent pharmacy practice. Commonwealth regulation is principally to provide at a sustainable cost, reasonable equality of access to essential pharmacy services.

It further follows that the purpose is not to regulate the commercial operation of pharmacy businesses beyond this point. Nor is it to give pharmacy regulatory authorities – the State and Territory Pharmacy Boards and the Pharmaceutical Council of Western Australia[9] – the perceived discretion to intervene in all aspects of a pharmacy's operations.

The Review's report, particularly in relation to ownership, but also in relation to registration and location, will be looking at any regulation, or interpretation of legislative provisions that appears to restrict the commercial and competitive ability of community pharmacies to operate as businesses. Using this test, if a regulation does not appear to relate to the provision of safe and competent pharmacy services, it should not be in a *Pharmacy Act* and other relevant legislation.

If community pharmacy as an industry, and pharmacy as a profession, are to continue to develop in line with the community's needs for pharmacy services, then it is essential that excess regulation be rolled back.

[9] Hereinafter cited collectively as "Pharmacy Boards".

CHAPTER 2: PHARMACY OWNERSHIP

NATURE OF THE RESTRICTIONS

INTRODUCTION

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

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

The Review sees these measures as part of a broad collective restriction that can be labelled "pharmacy ownership". Their effects on pharmacy businesses tend to overlap and are difficult to assess in isolation. They operate collectively, and need to be analysed collectively.

PHARMACIST-ONLY OWNERSHIP OF PHARMACIES

Under State and Territory *Pharmacy Acts*, the ownership of pharmacies primarily is confined to registered pharmacists.

Other than transitional arrangements for bankrupt businesses and deceased estates, the only exceptions to this general rule are for pharmacies owned and operated by friendly societies, and for 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 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.

The Western Australian *Pharmacy Act* also requires that the proprietor be a resident of that State.

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

NUMBERS OF PHARMACIES OWNED BY A PROPRIETOR

For pharmacist-owned pharmacies, each State has restrictions on the number of pharmacies that can be owned by an individual. The Northern Territory and the Australian Capital Territory do not regulate numbers of pharmacies in this way.

By jurisdiction, the numerical restrictions are:

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

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 pharmacist and external sources of capital, provided that those persons are also pharmacists;
- Bodies corporate, of whom all the directors are pharmacists; and
- Bodies corporate, of whom pharmacists hold the majority of shares, with the balance held as non-voting shares held by specified relatives of the pharmacist.

PECUNIARY INTEREST IN A PHARMACY BUSINESS

Except for South Australia and the Northern Territory, all State and Territory 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* extends this to include a proprietorial interest[10].

These provisions are construed to provide that no non-pharmacist can hold a share in a pharmacy business, nor profit directly from the transactions of that business. Several Acts also provide that bills of sale, mortgages or securities on a pharmacy business must not carry specific conditions. Conditions prohibited expressly by legislation include allowing the supply 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.

REGISTRATION OF PHARMACY BUSINESSES AND PREMISES

Most jurisdictions provide that pharmacy businesses and premises must be registered with their Pharmacy Boards. Registration of businesses means furnishing details to Boards about matters relating to ownership structures, the persons involved, and the address or addresses of the pharmacy business.

Registration of premises relates to Pharmacy Boards' approvals of pharmacy sites, and of their fitting out as pharmacies. 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.

[10] *Pharmacists Act 1974* (Vic), section 21(1).

OBJECTIVES OF THE RESTRICTIONS

In most jurisdictions the 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 supervision of their professional operation by the proprietor pharmacists;
- Protecting small independent pharmacy businesses from perceived "unfair competition" and market dominance from large pharmacy-owning corporations and chains;
- Making the proprietor of a business professionally accountable to Pharmacy Boards, 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.

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.

While pharmacy businesses sell a diverse range of general products and services, such as photographic and cosmetic products, in competition with other retailers, they have exclusive access to particular medicinal products and services. Most particularly, pharmacies have a near monopoly over the supply of prescription drugs and medicines, whether or not subsidised by the PBS, and some other scheduled medicines.

The total turnover of the community pharmacy industry is about $6,000 million a year[11]. Of this, about three-quarters is derived from the sale of prescription and of scheduled "pharmacist only" and "pharmacy only" over-the-counter medicines, such as cold and flu tablets[12]. In short, the sale of products with a retail value of around $4,500 million a year is reserved for pharmacies.

The range of provisions that, collectively, comprise a set of restrictions on ownership, are central to community pharmacy being a multi-proprietor industry, based on small and localised businesses. Even the permissible ownership structures best lend themselves to small-scale commercial operations.

Some would say that this is in keeping with pharmacy's perception of itself as a "cottage industry" providing convenient shopfront services to consumers. Others would say that this frustrates realising genuine economies of scale and scope in pharmacy, which could then be passed on to the consumer in terms of lower prices for pharmacy goods and services, including lower PBS outlays for taxpayers.

[11] Productivity Commission submission to the Review, page 8.
[12] Review consultations with the Pharmacy Guild of Australia and the Pharmaceutical Society of Australia, 7 September 1999 .

An overall effect of provisions such as pecuniary interest restrictions and the registration of pharmacies is that State and Territory Pharmacy Boards have a considerable indirect say in the management of pharmacy businesses. In some jurisdictions, the ambit of the Board 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 services[13].

The Review notes that the scheduling of medicines is being examined by a 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.

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 a net public benefit.

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.

COSTS OF THE RESTRICTIONS

There are costs to the restrictions, but they are not easy to quantify. They relate to the efficiency and performance of the community pharmacy industry in general, and of individual pharmacy businesses in particular.

The identifiable costs of the restrictions include:

- Putting barriers in the way of greater efficiencies in the community pharmacy industry, and in individual pharmacy businesses;
- Not allowing fully effective 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

Community pharmacies are small to medium businesses. A 1997 industry survey suggested that pharmacies then had an average of 3.8 full-time and 4.8 part-time staff, and average turnover per pharmacy of $1.2 million [14]. Under State *Pharmacy Acts*, no private pharmacy proprietor legitimately can have a direct interest in no more than four pharmacies.

The basic restrictions on who can be a pharmacy proprietor keep non-pharmacist entrepreneurs, managers and businesses out of the community pharmacy market. A large non-pharmacist retailer, such as a supermarket or a department store would have economies of scope and scale sufficient to lower unit costs for pharmacy services and items. This compares to the infrastructure of small pharmacy businesses, where overheads such as rent, utilities and salaries are likely to form a higher proportion of the pharmacy's overall running costs against their turnover.

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

[14] Pharmacy Guild of Australia, *1998 Guild Digest*, Tables 17 and 2.

The restriction on numbers of pharmacies necessarily constrains pharmacy businesses to a continuing cottage industry status. There is little incentive for efficient proprietors to develop and grow their businesses when an arbitrary ceiling is imposed on their holdings, and thereby their ability to extend their market share and penetration.

Conversely, there is little incentive in the ownership rules for inefficient proprietors to make way for others. As the 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"[15].

Not allowing fully effective competition

Another cost of maintaining the present restrictions is that pharmacist-owned pharmacies are relatively homogenous in their establishment, and their styles of operation which reduces consumer choice. Pharmacists with broadly similar training, career experiences and professional outlooks run them. Arguably, the majority of proprietors are pharmacists first, and businesspeople second – although it must be said that some are very astute businesspeople indeed.

In community pharmacy, competition based on service is not seen as desirable by some proprietors, and competition based on price is definitely not seen as desirable by the profession as a whole. Where not laid down by PBS mechanisms, a pharmacy's price setting tends to be in relation to what a pharmacist's local rivals may be charging for a non-PBS item. By contrast, a multi-outlet retailer would be able to set their prices with reference to regional and even national markets.

Service competition, while seen as thriving and desirable by industry and professional groups[16], appears to not be as healthy in practice. If consumer evidence to the Review is a reliable guide to the reality of the pharmacy market place, the quality of service that customers receive from their pharmacy is variable, depending primarily on which pharmacy they walk into, and whether they ask for assistance[17].

The entry into the industry of larger non-pharmacist retailers could go some way to stimulating both price and service competition in the industry. On the price side, their ability to realise greater returns to scale, to maintain stock and set prices across their own network of points of sale, and to promote their services potentially would lower costs per dollar of pharmacy sales.

On the service side, the lack of a more heterogenous pharmacy market might be in part overcome by allowing new entrants with new modes of provision. These new entrants would have to establish and keep market share against professionally-based competitors backed by extensive experience in the industry. To establish their credentials with consumers, and to perform competitively against seasoned rivals, these new entrants 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.

[15] 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

[16] Pharmacy Guild/Pharmaceutical Society consultation with the Review, 20 August 1999.

[17] See, for example, the Consumers' Health Forum submission to the Review, page 9.

Restricting sources of innovation

At the present time, retail pharmacy is a relatively closed industry, and pharmacist proprietors a relatively closed group[18]. Indeed, statistics suggest that pharmacist proprietors tend to be older, predominantly male, and many are no longer in active practice.

There is also a long tradition of interdependence between retail pharmacy and pharmaceutical wholesalers, as evidenced by the three major wholesalers' heavy involvement in sponsoring banner group and franchise arrangements, advancing loan guarantees to pharmacist proprietors, and sometimes in assisting community pharmacists when their businesses are in financial trouble. This intimate interdependence between community pharmacists and wholesalers is highly central to the way that the community pharmacy industry is presently distributed and constituted[19].

An incidental effect of deregulating participation in the community pharmacy industry would be the widening of potential sources of industry capitalisation, which would diversify potential influences on industry shape and direction.

The situation is an opportunity cost of the restriction of ownership to pharmacists. The narrow interpretation of existing pecuniary interest provisions in *Pharmacy Acts* also could discourage new and innovative associations between pharmacies, other businesses and "non-traditional" sources of capital. If these restrictions were removed, there would not only be progression toward greater economies of scale and scope, but just as importantly an inflow of capital investment and outside ideas into an industry that has traditionally been insular and self-contained[20].

The synergies that would emerge could result in more exciting competition and potentially innovative practice but, more importantly, service and price dividends for consumers.

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 mode of delivery of those services – mostly small to medium sized shopfront pharmacies in high streets and shopping centres, trading in isolation from other businesses (however physically proximate these may be), and many trading for standard opening hours only.

If ownership arrangements were made more open, consumers may well see not only cost savings and more competitive service from all pharmacies. They may also see real convenience gains from such opportunities as doing shopping on the same site, and having access to pharmacy services on up to 24 hours a day. Similarly, if a pharmacy is linked to a department or chain store, or even a small to medium general business, consumers may benefit by the range of shopping and convenience choices available to them, especially if these are reinforced by lower prices for at least some products and services.

[18] Australian Institute of Health and Welfare, *Pharmacy Labour Force 1994*, December 1996, Table 10.
[19] Sigma Pty Ltd's submission to the Review sets out the working nature of this interdependent relationship.
[20] This is recognised even by key supporters of pharmacy ownership restrictions: see the Commonwealth's submission to the Review, para 131.

BENEFITS OF THE RESTRICTIONS

Against costs such as these, the overall restrictions on pharmacy ownership may 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 by simplifying the points of interface between Government, the community pharmacy industry, and funding programmes such as the PBS;
- 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.

Promoting access to pharmacy services

As the two government submissions to the Review suggested[21], 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.

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.

Additionally, community pharmacy is the principal delivery vehicle for the Pharmaceutical Benefits Scheme. Arguably, the PBS distribution system is currently founded on the twin assumptions of a national dispensing network of local community pharmacies, serviced by pharmaceutical wholesalers geared to supply those small pharmacy businesses. New ownership arrangements would invariably mean a reconsideration of how the PBS's near monopsony of prescription medicines would be administered by Government, and how remuneration arrangements for PBS pharmacies may be negotiated and set. This is not to say that such an adjustment is not possible, but rather that with a more diffuse proprietorship and distribution of outlets, the task of reaching a workable set of outcomes would be more difficult for Government to achieve in taxpayers' best interests.

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 development[22]. These areas may be commercially unattractive to large retailers such as supermarkets and large department stores, which could be expected to concentrate their services in a given regional centre, and consequently make it harder for smaller business in less viable outlying localities to compete with them. If so, those smaller businesses may close, to the detriment of local communities' access to services, and with flow-on effects such as job losses.

[21] The Commonwealth Government and the Government of Western Australia.

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

More effective use of scarce community resources

A benefit of present ownership arrangements is that the stable Australia-wide network of pharmacist-owned pharmacies helps Governments keep a lid on the overall costs of health care, by assisting Government better to manage a large demand-driven PBS outlay and by making, in individual cases, low-level interventions in clients' health treatment that may remove the need for more complex and expensive treatment .

It follows that, 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 unmade outlays. Pharmacist ownership, while not directly responsible for such interventions, helps to facilitate a culture in community pharmacy that promotes and encourages staff commitments to professional care.

In their joint submission, the Pharmacy Guild and the Pharmaceutical Society commissioned KPMG Pty Ltd to undertake a cost-benefit analysis of the current pharmacist-owned pharmacy network[23]. The Review considered this analysis[24], having evaluated the broader analysis of the 1985 Bureau of Industry Economics study of community pharmacy[25]. Against this, the Review's separate commissioned analysis concluded that the KPMG analysis suggests that the actual quantifiable benefits of pharmacist ownership are much more moderate than the KPMG analysis suggests[26], but did not dismiss the KPMG conclusion of a quantitative net public benefit.

The other relevant area of cost control is the management of Pharmaceutical Benefits Scheme outlays by means of the Commonwealth-industry partnership embodied in the Australian Community Pharmacy Agreement.

In its submission, the Commonwealth 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 whole[27].

The Review understands that as a result of cooperation between the Commonwealth and the Pharmacy Guild (representing independent pharmacy owners), the two Agreements have realised new savings to Government of around $200 million[28]. The Commonwealth sees the Agreement, which assumes a pharmacy distribution network predicated on mostly pharmacist-owned pharmacies, as dependent on current ownership arrangements for its efficacy.

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[23] Using Australian and relevant overseas data, including the costs of pharmaceutical-related hospital admissions, savings arising from pharmacist 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.

[24] Reported in the Pharmacy Guild/Pharmaceutical Society submission to the review, Volume 3, pages 55-64.
[25] Bureau of Industry Economics, *Retail Pharmacy in Australia – An Economic Appraisal*, Canberra 1985.
[26] Applied Economics, *Qualitative Evaluation of Public Benefit from Pharmacy Legislation*, October 1999, pp 14-15.
[27] Commonwealth submission, para 3.25.
[28] Ibid, para 1.31.

Better linking pharmacy to overall health care provision

As health care trends and clinical practice continues 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, delivering public health programmes, such as methadone dispensing and needle exchange, and screening and care management programmes for acute and chronic conditions.

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

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. 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.[29]

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, 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. To encourage pharmacists to move to small rural localities, it may be that proprietorship – perhaps coupled with other measures - is a better incentive than simply offering them an attractive salary[30].

Placing professional considerations first

A benefit of restricting ownership of pharmacies to pharmacists is that a pharmacist proprietor is arguably more likely to place professional judgments before commercial considerations, or "people before profit". This assumes that a pharmacist is prepared *not* to sell a medicine to a consumer, if there is a professional judgment that the sale would be unwise or unnecessary.

Being accountable directly to Pharmacy Boards for the professional direction of their pharmacy practice, these owners have an obligation as both proprietors and professionals to ensure that the provision of pharmacy services under their control is safe and competent. Even if they are not active in the day-to-day affairs of the pharmacy, their status as members of the pharmacy profession has given them a sense of tradition and ethics which helps them 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 is affected by information asymmetry between the parties.

[29] Commonwealth submission, paragraph 3.34.

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

A proprietor's sense of practitioner responsibility and direct personal accountability therefore can translate into benefits to the community as a whole. If a practice is run on professional lines, with professional considerations to the fore, the focus of its management and staff can be on providing pharmacy services and advice of the best possible quality.

Simplifying lines of accountability for professional services

The ownership restrictions simplify lines of professional accountability in pharmacies. A professional proprietor can be liable professionally for not only his own conduct, but also for that of staff pharmacists and non-qualified staff working under professional direction.

A non-pharmacist corporation arguably would not be so easy to deal with in terms of maintaining relatively simple administrative, investigative and review processes managed by Pharmacy Boards with limited resources. The corporation's directors are likely to be non-pharmacists, and unless it was a chemist shop chain, pharmacy would probably not be its principal line of business.

This is not to say that non-pharmacist corporations would not be responsible for professional actions taken under their control[31]. Indeed, the existing examples of friendly societies and grandparented proprietors suggest that, on a moderate scale, there are precedents. 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 Pharmacy Boards, as part-time and self-funding bodies, would need to have the resources to deal effectively with new non-pharmacist proprietors and related accountability arrangements. They may also need to amend legislation, and to provide Boards with additional resources, to cover the additional costs of administering both these arrangements and those that may arise from defending Board decisions in administrative and judicial review processes.

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;
- 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 interferences in the professional practice of a pharmacist.

[31] Indeed, friendly society pharmacies are already accountable to Pharmacy Boards through their own boards of management. In its consultations with Pharmacy Boards, the Review found general Board 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.

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 breach 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).[32]

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 putting 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 of the major non-pharmacist retailers 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 in persuading the consumer of their commitment to providing quality pharmacy services.

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 benchmarkable standards against which the performance of pharmacies can be measured, and accreditation withdrawn if they fail to comply. This programme is interesting to note 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.

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

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 law[33]. If pharmacists' control of pharmacy business 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 a controlling interest in that business.

Such a model is operating in at least one overseas jurisdiction. If adopted in Australia, such ownership structures may achieve the purpose 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, while being consistent with the principle of pharmacist control of pharmacy-owning bodies corporate.

REPLACE PECUNIARY INTEREST WITH PENALTIES FOR PROFESSIONAL INTERFERENCE

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. 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 Pharmacy Boards[34].

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.

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.

Such an offence could be referred to the appropriate court by a Pharmacy Board or Health Complaints Commissioner as a complainant, after their investigating the facts of a matter reported to them by a pharmacist.

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 BY PHARMACISTS

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

[33] See *Pharmacy Act* (SA), section 18.

[34] See, for example, the 1998 NSW District and Court of Appeal litigation, *Terry White and Ors* v *Pharmacy Board of NSW.*

The Review believes that there is a net public benefit in leaving the ownership of pharmacies in the hands of registered pharmacists.

This conclusion is based on several points drawn from the cost-benefit analysis:

- A pharmacist who owns a pharmacy has a professional as well as a pecuniary interest in the safe and competent provision of pharmacy services by his or her pharmacy business;
- A pharmacist proprietor is accountable directly to a Pharmacy Board for the safe and competent provision of those services, while non-pharmacist proprietors would not be able to be made accountable without a major and costly readjustment of the regulatory infrastructure;
- There is a net public policy benefit in promoting pharmacist ownership in the community pharmacy industry to maximise the distribution of pharmacies into the wider Australian community, to promote through them 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 vehicle for distributing subsidised essential pharmaceutical medicines to all Australians, is predicated on this distribution network, and changes to that network may mean the costlier and less effective delivery of PBS medicines to people in need of them; and
- There is a 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 reinforces this professional role and culture.

In making this specific conclusion, the Review is aware that the terms of the National Competition Policy require jurisdictions to revisit decisions to retain regulation within ten years.

Recommendation 1

The Review recommends that legislative restrictions confining the ownership of pharmacies, with existing limited exceptions, to registered pharmacists and bodies corporate controlled by pharmacists, be retained.

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.

Recommendation 2

The Review recommends that any jurisdiction's residential requirements for pharmacy ownership be removed.

Friendly society and grandparented corporate pharmacies

The Review believes that the small percentage of permissible non-pharmacist owned pharmacies, those owned and operated by friendly societies[35] and grandparented corporations[36], should continue to be permitted to operate. Although the presence is greater in some jurisdictions than others, both types

[35] For the purposes of this discussion, a friendly society is defined as a society which provides specific benefits for its members on a mutual provident basis, in return for a membership fee.

[36] That is, those pharmacies owned by a non-pharmacist body corporate or individual before present legislative restrictions on ownership became effective in a given jurisdiction.

of pharmacies help to stimulate competition in the industry as a whole in terms of both price and service, and in terms of fostering commitments to best practice, quality and accountability from which all pharmacy consumers can benefit.

The treatment of these pharmacies, and friendly society pharmacies in particular, varies from jurisdiction to jurisdiction. In some jurisdictions, for instance, the presence of friendly societies is grandparented, and/or subject to special procedures in relation to their establishing new pharmacies. If the Review's recommendations about removing registration requirements for pharmacy premises and businesses are adopted, any such specific requirements for a particular class of pharmacies should also be removed.

The Review also believes that restrictions on the number pharmacies per friendly society in a given jurisdiction, as well as overall numbers of friendly society pharmacies in a jurisdiction, should also be lifted. Friendly societies should be able to apply on an even basis for such new PBS dispensing approvals that are given. While lifting such restrictions may give rise to fears of market dominance or large friendly society pharmacy chains, there are mechanisms outside *Pharmacy Acts*, notably the Australian Consumer and Competition Commission under Part IV of the Commonwealth *Trade Practices Act 1974*, that are capable of monitoring and addressing such concerns if necessary.

The present inconsistent ownership and related treatment of friendly society pharmacies across jurisdictions causes uncertainty and confusion for those societies, and indeed for privately owned pharmacies competing with them. It would be desirable, as part of implementing recommendations arising from this Report, for jurisdictions to consider making the treatment of friendly society pharmacies as nationally consistent as possible.

There is a further competitive issue concerning that part of friendly society pharmacies' income to which the mutuality principle applies.

It appears to the Review that the taxation treatment of mutual income gives friendly society pharmacies competitive advantages vis a vis privately-owned pharmacy businesses. Although mutuality as a structure and principle is best considered in current reviews of the Australian taxation system it is desirable, as a precursor of liberalising regulation in relation to friendly society pharmacies, to have the Australian Consumer and Competition Commission examine the operation of mutuality in the community pharmacy industry.

Recommendation 3

The Review recommends that:

(a) Friendly society and grandparented corporate pharmacies be permitted to continue to operate;
(b) The application of mutuality in the pharmacy sector be reviewed by the Australian Consumer and Competition Commission (ACCC);
(c) Depending on the outcome of any ACCC review, restrictions on the number of friendly society pharmacies, and the number of pharmacies held by a friendly society, in a given jurisdiction be lifted; and
(d) Provisions relating to friendly society and grandparented non-pharmacist owned pharmacies be made consistent across jurisdictions.

There will be further consideration of related issues in the Review's Final Report.

Other possible options

Chapter 3 on pharmacy location notes that regulatory practice in that areas has not kept up with developments in a wider range of health and community-based care trends in recent years. It concludes that private hospitals and aged and community care facilities particularly should be allowed greater discretion to plan and manage the dispensary services they need for these patients and clients, and that current PBS location rules frustrating this should at minimum be removed.

If such restrictions are relaxed, this may have some implications for how these clinical pharmacy services are operated and managed, ranging from contracting in pharmacists to provide the services, contracting out to community pharmacies or private specialist pharmacy services that serve a number of different facilities similar to the way wholesalers serve community pharmacies, or the direct integration of a dispensary service into a private hospital or aged care facility.

These questions may need to be considered by jurisdictions, depending on developments in PBS-linked provision arrangements for such health care facilities. Liberalisation of the PBS location controls for private hospital and aged care could create contestable opportunities for a range of pharmacy providers, and particularly competition for community pharmacists who may provide the greater part of the pharmacy services to small and medium-sized private hospitals under present arrangements.

It has also been suggested that Aboriginal Medical Services, which provide direct health care to Aboriginal and Torres Strait Islander communities, should also be allowed to own or operate in-house dispensary services. While the Review can see a genuine need for pharmacy services within these specialised facilities, this suggestion does raise a number of complex policy and funding questions for the Commonwealth, States and Territories, and for Aboriginal Medical Services themselves. At this time, it is more desirable for those parties to explore these issues further.

NUMBERS OF PHARMACIES

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

The Review believes that the current numbers in force in each State are haphazard and obviously inconsistent with each other, and for no apparent reason. Moreover, they are based on judgments that date back, on the whole, many decades. Indeed, they are reminiscent of the pharmacy practice of a bygone age, even a bygone century.

The numerical restrictions certainly frustrate the expansion of more efficient pharmacy businesses, and protect from undue competition those less efficient pharmacies and their proprietors from their more efficient colleagues. This may suit some proprietors, especially those running less efficient pharmacies, but it is arguably not in the interests of the community as a whole.

Removing the restrictions may appear to run contrary to the principle of pharmacist ownership supporting a localised and highly professional pharmacy service. This, however, may not need to 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 contracted in 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 number of pharmacies off-site without compromising the tenet of a proprietor's personal supervision of their operation.

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

Finally, anecdotal evidence and comments by several Pharmacy Boards to the Review suggest that the current numerical restrictions are easy for a determined pharmacist to breach, using various arrangements to mask the true size of their pharmacy holdings. It was also suggested that it is very difficult to prove a breach. If the rules can be so easily bent or broken, and non-compliance is so hard for authorities to deal with, their justification can be questioned.

On balance, the Review believes that it is no longer practical or appropriate to specify an alternative number of pharmacies in pharmacy legislation. This leads to the on-balance conclusion that there is not a net public benefit for the retention of the existing restrictions. If they are relaxed, however, developments should be monitored by jurisdictions, and the Australian Competition and Consumer Commission, to ensure that there is no undue market dominance or convergence in respect of pharmacy proprietors taking advantage of the change.

If they are to be lifted the restrictions in each jurisdiction should be, in the interests of consistency and market fairness, lifted simultaneously across jurisdictions.

Recommendation 4

The Review recommends that:

(a) Jurisdictions' restrictions on the number of pharmacies owned by a proprietor be lifted on a date consistent across jurisdictions; but

(b) The behaviour of the pharmacy market after the lifting the restrictions be monitored by jurisdictions and by the Australian Competition and Consumer Commission in accordance with Part IV of the *Trade Practices Act 1974*.

OWNERSHIP STRUCTURES

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

It does note that these structures are not permitted equally in 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. Perhaps the Council of Australian Governments might refer the matter to the Australian Health Ministers Council for consideration at first instance.

The Review also believes that a workable model of non-pharmacist minority shareholdings, provided that overall pharmacist control of the pharmacy business is maintained, is consistent with the principle of pharmacist control of pharmacy businesses, and should be considered in the interests of a more competitive industry environment. This requires, however, more exploration.

A further consideration of different ownership structures consistent with the pharmacist control principle, including minority shareholding models (with or without voting rights for those shareholders), and any possible exclusions from eligibility to be a minority shareholder, therefore will be included in the Review's Final Report.

Recommendation 5

The Review recommends that:

(a) The pharmacy ownership structures permitted by various State and Territory Acts be retained as consistent with the principle of pharmacist ownership and control;
(b) In the interests of national consistency and commercial certainty, the range of current permitted structures be adopted consistently by each jurisdiction; and
(c) New ownership structures consistent with the general principle of pharmacist control of pharmacies should be permitted.

PECUNIARY INTERESTS IN A PHARMACY BUSINESS

While not opposing the general principle of pharmacist ownership as desirable to the maintenance of a safe, competent and professional community pharmacy industry, the Review is concerned that pharmacy businesses controlled by pharmacists are affected by more red tape than many other businesses of the same size.

In particular, current pecuniary interest provisions are heavy-handed statutory mechanisms to achieve an aim that could be realised with much greater subtlety.

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

It is highly inappropriate for these provisions to be able to be used by regulatory authorities to mandate how a proprietor runs his or her business, so long as the proprietor is and remains responsible and accountable for the professional services delivered under their direction. It should be acceptable, for instance, for a proprietor to enter into a franchise agreement involving profit or turnover-sharing, a preferred-supplier arrangement with a pharmaceutical wholesaler, or a joint venture with a non-pharmacist company or entrepreneur, 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. A working definition of pharmacy services, similar to that adopted for this Report in Chapter 1, may assist regulatory authorities and courts in this regard. In most cases however, such as a cosmetics concession, or a banking or lottery agency, the matter is clear-cut.

On balance, the Review therefore believes that pecuniary and proprietary interest provisions should be removed from *Pharmacy Acts*, and replaced with a statutory offence of exercising improper or inappropriate influence over the professional conduct of a pharmacist, as outlined on page 20.

Recommendation 6

The Review recommends that:

(a) Provisions relating to parties other than the proprietor having a pecuniary interest in pharmacies, the terms of bills of sale for pharmacy businesses, or otherwise preventing pharmacy proprietors from developing lawful business associations with other parties be removed; and

(b) These provisions be replaced with a statutory offence of improper and inappropriate interference with the professional conduct of a pharmacist in the course of his or her practice.

REGISTRATION OF PHARMACY BUSINESSES AND PHARMACY PREMISES

The public benefit case for registering pharmacy businesses and premises is unclear.

On one hand, it may be desirable for pharmacies to conform to safety-driven siting, fitness for purpose and fitting-out standards. On the other, it could be argued that an efficient business is a safe business, and that unduly regulating these aspects of their operation is regulatory "overkill", given that pharmacist owners can face disciplinary action as responsible professionals if they fail to comply with such standards.

Regardless of their safety aspects, these rules are anti-competitive in their operation. They can be applied to prevent new and innovative pharmacy delivery ideas, such as collocating a pharmacist-owned business within the premises of a non-pharmacist retailer. It also believes that poor practice in this area can be addressed and rectified by Pharmacy Boards either on the basis of a public complaint, or as part of the process of re-registering a pharmacist – in other words, focusing on outcomes-based standards.

On balance, the prescriptive registration of pharmacy premises should be removed. Governments can set advisory guidelines, with Pharmacy Boards monitoring compliance, in relation to the physical siting and fitting-out of premises. As part of that compliance role, Boards may have the power to enter those premises to investigate complaints relating to the quality of the premises and their fittings.

On the question of registering pharmacy businesses, the Review believes that pharmacy business registration should be removed, as pharmacist registration arrangements deliver a similar outcome. Details of a pharmacist's pharmacy interests could, for instance, be recorded as part of his or her register entry, and if State and Territory registration databases are consistent in their content, information exchanged between jurisdictions should perform the same function as business registration, and that this would be a more efficient way of achieving similar results.

Any such information requirements for this purpose, 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. Commercial details such as sources of loans, mortgagors, and guarantors should not be required. They are a matter for the pharmacist, not Pharmacy Boards.

Recommendation 7

The Review recommends that:

(a) Regulations requiring the registration of pharmacy premises be removed; and
(b) Regulations requiring the registration of pharmacy businesses be removed.

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.

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 right for pharmacists. It is a privilege, conferred by the community in return for a high and consistent quality of pharmacy services at a reasonable cost.

Pharmacy proprietors need to work hard to maintain any privilege. Current experience suggest 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 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 protections 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 medicines[37].

Pharmacies and their pharmacist proprietors need to heed messages such as this. Besides their basic dispensing service, they need to live consistently 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 will quickly disappear.

These observations also can be translated to a policy response. Just as it is in the public interest for governments to intervene so that the community pharmacy network reaches all Australians fairly, it is equally in the public interest for governments to intervene to ensure that community pharmacies provide, at an enforceable high standard, the range of health services for which there is a demonstrable need in the community. This may not only include programmes like the Pharmaceutical Benefits Scheme. It could include public health and other programmes, such as methadone supply and access to needles and syringes for people with drug dependency problems.

[37] Consumers' Health Forum submission to the Review, page 2.

Recommendation 8

The Review recommends that Commonwealth, State and Territory governments ensure that legislation and agreements, including the Australian Community Pharmacy Agreement, 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.

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 location 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. Set out in the negative, these criteria include that a catchment area for the proposed pharmacy must *not* have:

- Less than 3,000 permanent residents;
- A proportion of aged persons and persons who are unemployed or receive pensions that is less than 10 per cent of the area's population and who can be serviced reasonably by other means;
- The equivalent of less than a full-time medical practitioner;
- Adequate services by other approved pharmacists;
- PBS and Repatriation Pharmaceutical Benefits Scheme prescription volumes of less than 3,000 in the last 12 months;
- Isolation from, or a poor public transport system to, general shopping does not hinder the bulk of the population;
- A mobile population with a high proportion of commuting workers;
- No general shopping facilities[38].

RELOCATION OF PHARMACIES

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

- 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;
- 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 beds[39].

Applications for both new pharmacy approvals and pharmacy relocations are considered by the Australian Community Pharmacy Authority (ACPA), which then makes recommendations to the

[38] Determination under Sub-section 99L (1) of the *National Health Act 1953*, PB13 of 1998, Clause 2.
[39] Ibid, Clauses 6-9A.

Secretary of the Department of Health and Aged Care. The Determination is the basis of its decision-making processes. The ACPA is established under section 99J of the *National Health Act*, but also owes its existence to the terms of the Agreement.

OBJECTIVES OF THE RESTRICTIONS

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

Their immediate objective was to provide a mechanism to enable the Commonwealth to contain the growth rate of PBS dispensing costs that reached unsustainably high levels by the late 1980s, in return for community pharmacies being assured of a reasonable remunerative framework for their 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, while it did not offer such assistance as part of its package, did maintain the assumption about an inherent national oversupply of pharmacies. The overall assumption about the importance of cost control in return for remunerative and other benefits for community pharmacy has been a feature of both Agreements.

EFFECTS OF THE RESTRICTIONS

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

- Keeping the approval of new pharmacies to a minimum in a national community pharmacy industry that has 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 applications[40].

Relocation approvals have been more forthcoming. Under the second Agreement, 940 of 1,128 applications have been approved to date[41].

But behind these figures is the fact that the applications have to be considered and recommended to the Secretary of the Department of Health and Aged Care by the ACPA. The Authority's decisions effectively determine the siting of new and relocated distribution points for PBS items. The Determination provisions thus are integral to deciding which pharmacies and proprietors have access to the PBS and its sales and fees by specifying where they may establish.

[40] Commonwealth submission to the Review, paras 4.22 – 4.24.
[41] ibid, para 4.35.

While being instituted and primarily intended by the Agreement parties as cost containment and remuneration-linked measures, the Determination's location restrictions therefore have also become instrumental to the shape and geographic distribution of the Australian community pharmacy network.

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 itself[42]. Because 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 is a more effective alternative to them.

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 competition;
- Providing a disincentive to undertake greater restructuring in the community pharmacy industry;
- Maintaining restrictions after the original need has passed and not recognising current health trends;
- Undue government intrusion in the community pharmacy market;
- Unintended consequences of the application of the rules; and
- Creating pharmacy access and retention difficulties for communities in areas of need, and particularly 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 in a locality from new competitors whom otherwise may establish themselves freely. Indeed, some of those potential competitors might have been be more efficient or better resourced than the existing pharmacy, and would have the ability to make big inroads into the existing pharmacy's market share. Alternately, the local competition may have been more vigorous and lively, and the quality of service to consumers enhanced, because of rivalry between evenly-matched pharmacies.

Such circumstances are not consistent with promoting the public benefits of wise medicine use based on quality pharmacy services. It is arguably in the community's interest to stimulate competition by promoting efficient pharmacies, rather than to allow inefficient pharmacies to be protected from fresh competition.

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

Avoiding the need for further industry restructuring

Keeping the location restrictions in place not only protects inefficient pharmacies. It also lessens the urgency for continuing the processes of community pharmacy industry restructuring started in the early 1990s.

While suggesting that the controls have led to a general significant improvement in the efficiency of the community pharmacy industry, supporting statistics for 1997-98 quoted in the Commonwealth's submission suggest that there is still some way to go to a truly efficient community pharmacy industry[43]:

- There are still 13 per cent of pharmacies with dispensing volumes below 10,000 prescriptions;
- There are still 32 per cent of pharmacies with dispensing volumes of between 10,000 and 20,000 prescriptions;
- There are 27 per cent of pharmacies with dispensing volumes of between 20,000 and 30,000 prescriptions; and
- Only 28 per cent of pharmacies have 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 be perpetuating inefficiencies by making it less attractive 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, and the business is there, there is no great incentive for 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 desirability of their ongoing presence may outweigh pure efficiency considerations. It also notes, and makes some suggestions later in this chapter that there are other, perhaps more effective ways, of achieving access-related policy objectives in these areas.

The need for the restrictions has passed

Another point that questions the efficacy of the location restrictions is that the overall numbers of pharmacies have remained relatively static since about 1993.

Before the commencement of the first Australian Community Pharmacy 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) it has hovered around this lower figure ever since.

The inference drawn from this stability is that the initial need for the imposition of tight controls on pharmacy location may well have passed. Even the control on relocations could be said to be fine-tuning of earlier outcomes, rather than a continuing of the restructuring process. This may benefit current proprietors, who benefit from a stable environment but also from the sale values of pharmacies rising steadily as demand to purchase businesses outstrips 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, often with high mark ups in the case of non-PBS items. Given this, it begs the question as to whether the restrictions need to remain and, if so, to what extent.

[43] Commonwealth submission to the Review, para 2.43.

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

The PBS location restrictions have been operating, with some modification, since 1990. Since them, 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. Generally, the thrust of Commonwealth and State policy has been encouraging choice between public and private care. Additionally, aged care facilities, both residential and community-based, have become more sophisticated and self-contained.

The exemptions from the distance criteria for these facilities is 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.

By effectively standing still at the beginning of the decade, the current Determination restrictions arguably have not served the community well. They reflect the pharmacy and health care outlook of 1990, rather than looking ahead to needs of the decade ahead. Resistance to changing the Determination criteria, based to some extent on professional self-interest, may therefore be working against positive change and reform that keeps the management of dispensing costs, and the shape of the industry itself, abreast of current and likely future trends.

Indeed, there is a case for arguing that private hospital dispensaries and more specialised aged care facilities are specialist health care facilities, and that these should have the discretion to put in place, and receive PBS dispensing approval, for in-house pharmacies on a case by case basis. If this is so, they could be treated as being beyond the scope of the Australian Community Pharmacy Agreement altogether.

Medical centres are more problematic. Simply because a medical centre or a group medical practice is established is in itself not a justification of a need for a new pharmacy. It may benefit that practice, but not necessarily benefit the community as a whole. There is a case, however, for taking into account projections of the demand for pharmacy services arising from the medical centre or group practice, so as to consider relocation of a pharmacy to a centre without reference to distance-based criteria, or indeed to provide for medical centres in new PBS approval criteria.

In Chapter 2, comment was made about the need to consider the position of Aboriginal Medical Services in relation to community pharmacy services. The point made in that chapter, that further discussion is needed between governments and Aboriginal Medical Services themselves to explore related issues, is also relevant to these suggestions.

Micromanagement of 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 pharmacy business.

Given that the Commonwealth, or the Australian Community Pharmacy Authority, may have little direct knowledge of local pharmacy markets, this degree of market management by government may not be appropriate in an economy demanding less rather than more public intervention in commercial markets.

Unintended consequences of rigidly defined and applied restrictions

The new approvals and relocation criteria in the Determination are intricate and precise.

It appears that disputes about whether a distance from the nearest pharmacy is less or more than one or two kilometres is the biggest source of angst about the rules. Several submissions to the Review highlighted some absurd situations caused by the strict application of the "shortest lawful route" criterion[44].

The Australian Community Pharmacy 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 it is given. But because of the commercial importance of the process to applicants, and to pharmacies objecting to applications, the ACPA process can be costly as a consultancy industry has sprung up around it to facilitate progress. It can also be prone to administrative and judicial review, as dissatisfied parties take their complaints to the Administrative Appeals Tribunal or the Federal Court[45].

Of course, affected pharmacists can eventually recover the high costs applying to the Authority and associated review and appeal costs from their customers in marking up goods and services which, unlike PBS medicines, are not price-controlled.

Lack of relevance to the needs of underserviced communities

A final point that calls the rules into question is the extent to which they serve the community's best interests, and particularly of those 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.

Against this background, 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"[46].

The paucity of new pharmacy approvals, even if the major proportion of those successful approvals have gone to rural and remote areas, suggests that it very difficult for a community to fulfil the definite community need criteria. Arguably, most of the criteria, such as the permanent population and full-time general practitioner provisions, make it very hard for a great many rural towns and even regions to demonstrate that they have a definite community need for pharmacy services.

Even the 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, therefore, the definite community need criteria may require some reform to ensure that the service needs of many rural communities have as much chance as possible of being met.

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[44] See, for example, the Peter Fardoulys (developer) and Graeme Levis (community pharmacist) submissions to the Review on the 2 km rule.

[45] 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.

[46] Commonwealth submission to the Review, para 4.49.

The Determination prevents 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, and close it down for reasons of commercial difficulty, or simply to retire. 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.

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 Pharmaceutical Benefits Scheme;
- Keeping the overall numbers of pharmacies at a level sustainable by the wider community; and
- Promoting industry stability generally.

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[47].

From an industry perspective, the Agreement-based stability and inbuilt restrictions on competition translate to the stability of pharmacist income, the sale and goodwill value of pharmacy businesses and returns on investment. 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 in negotiating lower dispensing fees, which pharmacists are prepared to wear on the understanding that the overall profitability and sale value of their businesses is unlikely to be compressed by overly aggressive competition.

Overall this assumes that there is a significant public dividend in terms of both the managed growth of a significant area of taxpayer outlay for a demand-driven programme, and in a diverse and localised community pharmacy network.

Protecting local pharmacy markets

Outside the one kilometre 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 have a PBS approval with relatively little threat of competition from new entrants to the local market.

[47] Commonwealth submission to the Review, para 1.31.

Such mechanisms guarantee a catchment area for a 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 services to their consumers.

The 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 underserviced. 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.

The dividend for the community is that pharmacies continue to operate in areas of marginal viability, and in rural and remote localities.

Stability in the PBS distribution network

As outlined in Chapter 1, the PBS is a near monopsony for the Commonwealth in terms of the purchase of the prescription items that it subsidises. On behalf of the Australian taxpayer, the Commonwealth has an interest to ensure that outlays on the PBS, as a demand-driven programme, are kept under control and grow at a manageable rate.

While providing a direct framework for cost containment, the Agreement and the resulting section 99L Determination 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 per 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: relative equality of access of all Australians to essential pharmaceutical and medicinal care.

Keeping the overall number of pharmacies at sustainable levels

At a national level, a major argument for the new PBS approval restrictions is that the overall number of pharmacies, despite the adjustments undertaken through the two Australian Community Pharmacy Agreements, is sufficient. On statistical evidence, it may well be still too high[48].

As mentioned previously, Commonwealth data suggests that there are still some lesser efficient operators who have held on through the adjustments of the last decade. While there may be no policy inclination to rationalise aggressively in the manner of the early 1990s, it can be argued that there is also no corresponding justification to inflate the total number of PBS approved pharmacies beyond the present level of 4,950.

Allowing more new pharmacies than can be sustained by the market simply creates further supply 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.

[48] See para 32.

While the restrictions, and the Agreement, are not necessarily the sole reasons that PBS dispensing costs have been contained more effectively, the strict application of the new approval rules go a long way towards containing systemic-based growth pressures in return for a stable PBS income structure for the remaining pharmacies.

The stability of pharmacy numbers helps guarantee industry stability and performance

Another arguable benefit of the regulation of pharmacy numbers and distribution through PBS-based mechanisms is that regulation helps maintain a general stability in terms of the community pharmacy industry, and individual businesses in the industry. This stability can be expressed both in terms of income and sale value per pharmacy.

The overall conditions of the Australian Community Pharmacy 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 businesses[49].

Related factors appear to include:

- 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, with attendant economies of scale benefits, of 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 is strong anecdotal evidence of the strong inflation of pharmacy values and income over the 1990s. This is supported by the Pharmacy Guild's annual industry surveys, which indicate that the average total annual income of surveyed pharmacies rose from $65,806 in 1989 to $138,714 in 1997– a net increase of approximately 110 per cent[50]. To a considerable extent, this growth was nurtured by the effective stopping of new PBS-approved pharmacies entering the market and the protection against aggressive local competition offered by the relocation rules.

ALTERNATIVES TO THE RESTRICTIONS

If the purpose of the restrictions on PBS-approved pharmacy numbers and the relocation of pharmacies is creating 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.

Alternative approaches include:

- Immediate or phased removal of the location restrictions, letting the market respond to consumer demand with minimal government intervention;

[49] These comments are based on Review staff's private discussions with pharmacy industry experts.
[50] Pharmacy Guild of Australia, 1998 Guild Digest, Table 1.

- Remuneration-based approaches to addressing pharmacy oversupply and undersupply in local catchment areas;
- Tendering for PBS approvals; and
- Measures aimed directly at addressing the pharmacy access needs of people in rural and remote communities.

REMOVAL OF THE LOCATION 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 restrictions altogether, and allow the pharmacy market to take its course.

This could be done on a "high road" or a "low road" basis. The "high road" would see the full removal of the relocation and/or the new approval restrictions at the earliest possible time. The "low road" would see a transitional period of several years, to avoid unduly disadvantaging those who have made investment or business decisions on the assumption of a continuing regulatory environment.

If the "low road" route were adopted, there would be an opportunity to reform the present restrictions and their administration to ensure that they operate more efficiently and equitably. A transition could be linked to the timing of the next Australian Community Pharmacy Agreement, or could run independently of the Agreement.

As an alternative to the present restrictions, letting the market operate more freely would:

- 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 the overall number of pharmacies. The first Australian Community Pharmacy 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 taking account of relative differences in either the level of pharmacy supply in given localities, or between pharmacies in terms of efficiency as measured by their dispensing costs.

The two Australian Community Pharmacy Agreements to date have used allowances – currently the Remote and Isolated Pharmacy Allowances – to support 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 unviable, or to merge with more efficient pharmacy businesses.

In terms of offering alternatives to the current location restrictions, it therefore seems a possible alternative to location-based restrictions on pharmacy numbers and distribution could be the better

linking of cost management priorities to the actual remuneration that pharmacists receive for dispensing PBS-subsidised items to consumers, and how remuneration is formulated.

Differential dispensing fees

If the parties to the Agreement decide to do so, a higher level dispensing fee package 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' income on an item by item basis, and provide an incentive for those pharmacists now operating in these areas. 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 fully effective as an incentive mechanism and to be cost sustainable, however, remuneration-based measures of a differential nature should also contain a disincentive for pharmacists considering moving to an area of pharmacy oversupply or saturation, such as a capital city CBD. Therefore, just as dispensing fees in undersupplied areas could carry a premium, fees in oversupplied areas could carry a commensurate downwards adjustment. This measure would, as well as partially offsetting the costs of the premiums, make moving into an oversupplied area less attractive, and would put pressure on less efficient pharmacies already located there to consider their trading futures.

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 remuneration 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 Scheme[51]*.*

Average cost-based remuneration structures support inefficient pharmacies while generally rewarding those who have lower fixed and variable costs. Moving away from average cost to industry good practice cost formulations – thereby linking remuneration structures to pharmacy efficiency – could go a long way to shaking out marginally viable and inefficient pharmacies in oversupplied areas. It could also effectively remove the need to regulate to cap pharmacy numbers and to reduce clustering of pharmacies by existing location-based measures.

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

As a caveat, however, if a marginal cost formulation were introduced there may need to be provisions 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

[51] Commonwealth submission to the Review, para 4.56.

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 a matter for the Australian Community Pharmacy Agreement, and that there would be additional administrative and implementation costs if these measures were adopted. It is, of course, up to the parties themselves to consider alternatives to the present controls in negotiating the next Agreement, being guided by the need to ensure that pharmacy services are provided 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. A competitive tendering process would allow the market to determine the level of remuneration on a pharmacy by pharmacy basis. Instead of capping pharmacy numbers of limiting relocation of pharmacies, the tendering processes could both be locality-focused and make inefficient pharmacies harder to sustain financially, restricting the overall numbers of PBS-approved pharmacies in a more targeted manner.

Under this approach the Commonwealth would tender 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. 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 in more populated areas.

There are significant risks with a competitive tendering approach, however. There is no guarantee that quality follows price and, 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 goes under. Careful consideration therefore needs to be given to maintaining the quality provision of pharmacy services in a competitive tendering environment. 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.

DIRECT MEASURES TO ASSIST RURAL AND REMOTE COMMUNITIES

Instead of existing location-based measures, including the Rural and Isolate 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 existing measures. This might include the following suggestions.

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 there involvement in such schemes if these 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 circumstances like these that a PBS approval could be issued to a local community and administered by a local council or community committee. The community would become the recognised as the approval holder for the purposes of the *National Health Act* and 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 by the pharmacist[52].

Such a proposal might well assist rural communities where the pharmacy market fails to meet its demonstrated need without such intervention, and would not be inconsistent with the general principle of pharmacist-owned pharmacies.

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, 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.

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, interprets each site as a separate site for PBS purposes, and therefore each site requires a new PBS dispensing approval.

Addressing such unintended consequences of legislative action is important if rural-specific elements of the current PBS-based location restrictions are to be dealt with by other means. It is also important for ensuring that regulation is flexible enough to permit the new way of promoting the practical delivery of services, for example, delivering medicines by “mobile pharmacies”.

[52] 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 on lines similar to a friendly society pharmacy. This would, however, not be consistent with the general pharmacist ownership principle endorsed in Chapter 2.

FINDINGS AND CONCLUSIONS

The PBS location rules, and the factors that underpin them, are inherently anti-competitive in their operation and their effects. They have had the effect of reducing Commonwealth outlays on the one hand, and generally protecting pharmacy catchment areas from new competition on the other.

On considering the costs and benefits of the Section 99L 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.

NEW 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 number of 4,950 PBS-approved pharmacies is around this sustainable level. Indeed, if the still-substantial numbers of low and medium prescription volume pharmacies are taken into account, it is possible that it still exceeds an optimum industry-wide number of pharmacies.

Given the level of spending on PBS medicines, and on associated remuneration to pharmacists, to grow well above the rate of inflation as new and costly medicines enter the market, the policy need to seek to restrict the growth of pharmacy numbers is accepted by the Review. Similarly, capping numbers by placing tight restrictions on approving new pharmacies to supply PBS medicines is acknowledged as a regulatory mechanism capable of realising this objective.

On balance, however, the Review questions whether the current restrictions are the best and fairest way of achieving the desirable outcome. They are targeted in their operation, and the criteria are set so tightly that it is not the pharmacy industry that suffers from their application. Instead, they can hurt many of the communities that the criteria ostensibly are meant to help.

There are more direct ways to encourage pharmacists to consider less serviced localities and to leave or avoid overserviced ones. The Commonwealth, using its purchasing power to implement remuneration-linked measures, could achieve more targeted effect than with catch-all location controls. They would also be more consistent with the Review's overall approach to pharmacy regulation that, as far as possible, pharmacy businesses should have as much freedom and discretion as possible over their commercial decision-making, without undue interference from governments and regulatory authorities.

Such other measures would also have the merit of being more likely to promote ongoing restructuring and efficiency improvement in the community pharmacy industry, whereas the existing new pharmacy restrictions promote relative inertia in this regard.

While noting that ultimately pharmacist remuneration matters are the concern of the parties to the Australian Community Pharmacy Agreement, the Review believes that the capping of pharmacy numbers by placing a heavy lid on new pharmacy approvals therefore should be seen as a last resort measure only, and that there are potentially better alternative measures for the purpose.

Recommendation 9

The Review recommends that:

(a) While accepting that regulatory limits on the number of pharmacies are justifiable, current restrictions on the approval of new pharmacies to dispense PBS benefits should be replaced; and

(b) These restrictions can be replaced by more targeted measures to achieve the outcome of managing the dispensing costs generated by the overall numbers of pharmacies approved to provide PBS services.

RELOCATION OF PHARMACIES

On considering the evidence, the Review does not believe that there is a benefit to the community as a whole from the current operation of the Section 99L Determination provisions for pharmacy relocations. In fact, it believes that the rules are highly restrictive and anti-competitive, and that they protect the self-interest of individual pharmacy proprietors at the expense of ensuring the best possible quality of pharmacy service delivery to the wider Australian community.

It is suprising that, in an industry that advocates pharmacist ownership of pharmacies as a guarantor of service competition between pharmacies, the frustration of such competition by inflexible and distance-based relocation rules can be tolerated. The restrictions give an inefficient or indifferently-performing pharmacy a two kilometre buffer zone to protect as its "patch" from the entrance of more efficient or more service-oriented competitors. The affected community loses in two ways: it is deprived of the services of the better performer, and it is stuck with those of the indifferent performer.

If service competition was allowed to flourish unrestricted in local pharmacy catchments, reinforced by an appropriate PBS remuneration structure to discourage oversupply, the intention of the relocation restrictions could be achieved by other means. Inefficient performers would be flushed out, there would be greater incentive to improve service quality, areas of oversupply would move towards equilibrium over time, and targeted measures could be introduced to assist areas undersupplied with pharmacies.

Recommendation 10

The Review recommends that PBS-related restrictions on the relocation of pharmacies from one site to another be removed.

TIMING THE REMOVAL OF THE RESTRICTIONS

If the parties to the Australian Community Pharmacy Agreement accept these recommendations, they will also need to decide upon the nature and timing of their implementation. If immediate removal of the location restrictions is adopted, the logical implementation time would be the conclusion of the present Agreement on 30 June 2000.

If it is accepted that there needs to be a transitional period to ensure that no pharmacy business suffers undue financial hardship as a result of the changes, it may be desirable to implement full removal after a period of several years.

The Review believes, on balance, that the removal of the restrictions as soon as possible is in the best interests of the community as a whole. If a transition period is adopted, however, it also believes that the present rules, and their administration by the Australian Community Pharmacy Authority, need to be reformed to make them more efficient, more transparent, and to minimise wherever possible inequitable outcomes of their rigid structure and application.

The Review's suggested "high road" and "low road" models to removing the restrictions, including suggestions about the future constitution and role of the Australian Community Pharmacy Authority, are outlined in more detail in Appendix 5. Consistent with its recommendations, the Review favours the "high road" model.

Recommendation 11

The Review recommends that the current PBS relocation restrictions be removed, and the new approvals restriction replaced by more targeted measures, at the end of the current Australian Community Pharmacy Agreement on 30 June 2000.

Recommendation 12

The Review recommends that if the parties to the Australian Community Pharmacy Agreement decide to retain the present restrictions in full or in part after 30 June 2000, the relevant provisions of the Section 99L Determination, and the constitution and operation of the Australian Community Pharmacy Authority, be revised to make them less competition-restrictive, more efficient, more transparent and more equitable.

CHAPTER 4: REGISTRATION OF PHARMACISTS

The purpose of this chapter is to canvass general principles for the registration of pharmacists arising from the provisions of States and Territories' *Pharmacy Acts*. More detailed comment on registration matters, drawing from the Review's close evaluation of individual Acts and delegated legislation, will be part of the Review's Final Report.

NATURE OF THE RESTRICTIONS

INTRODUCTION

All State and Territory *Pharmacy* and *Pharmacist Acts* impose restrictions on who may practise as a pharmacist, and how pharmacists may practise. These Acts also provide for the administrative machinery to oversee the effective operation of these regulations, and to hold pharmacists to account for their conduct as professionals.

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:

- Training and entry into the pharmacy profession;
- Ongoing practice as a pharmacist; and
- Activities of regulatory authorities.

ENTRY TO THE PROFESSION

In each jurisdiction pharmacy is a registrable profession. To obtain that 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 after graduation. In the case of overseas-trained pharmacists, this may include a period of supervised practice as part of the Australian Pharmacy Examining Council 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 practise and on-the-job training. Since World War II, training requirements have moved through apprenticeships and on-the-job training, to three-year degrees and supervised practice, to the current four-year degree requirement. This has mirrored developments in pharmaceuticals and pharmacology, which are fundamental to a practising pharmacist.

A graduate who has completed an appropriate course of study and supervised work experience must then demonstrate this knowledge to a registering authority by means of an examination under the supervision of their Pharmacy Board. Performance is measured against nationally recognised standards of competency. A national competency test based on these standards is being trialled at the time of writing.

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 is entitled to practise in the other jurisdictions.

Across States and Territories there are also a range of other personal requirements that an applicant for initial registration in a given jurisdiction must meet to the satisfaction of the local Pharmacy Board. Although they vary from jurisdiction to jurisdiction, such restrictions include:

- Good character or being a "fit and proper person";
- An understanding of the English language;
- Medical fitness to practise pharmacy;
- An understanding of State law;
- 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 circumstances[53]. In addition, most jurisdictions restrict explicitly the lawful use of the term "pharmacist", "pharmaceutical chemist" and similar titles and descriptions 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 pharmacists[54].

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. In some cases Pharmacy Boards may have 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.

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 also a requirement that all registered pharmacists in Western Australia become members of the Pharmaceutical Society of Western Australia. The Western Australian legislation specifies the Council's dual role as regulator and manager of the professional organisation for pharmacists.

[53] This restriction is the subject of a parallel NCP Review on Drugs and Poisons and is not discussed further here.
[54] Clause 15.1 Queensland *Pharmacy Regulation 1997*.

Pharmacy Boards generally consist of a combination of members appointed by the responsible minister and elected by registered pharmacists. This varies between jurisdictions for example board members are all 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 restrictions is to protect the safety of the Australian public by ensuring that pharmacy services are provided in a competent and accountable manner.

However, restrictions resulting from the legislation under review have come to fulfil other incidental functions 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, academia, and industry.

The first of these objectives is the subject of a parallel NCP review of Drugs and Poisons legislation and the second is discussed in Chapter 2. The last point is beyond the Terms of Reference of this Review.

EFFECTS OF THE RESTRICTIONS

The primary overall effects of these restrictions are to:

- Restrict the lawful practice of pharmacy only to those who have satisfied registration and re-registration requirements;
- Place controls, through legislation and its interpretation by Pharmacy Boards and the courts, on the practice of pharmacy; and
- Establish, through Pharmacy Boards, mechanisms that govern professional practice and conduct, and which can entrench 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 to five years[55].

The core of this training remains a foundation in the basic sciences – the biology and chemistry 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 superior knowledge of therapeutics. Expanded university curricula are also paying more attention to practice skills such as interpersonal communication and business management.

Notwithstanding the length of time taken in training, pharmacy is a very popular course of university study. 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 are excluded on the basis of their results.

[55] Assuming that jurisdictions retain the requirement for a prescribed period of supervised practice before registration.

RESTRICTIONS ON PRACTICE

Once currently registered, in all jurisdictions a pharmacist may continue on the register until retirement or death, unless he or she comes to the attention of their Pharmacy Board for a fundamental breach of professional standards and is deregistered. The only basic requirement is the annual registration fee[56], which is used to fund the operations of the Pharmacy Boards. In no jurisdiction is there an explicit 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 Board'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. In many cases, however, it is the individual pharmacist who draws the Board's attention to his or her recency of practice and the Pharmacy Board has some latitude in interpreting the legislative requirements.

Pharmacists are expected to comply with set practice standards and codes of conduct. Breaches of these can be dealt with by disciplinary processes administered by Pharmacy Boards. Disciplinary sanctions can range from cautions to fines, and ultimately de-registration whereby a pharmacist can lose his or her livelihood.

REGULATORY STRUCTURES

Given their professional core membership, and their integral role in administering *Pharmacy Acts* and professional matters, Pharmacy Boards have become sources of advice to governments. Boards, after all, are "on the spot" and, whether or not Acts give them the direct power to advise governments on professional matters[57], they are effectively a port of call for such advice when it is needed. While Pharmacy Boards are often looked to for advice by government, however, they are not constituted, selected or resourced to play such a role.

Depending on the jurisdiction, and the wording of enabling provisions of their Acts, Pharmacy Boards can have a very wide embrace in both the practice of pharmacy and the conduct of pharmacy businesses. In some cases, this intrudes into general business that, while conducted on pharmacy premises, has little direct bearing on the safe and proper provision of professional pharmacy services.

While such powers of interpretation may have been upheld by a court, as in the *Chappuis* v *Filo* decision in New South Wales[58], it appears that Pharmacy Boards have tended to gain or acquire by convention a discretion to intervene in any aspect of a pharmacy's activities that they deem relevant to the conduct of professional services. This sense of perceived responsibility for all aspects of activity in pharmacy, often expressed in terms of maintaining professional integrity and dignity, was a consistent theme in the Review's consultations with Pharmacy Boards.

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

[57] 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".

[58] (1990) 19 NSWLR 490.

In many jurisdictions the statutory role of Pharmacy Boards goes beyond enforcing regulation to encompass:

- Reviewing and developing professional standards,
- Setting standards and implementing programmes for pre-registration training of pharmacy graduates;
- Commissioning and hosting professional education activities;
- Having carriage of, or considerable influence on, the development of pharmacy policy; and
- Distributing 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 to the community in terms of the restrictions imposed on both pharmacists and pharmacy businesses. The Review needs to analyse whether the benefits of these restrictions to the community as a whole outweigh their costs, and whether there are non-regulatory alternatives which 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 practise. Anecdotal evidence suggests that the latter obligation is often performed with low or even no remuneration from the host pharmacy.

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.

Concerns have been expressed that students from rural and regional areas are not represented in sufficient numbers in university pharmacy courses. This exacerbates the problem that, in common with many health professions, it is difficult to attract pharmacists from an urban background to work in rural and regional areas. Some pharmacy schools have, however, addressed this workforce issue by means of quotas for students from rural areas.

Entry requirements for university courses are not specified in *Pharmacy Acts* and therefore are outside the scope of the Review's Terms of Reference. 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.

Barriers to entry of overseas trained pharmacists

All jurisdictions recognise automatically 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 the Australian Pharmacy Examining Council.

However reasonable they may be, the requirements to meet Australian standards are barriers that have to be overcome by overseas-trained pharmacists to practise in Australia. They have personal costs for the individuals who do not pass them successfully. They also have a broader cost in terms of losing the skills of pharmacists who may otherwise have been able to make a professional contribution to the community.

Restrictions on practice

Costs to the individual pharmacist

Costs generated by regulations governing the ongoing practice of pharmacy include:

- Re-registration fees; and
- Restrictions on their ability to practise their chosen profession/conduct a private business as they see fit, and being unable to take advantage in some cases of more beneficial tax and business arrangements.

Costs to the public

The costs to the public generated by legislation governing the ongoing practice of pharmacy include:

- Potential dangers to health if poor and incompetent practice is not detected and dealt with;
- Reduced range of models of pharmacy practice available (eg mobile pharmacies or interdisciplinary primary health facilities); and
- Potentially greater costs for pharmacy goods and services due to high salaries needed to attract staff pharmacists, particularly in regional areas[59].

Regulatory structures

There are costs inherent in administering and running Pharmacy Boards that are mostly borne by the profession via registration fees.

There are potential costs to the public in terms of conflicts between the public interest and the interests of the profession which arise because of the composition and structure of Pharmacy Boards.

Costs may be borne by the pharmacist owners as a result of restrictions placed on pharmacy businesses by Pharmacy Boards. 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.

[59] The Review heard evidence that a pharmacy in regional Victoria had to offer a starting salary of $60,000 a year to attract a recent graduate.

Pharmacy Board registrars, who are in a very influential position, can also use that influence negatively if they interpret their Board's powers either too widely or too narrowly. This can translate as a cost to the community in terms of such regulations affecting the overall efficiency and ability of pharmacy businesses to manage their affairs.

BENEFITS OF THE RESTRICTIONS

Entry to the profession

The benefit of restricting entry to the profession is that the public can be guaranteed that all registered pharmacists have:

- Graduated from a course of study which has provided them with sufficient scientific underpinnings, knowledge of therapeutics and an ability to apply this theoretical knowledge;
- Been exposed to pharmacy practice in an actual clinical setting for a prescribed period of time under the individual supervision of an experienced pharmacist; and
- Reached an acceptable standard of proficiency to enable them to practise unsupervised in a community or clinical setting.

As a result of the entry restrictions there is an increasingly well-educated pharmacy workforce which conveys benefits such as:

- Less risk of medication misadventure;
- Reduced numbers of unnecessary GP visits due to effective treatment of symptoms and minor ailments by pharmacists;
- Better disease management by appropriate referral to GPs; and
- Better quality use of medicines.

Ongoing practice as a pharmacist

The benefits of the current restrictions on 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 process[60], and lapses in safe and competent practice can be dealt with through complaints and disciplinary processes;
- Public protection is enhanced by regulations allowing the board to compel pharmacists re-joining the profession after a period when they are not practising to undergo some re-training or continuing education; and
- The existence of disciplinary sanctions 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 Pharmacy Board structures and compositions benefit the public by providing guidance in the interpretation and enforcement of professional regulations, and in their ability to enable Boards to work with pharmacists to help them provide professional services of an expected high standard.

[60] Association of Pharmacy Registering Authorities submission to the Review, page 3.

Involvement by Pharmacy Boards in standard setting and the development of policy is a potential benefit both the public and the profession by ensuring that standards are reasonable and that public policy is well informed.

The ability of Pharmacy Boards to exercise discretion can benefit both the profession and the public by allowing common sense and professional experience to be brought to bear in individual circumstances.

Because of their own extensive experience, full-time Board registrars also usually exercise considerable influence in their own right. A registrar can influence their Board in the exercise of their powers in a manner that is lawful, efficient and effective.

ALTERNATIVES TO THE RESTRICTIONS

The Review has 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 might include:

- Deregulation;
- Self-regulation by the pharmacy profession; and
- Minimal legislative regulation by governments.

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 could exercise their preference for safety by choosing qualified and experienced pharmacists.

There are in place 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 and fair trading legislation would allow individuals to be prosecuted for falsely describing or misrepresenting their qualifications; and
- Consumers could also take legal action for damages against anyone who had injured them through incompetent or negligent practice.

However there are a number of matters which may argue against deregulation, such as:

- There are significant asymmetries of information between pharmacists and consumers where not only are consumers risking economic loss, but their personal health and even lives are at risk; and
- 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 private health insurers and the health system generally, and therefore individuals may be tempted to take risks which are not socially optimal; and
- There are social policy objectives in assuring the public of the safety and efficiency of the health system.

SELF-REGULATION BY THE PHARMACY PROFESSION

Professional self-regulation has been seen increasingly as a "more flexible alternative to direct government regulation[61]". Some professions, such as accountancy have well-developed self-regulation processes.

Advantages of this approach, as outlined by the Taskforce on Industry Self-Regulation[62], can be that self-regulation:

- Promotes good practice;
- Targets specific problems within industries;
- Imposes lower compliance costs on business; and
- Offers quick, low-cost dispute resolution procedures to consumers.

The potential weaknesses of self-regulation in this area are similar to those mentioned above for deregulation.

MINIMAL REGULATION BY GOVERNMENTS

A minimal model of regulation involves the government of each jurisdiction in setting standards for pharmacists that could be more easily updated[63] than would be the case if standards were spelt out in the legislation itself.

The Review stresses that such standards, guidelines and statutory based statements should impose only those restrictions on competition that are necessary to ensure public benefit and that these should be efficient and effective, and enforceable.

In practice, jurisdictions may choose to adopt standards developed by professional pharmacy bodies or may develop their own standards, possibly in consultation with consumers, and in keeping with their own health policy priorities. This approach is practical, since there are many developments (such as the growth of mail-order and Internet pharmacy, general health care trends and the evolution of the professional role of the pharmacist) which cannot be envisaged clearly at any one point in time. It is also possible that an overly prescriptive approach to legislation may inhibit desirable public policy innovations such as integrated or coordinated care initiatives.

Pharmacist standards in this context could cover areas such as:

- Minimum entry standards and/or pre-registration training and experience requirements for initial registration;
- Recognition of overseas qualifications and prior experience;
- Requirements for re-registration (eg payment of annual fee, competence assessment); and
- Nationally accepted generalist professional practice standards (such as current Pharmaceutical Society of Australia professional standards).

[61] Taskforce on Industry Self-Regulation, *Issues Paper*, October 1999.
[62] Ibid.
[63] The Review stresses that any amendments to these guidelines should themselves need to be in accordance with National Competition Policy principles.

Essentially a minimal approach would involve keeping primary Acts simple, defining, for example:

- The constitution and powers of the regulatory agency, including a complaints investigation and disciplinary framework;
- The legally enforceable nature of the pharmacist standards adopted by the jurisdiction; and
- Implementation of mutual recognition principles.

Registration and practice standards and requirements would then be set out in delegated legislation or in other documents promulgated under the primary Act. They would be easier to amend as professional and health care trends and requirements change over time, yet would have the full backing of the Act as statutory instruments.

In recent and ongoing reviews of pharmacy and other health practitioner legislation, this type of legislative approach seems to be an accelerating trend. The Review is very attracted, for example, by the template offered by the Victorian model health practitioner legislation developed in recent years, of which the *Osteopaths Act 1996* (Vic) is an example. Other jurisdictions are developing similar legislation of their own along similar lines to the Victorian model.

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 five general areas:

- General regulatory principles;
- Entry to the profession and initial registration;
- Ongoing practice;
- Disciplinary matters; and
- Regulatory authorities.

GENERAL REGULATORY PRINCIPLES

In Chapter 1, the Review indicated that 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 services[64].

Registration

Public safety is the *raison d'etre* 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;

[64] See Page 6 of this report.

- Consumers must place a high level of trust in pharmacists because of this information asymmetry, 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 the public can be placed in great jeopardy.

A broad examination of State and Territory *Pharmacy Acts* and regulations indicate that they do operate to protect the public from unsafe and incompetent pharmacy practice. But, as considered earlier, they can also go beyond this into areas that do not truly relate directly to competent professional practice. Either expressly or by interpretation by regulatory authorities, they attempt in varying degrees to regulate the commercial behaviour of pharmacies. They also place requirements on pharmacists and pharmacy practice that may be jurisdiction-specific and not required in other States and Territories.

Having examined the non-regulatory alternatives, the Review considers on balance that legislative regulation of the profession, based on registering a pharmacist as competent to a minimum standard, is justifiable in the public interest. However such regulation should be the minimum necessary to achieve the stated public interest objectives.

On this basis, the statutory requirement for registration of pharmacists as evidence of having attained a minimum standard of competence to practise unsupervised, is justifiable in the public interest. The restriction of the lawful practice of pharmacy to registered persons therefore is also justifiable.

Similarly, restrictions on who may use the titles of "pharmacist", "chemist" and the like for professional purposes are also reasonable restrictions on competition in the interest of protecting the public from incompetent, fraudulent and charlatan practice.

Recommendation 13

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; and

(b) The use of the title "pharmacist" and other appropriate synonyms for professional purposes may also be regulated by legislation in the public interest.

National consistency of registration practice and legislation

The underlying principles of pharmacy practice and the body of professional knowledge needed to practise pharmacy are the same across the nation. After nearly a century of Federation, there is still relatively little in the way of a consistent national legislative approach to pharmacy and pharmacist regulation. This has contributed to inefficiencies and duplication of effort and, despite current mutual recognition principles, still inhibits the free movement of pharmacists and the trans-border operation of pharmacy businesses.

In approaching these issues, the Review considered whether there is a need for common 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.

There is national regulatory interaction through the Association of Pharmacy Registering Authority (APRA), and that some jurisdictions are developing standard professional regulation legislation of their own in areas including pharmacy.

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.

Recommendation 14

The Review recommends that:

(a) State and Territory regulation of pharmacists and pharmacy practice apply specifically to the safe and competent practice of pharmacy;
(b) Regulations not concerned with the safe and competent practice of pharmacy should be removed; and
(c) Jurisdictions work to ensure, as far as possible, the harmonisation of registration and re-registration requirements, in the interests of national consistency and occupational mobility.

ENTRY TO THE PROFESSION AND INITIAL REGISTRATION

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, provides 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 tertiary course can be applied in practical situations.

Recommendation 15

The Review recommends that current training and experience requirements for initial registration be retained.

ONGOING PRACTICE

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, it is necessary for pharmacists to maintain professional standards of competence once they are registered.

Presently re-registering pharmacists, while they 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 Pharmacy Boards 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 jurisdictions, a Pharmacy Board 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 partially physically or intellectually incapacitated. In these circumstances, a Pharmacy 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 16

The Review recommends that:

(a) Existing re-registration requirements for pharmacists re-entering the profession following a period out of practice be 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, be retained.

Demonstration of competence by practising pharmacists

Notwithstanding Recommendation 16, there is nevertheless 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 remain passive (ie it is assessed when called into question by a complaint or investigation), or it can be active (ie it is assessed as a regular requirement in the re-registration process, whether or not there is an immediate cause for complaint).

There are two feasible "active" approaches to maintaining and improving professional standards:

- Providing incentives to pharmacists to improve their knowledge and skill level; and
- Mandating minimum standards for continuing education and/or demonstrating ongoing competence.

Incentives

Financial or other benefits, perhaps as part of remuneration or fee-based arrangements, could be used to encourage pharmacists to maintain or upgrade their skills according to set standards and guidelines.

While this approach has its attractions, there are cost implications and practical difficulties. There is, for instance, a real financial limit on governments in offering incentives to pharmacists. There is also a policy argument suggesting that pharmacists should not be given additional reward for performing at a normally expected standard.

The main government source of pharmacist remuneration is the dispensing fee structure under the Pharmaceutical Benefits Scheme (PBS). While it may be possible to build incentives into PBS linked remuneration, this would represent a major Commonwealth intrusion into areas of State and Territory regulatory responsibility. It would also have a significant cost implication for the taxpayer.

The Review may comment further on related questions in its Final Report.

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 knowledge. One of the most frequently cited means for achieving this has been compulsory continuing professional education (CPE). However, there are a number of difficulties with this 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 practise;
- Pharmacy Boards who 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.

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.

If any practising pharmacist should be able to demonstrate their practice level is at least equivalent to that of an initial registrant, it seems feasible to suggest that an competency examination similar to APCAT or the APEC examination could be passed periodically (say every three to five years) by currently registered pharmacists as a condition of renewed registration.

The Review is aware that at least one jurisdiction 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.

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 framework, requires very considerable justification.

Nevertheless, it can be argued that such an approach would:

- Replace a diverse range of existing restrictions which can be imposed by Pharmacy Boards 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;
- Able to ensure that competency assessment mechanisms in place are evaluated to ensure that they remain effective.

Recommendation 17

The Review recommends that within three to five years jurisdictions should explore and implement competency-based mechanisms as part of re-registration processes for 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 Pharmacy Boards, 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, and in other professional regulation legislation developed by jurisdictions in recent years. The Review commends such developments.

Recommendation 18

The Review recommends that complaints and disciplinary processes should be set out clearly, and those processes should be accessible, public, transparent and subject to the principles of natural justice and external review.

REGULATORY AUTHORITIES

If regulations exist governing the registration of pharmacists it is necessary for these to be implemented by some government regulatory authority.

The Review notes that in Western Australia the pharmacy authority (the Pharmaceutical Council of Western Australia) fulfils a dual function of professional organisation and regulatory body. This is undesirable because there are instances where protecting the "good name" of the profession and promoting the interests of the profession generally may be in direct conflict with the public interest.

In other jurisdictions, the fact that Boards are composed predominantly of pharmacists, and in most cases their registrars are either qualified pharmacists and/or deeply experienced in pharmacy profession matters, exposes them to similar risks of placing the profession before the public interest.

A major disadvantage of Pharmacy Boards having a discretion to interpret their powers broadly is that there is the potential for intrusions into all aspects of a pharmacy business, scrutinising not only professional activity but also commercial judgments and activity on the part of proprietors and their staff. This was discussed in Chapter 2 in relation to the pecuniary interest provisions of *Pharmacy Acts*. Such activities can be an impediment to competition between pharmacies, and between pharmacies and other businesses. Indeed, an activist Pharmacy Board, choosing to interpret its jurisdiction broadly or narrowly as a case may require, can do much to shape the commercial and competitive conduct of community pharmacy within its jurisdiction as it wishes.

The composition, role and functions of regulatory authorities will be considered in more detail in the Review's Final Report, after it has completed its detailed analysis of State and Territory *Pharmacy Acts*.

Recommendation 19

The Review recommends that:

a) The role of regulatory authorities, such as Pharmacy Boards, is defined clearly in legislation in terms of their being standards monitoring, not standard setting, bodies;
b) Regulatory authorities should concentrate on their core business – ensuring that the public is protected from the unsafe, incompetent and unscrupulous professional conduct of pharmacists;
c) The composition, functions and charter of regulatory authorities should be set out clearly in legislation and should not unduly restrict or hamper competition and non-professional activity in the pharmacy industry by the way they operate;
d) Regulatory authorities are composed and structured so that they are accountable to the community through Government, and focus on the interests of the public not the interests of the profession; and
e) Regulatory authorities apply nationally consistent principles in disciplinary matters and cooperate, as necessary, with other jurisdictions in this respect.

Appendix 1

SUMMARY OF RECOMMENDATIONS

Recommendation 1

The Review recommends that legislative restrictions confining the ownership of pharmacies, with existing limited exceptions, to registered pharmacists and bodies corporate controlled by pharmacists, be retained.

Recommendation 2

The Review recommends that any jurisdiction's residential requirements for pharmacy ownership be removed.

Recommendation 3

The Review recommends that:

(a) Friendly society and grandparented corporate pharmacies be permitted to continue to operate;
(b) The application of mutuality in the pharmacy sector be reviewed by the Australian Consumer and Competition Commission (ACCC);
(c) Depending on the outcome of any ACCC review, restrictions on the number of friendly society pharmacies, and the number of pharmacies held by a friendly society, in a given jurisdiction be lifted; and
(d) Provisions relating to friendly society and grandparented non-pharmacist owned pharmacies be made consistent across jurisdictions.

Recommendation 4

The Review recommends that:

(a) Jurisdictions' restrictions on the number of pharmacies owned by a proprietor be lifted on a date consistent across jurisdictions; but
(b) The behaviour of the pharmacy market after the lifting the restrictions be monitored by jurisdictions and by the Australian Competition and Consumer Commission in accordance with Part IV of the *Trade Practices Act 1974*.

Recommendation 5

The Review recommends that:

(a) The pharmacy ownership structures permitted by various State and Territory Acts be retained as consistent with the principle of pharmacist ownership and control;
(b) In the interests of national consistency and commercial certainty, the range of current permitted structures be adopted consistently by each jurisdiction; and
(c) New ownership structures consistent with the general principle of pharmacist control of pharmacies should be permitted.

Recommendation 6

The Review recommends that:

(a) Provisions relating to parties other than the proprietor having a pecuniary interest in pharmacies, the terms of bills of sale for pharmacy businesses, or otherwise preventing pharmacy proprietors from developing lawful business associations with other parties be removed; and
(b) These provisions be replaced with a statutory offence 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) Regulations requiring the registration of pharmacy premises be removed; and
(b) Regulations requiring the registration of pharmacy businesses be removed.

Recommendation 8

The Review recommends that Commonwealth, State and Territory governments ensure that legislation and agreements, including the Australian Community Pharmacy Agreement, 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.

Recommendation 9

The Review recommends that:

(a) While accepting that regulatory limits on the number of pharmacies are justifiable, current restrictions on the approval of new pharmacies to dispense PBS benefits should be replaced; and
(b) These restrictions can be replaced by more targeted measures to achieve the outcome of managing the dispensing costs generated by the overall numbers of pharmacies approved to provide PBS services.

Recommendation 10

The Review recommends that PBS-related restrictions on the relocation of pharmacies from one site to another be removed.

Recommendation 11

The Review recommends that the current PBS relocation restrictions be removed, and the new approvals restriction replaced by more targeted measures, at the end of the current Australian Community Pharmacy Agreement on 30 June 2000.

Recommendation 12

The Review recommends that if the parties to the Australian Community Pharmacy Agreement decide to retain the present restrictions in full or in part after 30 June 2000, the relevant provisions of the Section 99L Determination, and the constitution and operation of the Australian Community Pharmacy Authority, be revised to make them less competition-restrictive, more efficient, more transparent and more equitable.

Recommendation 13

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; and
(b) The use of the title "pharmacist" and other appropriate synonyms for professional purposes may also be regulated by legislation in the public interest.

Recommendation 14

The Review recommends that:

(a) State and Territory regulation of pharmacists and pharmacy practice apply specifically to the safe and competent practice of pharmacy;
(b) Regulations not concerned with the safe and competent practice of pharmacy should be removed; and
(c) Jurisdictions work to ensure, as far as possible, the harmonisation of registration and re-registration requirements, in the interests of national consistency and occupational mobility.

Recommendation 15

The Review recommends that current training and experience requirements for initial registration be retained.

Recommendation 16

The Review recommends that:

(a) Existing re-registration requirements for pharmacists re-entering the profession following a period out of practice be 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, be retained.

Recommendation 17

The Review recommends that within three to five years jurisdictions should explore and implement competency-based mechanisms as part of re-registration processes for pharmacists.

Recommendation 18

The Review recommends that complaints and disciplinary processes should be set out clearly, and those processes should be accessible, public, transparent and subject to the principles of natural justice and external review.

Recommendation 19

The Review recommends that:

(a) The role of regulatory authorities, such as Pharmacy Boards, is defined clearly in legislation in terms of their being standards monitoring, not standard setting, bodies;
(b) Regulatory authorities should concentrate on their core business – ensuring that the public is protected from the unsafe, incompetent and unscrupulous professional conduct of pharmacists;
(c) The composition, functions and charter of regulatory authorities should be set out clearly in legislation and should not unduly restrict or hamper competition and non-professional activity in the pharmacy industry by the way they operate;
(d) Regulatory authorities are composed and structured so that they are accountable to the community through Government, and focus on the interests of the public not the interests of the profession; and
(e) Regulatory authorities apply nationally consistent principles in disciplinary matters and cooperate, as necessary, with other jurisdictions in this respect.

Appendix 2

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.

In the case of Tasmania and Queensland, the review will not cover the registration of pharmacists as this legislation has already been reviewed.

The review will have regard to the relevant sections of the Competition Principles Agreement, the COAG Guidelines and Principles for National Standard Setting and 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.

ATTACHMENT A

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;

(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;

the following matters shall, where relevant, be taken into account:

(d) government legislation and policies relating to ecologically sustainable development;

(e) social welfare and equity considerations, including community service obligations;

(f) government legislation and policies relating to matters such as occupational health and safety, industrial relations and access and equity;

(g) economic and regional development, including employment and investment growth;

(h) the interests of consumers generally or a class of consumers;

(i) the competitiveness of Australian business; and

(j) the efficient allocation of resources."

Appendix 3

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 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 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 business; and
- The efficient allocation of resources.

The *Competition Principles Agreement* also requires that legislation review consider the following:

- The objectives of the legislation;
- The nature of the restriction on competition;
- The likely effect of the restriction on competition and on the economy generally;
- The costs and benefits of the restriction and their balance; and
- 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 achieving 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 used with permission.*

Appendix 4

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-up applied by wholesalers and by 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 is used to establish a price 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 to12 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 acknowledgement.

Appendix 5

ALTERNATIVES TO EXISTING REGULATION FOR NEW AND RELOCATED PHARMACIES

Further to the Recommendations 10-13 in Chapter 3,two routes for reform of the *National Health Act 1953's* Determination under Section 99L are outlined. The "high road" option is for change in the short term, and a "low road" leading to the same destination, but with a transitional period.

Consistent with Recommendation 12, the "high road" is the Review's preferred option.

The desirability of introducing special provisions for the retention of pharmacies in rural and remote areas (see Chapter 3) is a related but separate issue.

"HIGH ROAD"

The "high road" model would remove the current location restrictions as soon as possible. The new approvals rules would be replaced by other measures, and relocation rules not replaced. There would not be any phasing or interim arrangements.

- Changes could come into effect at the beginning of the next Australian Community Pharmacy Agreement, on 1 July 2000.

RELOCATION

From 1 July 2000, existing pharmacies would be free to relocate to a site regardless of its proximity to another pharmacy, unless the Australian Community Pharmacy Authority (ACPA) can demonstrate that a relocation is not in the public interest. The ACPA would therefore, assuming that it is retained, take on a monitoring and reviewing role compared to its present determinative brief.

NEW APPROVALS

The current location rules for new pharmacies would be abolished as of 1 July 2000. Other incentives, such as remunerative and/or other financial measures, would be introduced to make establishing a pharmacy in an oversupplied area less attractive, establishing in an undersupplied area more attractive.

"LOW ROAD"

The "low road" would provide for a more incremental progression to the "high road" model. It would allow for a phasing in of new arrangements, and would recognise that many pharmacy proprietors have made business investment decisions in recent years that have anticipated some continuity in the present arrangements.

- "Low road" would be fully implemented within three to five years, with the interim revised rules commencing from 1 July 2000. This may or may not be contiguous with the next Australian Community Pharmacy Agreement.

RELOCATION

For the agreed period, the existing relocation rules would continue, with modifications to make their operation more equitable and practical, and to better reflect contemporary and evolving trends in health care delivery in and beyond pharmacy. These interim adjustments, which would come into effect from the start of the next agreement, on 1 July 2000, would 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;
- Abolishing the need for ACPA approval of relocations within a 1 kilometre radius, provided that the new premises satisfy any local State or Territory requirements;
- Changing the Determination definition of the "shortest lawful distance door to door" to the "shortest reasonable vehicular 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; and
- Relocations into medical centres, private hospitals with inpatients (without a minimum bed requirement) and aged care facilities (including multi complex facilities) would be treated in the same way as shopping centres – the distance criteria would not apply, although other eligibility and safeguard criteria may be put in place to protect the public interest.

NEW APPROVALS

For the transitional period, the existing rules for new 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 take such factors into account as:

- Local population health characteristics (eg aged persons, persons with chronic illnesses, people with serious disabilities) rather than disadvantaged social groups;
- The proximity of the nearest pharmacy and nearest hospital;
- The local community's ability to support the pharmacy business;
- Easing the GP requirement to being within a reasonable travelling distance (of say 10km) rather than present in a town full or part time; and
- Changing the population definition to reflect a locality's year-round profile, rather than simply the number of permanent residents.

With appropriate eligibility criteria and safeguards against excessive servicing and improper direction of professional pharmacy matters, and provided that a relocation cannot be arranged, consider also new 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.

These "low road" interim arrangements would apply until the restrictions are abolished altogether at the end of the transitional period.

THE AUSTRALIAN COMMUNITY PHARMACY AUTHORITY (ACPA)

Whether or not it operates in a "high road" or a "low road" scenario, there is a case for restructuring the composition and functions of the Authority to ensure that it, and whatever rules it administers, are as responsive as possible to the needs of the community as a whole.

"HIGH ROAD"

There is a case for retaining the ACPA if the current location restrictions are removed.

The Review is attracted to the Productivity Commission's[65] suggestion that, in a deregulated relocation regime the ACPA have a scrutinising role, looking to ensure that the public interest is not affected adversely by the proposed move. In this sense, public interest could be taken into account where it was proposed to relocate a pharmacy into an already saturated market, or the removal of a pharmacy from an area that is already, or would become, underserviced.

"LOW ROAD"

Under the transitional approach the Authority would:

- Be recognised 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 and the Pharmaceutical Society of Australia;
- 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 who should also be a pharmacist; and
- Interpret the Determination rules fairly and consistently. The ACPA in doing so could exercise limited discretion on matters such as distance from the nearest pharmacy, but it should also be required set out the limits of that discretion, and its procedures for dealing with members' conflicts of interest, in published guidelines approved by the Minister.

[65] Productivity Commission submission, page 47.