



Productivity Commission Submission to the National Review of Pharmacy

November 1999

ISBN 1 74037 0546

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An appropriate citation for this paper is:

Productivity Commission 1999, *Productivity Commission Submission to the National Review of Pharmacy*, Canberra, November.

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Foreword

This submission to the National Competition Policy review of pharmacy regulation has its origins in a research project on the community pharmacy sector that followed the Industry Commission's inquiry into the pharmaceutical industry (IC 1996). The Industry Commission had intended to submit that work to the first of the State or Territory National Competition Policy reviews of pharmacy. However, with the agreement by governments to suspend their individual reviews pending the current national review, it did not complete the project.

This submission updates and builds on that previous research. The focus of the Commission's efforts has been on setting out the benefits and costs of the regulations that currently apply to the community pharmacy sector, and canvassing less restrictive ways of meeting the underlying objectives.

The Commission presented an earlier version of the submission to the Review in August. The submission's discussion of price advertising in the pharmacy sector has been modified in the light of input from the Review and other interested parties.

While the Commission has not had the benefit of the public consultation that is available to the Review, it hopes that its submission will provide useful benchmarks for assessing whether the current regulatory restrictions on competition are in the public interest.

Gary Banks

Chairman

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Overview

The community pharmacy sector is an integral part of Australia's health care system. It is the main retail outlet for a wide range of medicines and health care products, including:

- prescription drugs;
- over-the-counter drugs that are available only from pharmacies; and
- 'non-scheduled' drugs and health care products that are also available from other retail outlets.

Community pharmacies also sell a wide range of other goods, including cosmetics and household and personal products, and provide advice to many consumers on the safe and effective use of medicines and other health care issues. Australia's 5000 community pharmacies currently employ some 40 000 people and have a turnover of more than \$6 billion a year.

An array of Commonwealth, State and Territory regulations is in place to encourage the safe and effective use of medicines, to promote equitable access to pharmacy services and to help contain the budgetary cost of the Pharmaceutical Benefits Scheme (PBS).

A number of these regulations also reduce competition in the provision of pharmacy services. For instance, State and Territory regulations generally limit ownership of pharmacies to qualified pharmacists, thereby preventing supermarkets and other general retailers from offering pharmacy services. Similarly, Commonwealth regulations limit the number and location of pharmacies approved to dispense PBS drugs and prohibit pharmacists from competing for business by discounting patient charges for subsidised PBS drugs.

These restrictions on competition accordingly inflate the costs of pharmacy services and reduce consumer convenience. They have also retarded the development of alternatives to conventional pharmacy services — including mail-order pharmacy, which is widely used in a number of other countries.

The National Competition Policy review of pharmacy

This Review of pharmacy regulation is occurring in accordance with the requirements of the Competition Principles Agreement. The agreement commits all Australian governments to dismantle anti-competitive legislation unless that legislation can be shown to be in the public interest, and restrictions on competition are the only way of achieving the underlying objectives.

The Commission sees this Review as being very significant. Community pharmacy is important both economically and socially. At the same time, the large and growing cost of drug treatments makes it imperative that pharmacy services are delivered efficiently as well as effectively.

In looking at the regulatory arrangements for the sector, the Commission has not made judgements as to whether particular regulations are in the public interest. This is properly a task for the Review, which can draw on public consultation and feedback to help inform it. Rather, the Commission has sought to:

- discuss the benefits and costs of the regulations for consumers, pharmacists and the wider community; and
- canvass alternative ways of meeting the underlying objectives.

In undertaking such assessments, the need to promote the safe use of medicines and to ensure adequate access to high quality pharmacy services will continue to be fundamental objectives. However, the Review will need to assess whether some of the current regulations go beyond what is necessary to meet these objectives and thus involve an unnecessary burden for the community.

What role for competition?

Significantly, a number of other developed countries have determined that there are advantages in using competition to encourage the efficient delivery of pharmacy services. Drawing on approaches in these countries, the Commission has explored two broad options which would encourage greater competition in the provision of pharmacy services, while still addressing the objectives of the current regulatory regime:

 a package of relatively modest changes, including: some easing of ownership restrictions; fine tuning of licensing and drug scheduling requirements; changes to the basis for remunerating pharmacists for dispensing some PBS drugs; and modifications to the location controls; and a 'pro-competitive' reform package, involving: the abolition of most ownership
controls (together with any premises requirements that prevent general retailing
outlets offering pharmacy services); facilitation of price advertising by
pharmacists (including an end to the prohibition on the discounting of patient
charges for subsidised PBS drugs); a reduced role for the Commonwealth in
determining pharmacists' remuneration for dispensing subsidised PBS drugs;
and the abolition of controls on new pharmacy approvals and pharmacy
relocations.

Several of these regulations are not expressly covered by the terms of reference for the Review. However, the interaction among the various regulations highlights the need to adopt a broad perspective when looking at future arrangements for the pharmacy sector.

In putting these options forward, the Commission has tried to provide the Review with some indicative benchmarks against which to assess the current arrangements. It has outlined the broad impacts of these alternatives and, as far as possible, indicated whether they are likely to be significant.

Social and adjustment issues

In canvassing policy alternatives, the submission recognises that there are likely to be adverse impacts for some consumers. In particular, relaxation of ownership controls would probably result in fewer pharmacies in suburban areas of the major cities and towns, and possibly in some small country towns.

That said, maintaining the current regulations will not prevent possibly significant changes in the distribution of pharmacy services. For example, despite the ownership controls, some suburban pharmacies are finding it difficult to survive in the face of the trend for consumers to shop in major shopping complexes. Similarly, the relocation controls have not been able to sustain pharmacies in some small country towns where demographic changes are reducing the customer base. In some of these towns, greater competition might in fact improve access to pharmacy services. For instance, scope to offer pharmacy services within supermarkets and other general retail outlets could reduce the minimum population required to support a pharmacy service.

More broadly, adverse access effects for a relatively small number of consumers are not, by themselves, sufficient reason to reject greater competition. Indeed, their very existence would indicate a benefit to the majority of consumers from cheaper prices, better service and/or greater convenience.

Moreover, it will be important for the Review to examine policy alternatives that deal with access issues directly, rather than by restricting competition. For example, facilitating the development of mail-order pharmacy would be one way of assisting those consumers without access to conventional pharmacy services in both city and country areas.

The submission also recognises that a more competitive pharmacy market would almost certainly lead to some employment losses in the sector, and reduce the value of some pharmacies. The provision of adjustment assistance would be one way of addressing such impacts, while still allowing consumers to benefit from a more competitive market. Indeed, adjustment assistance might have a role as a 'circuit breaker' in a sector where regulatory change has proved difficult to achieve in the past. That said, industry-specific adjustment assistance has a number of drawbacks, particularly if it involves financial compensation to the owners of businesses.

In sum, this submission suggests that the careful implementation of greater competition in the pharmacy sector has the potential to provide cost savings and convenience benefits to a wide range of consumers, as well as reducing the cost of the PBS for taxpayers. Thus, if this Review were to recommend continuation of the current regulatory restrictions on competition, it would need to demonstrate why the other ways of meeting safety and access objectives would be ineffective or inappropriate.

1 Introduction

The community pharmacy sector is an integral part of Australia's health care system. It is the main retailing network for a wide range of medicines and health care products. Community pharmacists also provide advice to many consumers on the safe and effective use of medicines and other health care issues.

An array of government regulations apply to the sector. At the State/Territory level, licensing requirements for pharmacists, ownership restrictions, scheduling requirements (that prescribe which medicines must be sold through pharmacies) and regulations governing the promotion of medicines have been in place for many years. At the Commonwealth level, the Pharmaceutical Benefits Scheme (PBS) is a major source of pharmacy income. As well as regulating remuneration to pharmacists for dispensing PBS drugs, the Commonwealth controls the establishment of new pharmacies and the relocation of existing pharmacies. Like the States and Territories, it also regulates the promotion of medicines.

The rationale for these regulations is to improve economic and social outcomes:

- The aim of most State and Territory regulations is to promote the delivery of quality pharmacy services and to encourage the safe and effective use of medicines.
- The Commonwealth PBS regulations are designed to promote equitable access to pharmacy services and (along with a range of other measures) to contain the budgetary cost of the scheme.

However, there have been long standing concerns about the anti-competitive effects of the regulations. In this regard, a number of studies — Ralph 1979, BIE 1985, IAC 1986 and the NCA 1996 — have argued that an important effect of the regulations is to increase drug dispensing costs and thereby drug prices.

This national review of pharmacy is being conducted in accordance with the requirements of the Competition Principles Agreement, under which all Australian governments have undertaken to reform anti-competitive legislation unless:

- the benefits to the community as a whole from the restriction on competition outweigh the costs; and
- restrictions on competition are the only way to realise those benefits.

The focus of the Review is on:

- State and Territory legislation governing pharmacy ownership and the registration of pharmacists; and
- Commonwealth legislation relating to the location of pharmacies approved to dispense drugs subsidised under the PBS.

The Commission sees this Review as being significant, particularly for community pharmacy which employs around 80 per cent of Australia's pharmacists. Community pharmacy is very important both economically and socially. At the same time, the large and growing cost of drug treatments makes it imperative that pharmacy services are delivered efficiently as well as effectively. Given the interrelated nature of the State and Territory and Commonwealth regulations, the Commission welcomes the multi-jurisdictional focus of the Review.

The Commission's predecessors undertook a range of work germane to the sector. This included two major reviews of the pharmaceutical industry (IAC 1986 and IC 1996). Also, as a follow-on to the latter review, the Industry Commission commenced a more specific research project on the community pharmacy sector which it had intended to submit to the first of the State or Territory National Competition Policy reviews. However, with the agreement by governments to suspend their individual reviews pending the current national review, the Commission did not complete the project. This submission updates and builds upon that previous research.

In this submission, the Productivity Commission has not sought to come to firm conclusions on whether particular regulations are in the public interest. This is properly the task for the Review, which can draw on public consultation and feedback to help inform it. Rather, the Commission has sought to:

- discuss the benefits and costs of the key regulations for consumers, pharmacists and the wider community; and
- canvass the merits of alternative ways of meeting the objectives of the current regulations.

Assessment of the costs and benefits of the current restrictions and of alternative approaches will be an integral part of the Review.

² PHARMACY SUBMISSION

The Commission's submission does not cover all of the areas that the Review is addressing. For example, the submission is only concerned with community pharmacy and does not look at issues relating to pharmacists employed in hospitals and clinics, or engaged in research. Nor does the submission address the potential ramifications for pharmacy regulation of any wider changes in the health care system.

At the same time, the submission comments on some matters that are not expressly covered by the terms of reference for the Review. For instance, it describes how medicines and poisons scheduling and reimbursement to pharmacists for dispensing PBS drugs interact with the ownership controls. In the Commission's view, these sorts of interactions highlight the value of adopting a broad perspective. Similarly, the Discussion Paper released for this Review notes in relation to the concurrent National Competition Policy review of medicines and poisons scheduling:

Jurisdictions may also need to look at the findings and recommendations of both reviews in order to implement effective regulatory structures and arrangements in the pharmacy profession. (NCPRP 1999, p.6)

By way of background, the submission also provides an overview of the community pharmacy sector and the current regulatory framework.

2 The community pharmacy sector

2.1 Introduction

There are about 5000 community pharmacies in Australia. Together, they constitute the main retail outlet for prescription and other medicines. In addition, they sell health care, cosmetic, household and personal products, provide advice to consumers about medication and health care, and deliver ancillary medical services such as blood pressure and cholesterol testing.

Total turnover in the sector was close to \$6 billion in 1995–96 (the latest year for which such data are available). The sector employs around 40 000 salaried pharmacists and trained assistants (Pharmacy Guild 1999a).

An array of Commonwealth, State and Territory regulations (see chapter 3) influence the sector's functions and structural characteristics. Technological developments have also had an impact. In particular, the greater availability of prepackaged medicines has reduced the pharmacist's compounding role. Concurrent with this development has been the trend for pharmacies to diversify into the retailing of cosmetic, household and personal products.

This chapter looks at the functions and structural characteristics of the sector. While some of the available statistical information is dated, it nonetheless helps to set the scene for the discussion of the regulatory environment that follows.

2.2 Functions

Dispensing and other retailing

Pharmacies sell a diverse range of products including:

• prescription drugs whose supply must be approved in writing by a medical practitioner;

- over-the-counter drugs that are available only from pharmacies;
- less potent over-the-counter drugs that are also available from general retail outlets; and
- other health care and non-therapeutic products including cosmetics, household items such as photographic film and batteries, and personal products such as shampoos and nappies.

Community pharmacies dispensed most of the 170 million prescriptions supplied Australia-wide in 1997–98. (A small proportion was dispensed by private hospitals and approved doctors in remote locations). Some 124 million, or more than 70 per cent, of these prescriptions were subsidised under the Pharmaceutical Benefits Scheme (PBS) and the Repatriation Pharmaceutical Benefits Scheme. Most of the remainder were prescriptions for PBS drugs supplied to general users for whom no subsidy was applicable (DHFS 1998).

Sales of prescription drugs have become increasingly important for most pharmacies. In 1995, they accounted for over 60 per cent of the value of total pharmacy sales, compared with 40 per cent in 1981 (Pharmacy Guild 1995). While virtually all pharmacies have experienced growth in the share of prescription sales, larger pharmacies rely less on these sales than smaller ones (Nielsen 1996).

The increased share of prescription drugs has come mainly at the expense of those drugs and other products which are also available from general retailers. Pharmacy market shares for products subject to competition from general retailers vary widely — for example, over 50 per cent for infant formulae, 20 per cent for disposable nappies and 7 per cent for toothbrushes. That said, it appears that, over time, pharmacies have been losing market share in most of these products (Nielsen 1996).

The increasing reliance of pharmacies on prescription drug sales is significant given that remuneration for dispensing subsidised PBS drugs is regulated. As described in chapter 3, this remuneration consists of a regulated mark-up on wholesale drug prices, plus a dispensing fee negotiated between the Commonwealth and the Pharmacy Guild. In 1992–93, Commonwealth remuneration to pharmacists for dispensing PBS drugs amounted to about \$500 million (NCA 1996, p. 320), or around one-third of total Commonwealth expenditure on the scheme. If this share has remained the same, remuneration to pharmacists for PBS dispensing in 1997–98 would have been around \$900 million, or some \$180 000 a pharmacy.

But it is important to note that, through their dispensing practices, pharmacists can help to contain PBS expenditure. Since the relaxation of 'generic substitution'

provisions in 1994, pharmacists have been able to dispense a lower-priced brand of a drug, provided:

- the relevant schedule specifies that it is interchangeable with the brand prescribed by the medical practitioner; and
- the practitioner does not expressly forbid substitution.

Monitoring drug use and administrative functions

Allied to the dispensing function, pharmacies store medicines and maintain patient medication records. Developments in computer technology have enhanced the scope for, and level of, record keeping and patient monitoring.

Pharmacies also carry out some PBS-related administrative tasks previously performed by the Health Insurance Commission. These include verifying entitlements to PBS drugs at concessional prices, inserting prescriber numbers and updating prescription record forms. Pharmacies receive a fee for carrying out these functions.

Further, some pharmacies provide agency type services for other organisations. For example, a significant number of pharmacies in rural and remote areas act as agents for Medicare and some of the health funds. And, in a joint venture between the Pharmacy Guild and Bank West, pharmacies will soon be offering a range of banking services.

Advice and counselling

Community pharmacists provide advice and counselling to consumers on drug therapy, treatment of minor ailments and injuries, the appropriateness of over-the-counter drugs and preventive health. There is, thus, scope for pharmacists to help treat minor illnesses and to provide drug support for more serious chronic, but stable, conditions, without the need for ongoing involvement by medical practitioners. This can reduce the overall cost of health care.

However, the extent and value of counselling provided to consumers is not easy to measure.

Pharmacists claim that such services are increasingly offered and used. A 1994 industry survey of pharmacy customers indicated that close to 60 per cent of respondents received some type of counselling from the pharmacist on their last script. Further, the survey indicated that nearly two-thirds of pharmacies

provided specialist counselling on diabetes, asthma, blood monitoring and other health related areas to an average of 7 per cent of patients. There was little variation in the reported level of counselling between pharmacies (Pharmacy Guild 1995).

- In contrast, a survey on asthma medication by the Australian Consumers Association (ACA 1997) raised questions about the adequacy of pharmacy counselling. The ACA reported that, when giving counselling and advice about asthma medication, almost half of the pharmacies surveyed had failed an expert panel's criteria for acceptable practice. The panel rated fewer than one third of pharmacies as 'good' or 'excellent'.
- And, a 1998 survey by the Evaluation Committee of the National Asthma Council found that while pharmacists' knowledge of asthma symptoms and preventive medication has improved significantly since 1991, there are still some problems. The survey found, for example, that around 40 per cent of respondent pharmacists 'seldom or never' recommended the use of a peak flow meter, or educated clients in the use of peak flow readings. Further, some 10 per cent of respondents 'seldom or never' refer patients on non-prescription asthma medication to a medical practitioner (Gattera et al 1998, p.976).

Pharmacists also provide advice on the appropriate use of medication by patients in nursing homes. The 1994 industry survey indicated that around one-third of pharmacists provided this service (Pharmacy Guild 1995). The Commonwealth provides extra remuneration to pharmacists who conduct medication reviews in nursing homes (see chapter 3).

2.3 Structural characteristics

Industry size

As noted, in 1995–96, turnover in the community pharmacy sector was close to \$6 billion, or about 5 per cent of total retail turnover in Australia. In that year, pharmacy turnover was only marginally less than in takeaway food retailing (\$7 billion) and higher than in newspaper, book and stationery retailing (\$5 billion).

Pharmacy numbers and restructuring

There are currently around 4950 community pharmacies in Australia catering on average for about 3800 people each (DHFS 1998). The number of pharmacies is well below the peak of nearly 6000 in the early 1970s, equivalent to an average of one pharmacy for just over 2000 people (see figure 2.1).

7 000 6 000 5 000 4 000 3 000 2 000 1 000 1960 2000 1965 1970 1975 1980 1985 1990 1995

Figure 2.1 Number and population ratio of community pharmacies, 1960 to 1999

Sources: DHFS 1996, 1997 and 1998; DHSH various years; and Feros 1992.

Most of the decline in pharmacy numbers occurred between 1990 and 1995 and reflected restructuring agreed to by the Commonwealth and the Pharmacy Guild. A desire to promote economies of scale in dispensing, and thereby to contain the cost to the Commonwealth of dispensing PBS drugs, underscored the restructuring arrangements (see chapter 4). For its part, the Commonwealth provided over \$40 million to facilitate 630 pharmacy closures and 64 amalgamations. Over the five-year period, only 72 new pharmacies were approved to dispense PBS drugs.

The restructuring arrangements targeted pharmacies with low PBS prescription volumes (see table 2.1). Partly as a result of the restructuring, there was a one-third increase in the average number of PBS prescriptions dispensed by pharmacies between 1989–90 and 1993–94 (Demirian 1995).

Nonetheless, average dispensing volumes in Australia have remained well below the level required to exhaust scale economies (see chapter 4). In 1997–98, Australian pharmacies dispensed around 35 000 prescriptions on average (DHFS 1998), roughly the same volume as at the end of the restructuring program. Moreover, towards the end of that program, the large majority of pharmacies still had dispensing volumes below the 35 000 average (see figure 2.2).

Table 2.1: Closures and amalgamations of pharmacies, 1990–91 to 1993–94^a

| PBS prescriptions processed | Number of pharmacy closures | Number of amalgamations | Total reduction |
|-----------------------------|-----------------------------|-------------------------|-----------------|
| 0 - 5 999 | 125 | 21 | 146 |
| 6 000 - 11 999 | 278 | 15 | 293 |
| 12 000 - 17 999 | 136 | 13 | 149 |
| 18 000 - 23 999 | 42 | 11 | 53 |
| 24 000 - 29 999 | 13 | 1 | 14 |
| 30 000 - 35 999 | 6 | 0 | 6 |
| 36 000 - 41 999 | 2 | 1 | 3 |
| 42 000 - 47 999 | 0 | 0 | 0 |
| 48 000 + | 1 | 0 | 1 |
| Total | 603 | 62 | 665 |

^a Excludes closures and amalgamations under the provisions of the 1990–95 agreement between the Pharmacy Guild and the Commonwealth which occurred after June 1994. As noted in the text, there were a total of 630 pharmacy closures and 64 amalgamations under the agreement.

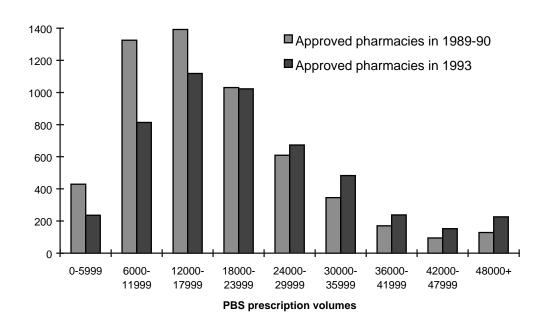
Source: Demirian 1995.

Location

In June 1998, nearly 73 per cent of pharmacies were located in urban areas. On average, across Australia, urban and rural pharmacies served similar populations (see figure 2.3), although there were some significant variations in particular jurisdictions (DHFS 1998). An objective of Commonwealth policy — reflected in requirements relating to the approval of new pharmacies and the relocation of existing pharmacies (see chapter 3) — is to have similar pharmacy to population ratios across Australia.

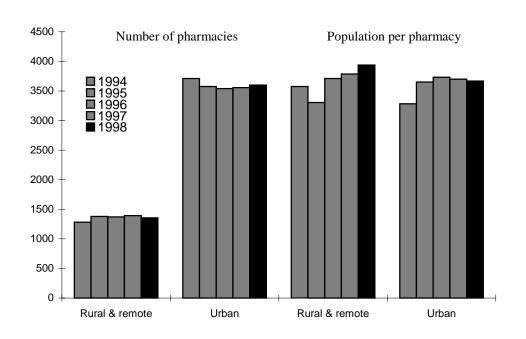
The large majority of community pharmacies are located in smaller shopping centres. Reflecting this, in 1995, more than 72 per cent of community pharmacists worked in non-mall complexes. Around 21 per cent worked in shopping malls and about 6 per cent in medical centres (AIHW 1998). As discussed in chapter 4, State and Territory ownership restrictions and the Commonwealth's location controls help to explain the relatively small proportion of pharmacies located in major shopping centres.

Figure 2.2 Distribution of pharmacies by PBS prescription volumes



Source: Demirian 1995.

Figure 2.3 Geographical distribution of pharmacies, 1994 to 1998



Source: DHFS various years

Ownership and supply arrangements

Ownership

Individual pharmacists own more than 50 per cent of Australia's pharmacies, with most of the remainder owned by partner-proprietors (AIHW 1998). This ownership structure reflects State regulations that generally preclude corporate ownership by non-pharmacists and limit the number of outlets an individual pharmacist can own (see chapter 3).

Supply arrangements

Pharmaceutical wholesalers distribute most drugs sold by pharmacies. For PBS drugs, Commonwealth regulation provides for a wholesaling margin of 10 per cent of the negotiated price to the manufacturer. However, in the major population centres, this margin is often discounted. Because of the Commonwealth prohibition on discounting patient charges for subsidised PBS drugs (see chapter 3), these discounts often add to the pharmacist's margin.

Pharmaceutical wholesalers also act as guarantors for many pharmacists seeking to finance new pharmacy ventures or pharmacy improvements, relocations or mergers. And, many pharmacists hold shares in wholesalers.

Another feature of supply arrangements are pharmacy buying groups designed to take advantage of high volume buying power. At the time of the Nielson Report in 1996, there were about 20 such groups having more than 3000 members. The biggest were Amcal and Buyrite with more than 600 members each, and Chemmart and Health Care with over 300 members each (Nielsen 1996).

Employment

In 1995 — the most recent year for which comprehensive data are available — Australia had around 13 500 employed pharmacists. Nearly 80 per cent of these worked in community pharmacy, with most of the remainder working in hospitals or clinics. Of the 10 700 community pharmacists, around 5000 were sole or partner proprietors, with the rest working as salaried pharmacists (AIHW 1998).

Pharmacies also employ a significant number of trained assistants. According to the Pharmacy Guild (1999b), trained assistants account for some 25 000 of the 40 000 persons employed in the sector. ABS census data for the early 1990s indicated that

nearly three-quarters of the pharmacy work force was female and that about half of pharmacy employees worked part-time (ABS 1993).

Profitability

Published information on profitability in the community pharmacy sector is very dated. ABS census data indicate that, in 1991–92, pharmacies were generally more profitable than many other retailing businesses:

- Pharmacies had rates of returns on assets and net worth of 17 and 37 per cent respectively. These rates compared favourably with the respective 'all retailing' averages of 7 and 30 per cent.
- The average pharmacy operating profit margin was several times greater than the all retailing average 8 per cent compared to 2 per cent.
- While pharmacy unit labour costs were close to the retailing average, pharmacy operating profit per person employed was much higher \$8500 compared to \$3300 (ABS 1993).

Caution is, however, required in comparing pharmacy profitability with that in other retailing activities. For example, higher profits in the pharmacy sector might partly reflect the return to a greater investment in human capital than in many other areas of retailing. Thus, comparison with profitability in other professional services such as conveyancing and will drafting could also be relevant. Further, the average data reported above may conceal significant variations in profitability across regions and between urban and rural areas.

Nonetheless, the data above are not in conflict with the view that the regulatory arrangements for community pharmacy underpin relatively high rates of return in the sector. Further, Demirian (1996) reports that average gross pharmacy margins in 1994–95 were nearly 5 per cent higher than in the previous year, following the significant industry restructuring of the early 1990s. And, the need for the Commonwealth to restrict new pharmacy approvals (see chapter 3) is an indirect indication of sound profitability, at least in the major population centres.

2.4 Mail-order pharmacy

In looking at the market for pharmacy services, it is important to recognise that there are substitutes for conventional face to face services. A case in point in mail-order pharmacy.

Mail-order pharmacy is a system in which consumers mail, e-mail or fax their medication requirements to a central dispensing centre staffed by qualified pharmacists. Medications are then mailed or couriered to patients, with accompanying written advice on safe and effective usage of those medications. Mail-order pharmacies may also offer a phone service to consumers who have additional questions.

Mail-order pharmacy has long been used in Australia to provide medications to consumers in remote locations. More recently, Pharmacy Direct has operated a mail-order business based in New South Wales supplying medications to consumers anywhere in Australia. There are also international mail-order pharmacy businesses offering to supply anywhere in the world.

There is evidence of growing demand for mail-order pharmacy services in Australia, largely as a result of the significant price savings on offer. Apparently, Pharmacy Direct's prices for both prescription and non-prescription items are as much as 50 per cent below the prices in major community pharmacies (Wilson 1999). Significant price savings have also been a feature of mail-order systems in a number of overseas countries (see box 5.2).

However, the market share of mail-order pharmacy in Australia is still very small. As discussed in chapter 5, this is partly a result of the regulatory arrangements.

3 Current regulatory arrangements

The community pharmacy sector is subject to an array of government regulations:

- State and Territory regulations govern the licensing of pharmacists and pharmacy premises, pharmacy ownership, advertising of medicines, and poisons (and medicines) distribution.
- Commonwealth regulations apply to the advertising of medicines and to the pharmacy component of the Pharmaceutical Benefits Scheme (PBS) including the prices charged to consumers for PBS drugs, pharmacists' dispensing fees and pharmacy location.

Box 3.1 summarises the main regulations.

The regulations, which are partly a product of history, aim to meet a range of objectives including:

- promoting equitable access for consumers to pharmacy services;
- ensuring service quality and promoting the safe use of medications;
- providing information to consumers;
- promoting pharmacy as a profession; and
- containing the cost of drugs supplied under the PBS.

However, there are concerns that, in pursuing these objectives, the regulations unnecessarily reduce competition in the provision of pharmacy services.

As a backdrop to the discussion in chapter 4 on the benefits and costs of the regulatory regime, this chapter provides a description of the key regulations and the Commission's understanding of how, in the broad, they operate.

Box 3.1 Key regulations affecting the community pharmacy sector

State and Territory

- Licensing requirements for pharmacists and pharmacy premises. Amongst other things, these cover:
 - educational qualifications and experience;
 - recognition of overseas trained pharmacists; and
 - premises (and site) standards.
- Regulation of pharmacy ownership. In most jurisdictions, the provisions generally:
 - limit ownership to qualified pharmacists (and thereby largely preclude corporate ownership by non-pharmacists);
 - limit the number of pharmacies owned; and
 - require a pharmacist to be in attendance at all times a pharmacy is open for business.
- · Controls on poisons (and medicines) distribution.
- Controls on advertising relating to the promotion of:
 - more potent medicines to the public; and
 - pharmacy services.

Commonwealth

- Regulations relating to the PBS. These include provisions that:
 - set pharmacists' dispensing fees;
 - prohibit the discounting of consumer contributions for subsidised PBS drugs;
 - control the location of new and established pharmacies approved to dispense PBS drugs; and
 - provide additional payments to pharmacies in isolated and remote locations.
- Controls on advertising relating to:
 - the promotion of more potent medicines to the public; and
 - misleading advertising.

3.1 State and Territory regulations

Although there is considerable variation across the State and Territories in the details of pharmacy regulations, the broad thrust and intent of the regulations have much in common.

Licensing of pharmacists and pharmacy premises

All States and Territories have Pharmacy Acts that, amongst other things, require the licensing (or registration) of pharmacists. And many require the licensing of pharmacy premises.

The Acts are, in the main, administered by State and Territory Pharmacy Boards. The Boards are self-funding statutory bodies under the direct or indirect control of State and Territory health departments.

Pharmacists

To be licensed as a pharmacist in a State or Territory, an applicant must meet specific standards. These pertain to education and experience as well as to personal qualities (for example, having no criminal record and/or being a 'fit and proper' person).

Although the standards for Australian-trained pharmacists vary somewhat between States and Territories, mutual recognition legislation requires the States and Territories to accept the requirements of other jurisdictions.

Requirements relating to the licensing of overseas-trained pharmacists also vary across jurisdictions, particularly in regard to the automatic recognition of overseas qualifications. For example, in New South Wales, only applicants from New Zealand gain automatic recognition whereas, in South Australia, qualifications awarded in Great Britain, Northern Ireland and Ireland are also automatically recognised. In some of the other jurisdictions, the basis for automatic registration is a qualification from a recognised institution, rather than a recognised country.

For Australian-trained pharmacists, education and experience standards have increased significantly over the years — from apprenticeship, through college training to a university degree. (The requirement for graduate entry into the pharmacy profession became mandatory across Australia in 1972.) Most States and Territories now require the completion of a three year Bachelor of Pharmacy degree course and a one year pre-registration traineeship under the supervision of a registered pharmacist.

Pharmacy premises

A number of Pharmacy Acts specify requirements that pharmacy premises must meet in order to be registered. These include physical requirements relating to space, ventilation, lighting, sanitation, fittings, cleanliness, security of premises and public access to the premises. Some of the Acts also prohibit the installation and use of drug vending machines and the operation of pharmacies within supermarkets and other similar retail outlets. An example of the last type of provision is given in Section 27(2) of the *Victorian Pharmacists Act 1974* which specifies that:

[The Victorian Pharmacy Board] may refuse to approve of the use of any premises as a pharmacy if the premises are freely accessible to persons from other premises where a business other than that of a pharmacist is carried out.

Victorian Pharmacy Board guidelines (1996) amplify this requirement, stating that premises are only suitable for pharmacy practice if they do not have access to other premises and do not have any other businesses conducted in them.

Premise requirements are also embodied in State and Territory poisons and drug legislation, and in Commonwealth controls on the location of pharmacies (see below).

Pharmacy ownership

All States regulate the ownership of pharmacies. While the wording of some of the State Pharmacy Acts leaves scope for interpretation, the thrust of the legislation is to:

- restrict ownership of pharmacies to pharmacists, and thereby largely preclude corporate ownership by non-pharmacists; and
- restrict the number of pharmacies a pharmacist can own or have a financial interest in (see table 3.1).

The main exception to the prohibition of ownership by non-pharmacists is provision in a number of States for friendly societies to distribute medicines to their members. Across Australia, friendly societies operate around 70 pharmacies.

Pharmacy Acts in the Territories are silent on ownership issues. For example, the Northern Territory *Pharmacy Act 1996* requires only that a pharmacy be managed by a pharmacist.

However, restriction of ownership to pharmacists is the accepted policy in these jurisdictions (NCPRP 1999, p. 10).

In addition to ownership controls, all States and Territories have regulations requiring that a pharmacist be in attendance when a pharmacy is open for business.

Table 3.1 Restrictions on pharmacy ownership

| Jurisdiction | Number of pharmacies a pharmacist may own | Ownership by non-pharmacists |
|------------------------------|---|---|
| New South Wales | 3 ^a | Not permitted |
| Victoria | 3 | Friendly societies, registered funded agencies, private hospitals and privately-operated recognised hospitals |
| Queensland | 4 | Friendly societies |
| South Australia | 4 | Friendly societies and prescribed relatives of pharmacists |
| Western Australia | 2 | Friendly societies |
| Tasmania | 2 ^b | Friendly societies |
| Australian Capital Territory | Unlimited | No formal restriction ^c |
| Northern Territory | Unlimited | No formal restriction ^c |

^a Also permitted are 1 additional partnership in an 'after hours' pharmacy and any number of approved branch pharmacies.

Source: NCPRP 1999, p. 45.

Poisons (and medicines) distribution

The distribution in Australia of medicines and poisons is subject to specific State and Territory legislation. That legislation contains provisions covering the classification (or 'scheduling') of medicines and poisons and the labelling, packaging and advertising (see below) of these items. This legislation is the subject of a concurrent National Competition Policy review.

In an attempt to achieve scheduling uniformity across Australia, the National Drugs and Poisons Schedule Committee (made up of State, Territory and Commonwealth officials) publishes the *Standards for the Uniform Scheduling of Drugs and Poisons* (SUSDP). This classifies medicines and poisons into (effectively) eight schedules, according to their use and potency (see box 3.2). Medicines for human use usually fall into the following schedules:

- Schedule 4 (S4) medicines restricted to supply by prescription and dispensed through pharmacies;
- Schedule 3 (S3) over-the-counter medicines which must be supplied under the direct supervision of a pharmacist, medical or dental practitioner; and

b Also permitted is 1 additional 'after hours' pharmacy (or 2 additional 'after hours' pharmacies if the pharmacist already owns 2 other pharmacies).

c Restriction of ownership to pharmacists is, however, accepted practice — see text.

| Box 3.2 | Schedule descriptions in the Standards for the Uniform Scheduling of Drugs and Poisons | |
|----------------------------|---|--|
| Schedule 1 | Currently inoperative | |
| Schedule 2 | Poisons for therapeutic use that should be available to the public only from pharmacies; or where there is no pharmacy service available, from persons licensed to sell schedule 2 poisons. | |
| Schedule 3 | Poisons for therapeutic use that are dangerous or are so liable to abuse as to warrant their availability to the public being restricted to supply by pharmacists or medical, dental or veterinary practitioners. | |
| Schedule 4 | Poisons that should, in the public interest, be restricted to medical, dental or veterinary prescription or supply, together with substances or preparations intended for therapeutic use, the safety or efficacy of which requires further evaluation. | |
| Schedule 5 | Poisons of a hazardous nature that must be readily available to the public but require caution in handling, storage and use. | |
| Schedule 6 | Poisons that must be available to the public but are of a more hazardous or poisonous nature than those classified in Schedule 5. | |
| Schedule 7 | Poisons which require special precautions in manufacture, handling, storage or use, or special individual regulations regarding labelling or availability. | |
| Schedule 8 | Poisons to which the restrictions recommended for drugs of dependence by the 1980 Australian Royal Commission of Inquiry into Drugs should apply. | |
| Schedule 9 | Poisons which are drugs of abuse, the manufacture, possession, sale or use of which should be prohibited by law except for amounts which may be necessary for medical or scientific research conducted with the approval of Commonwealth and/or State Health Authorities. | |
| Source: AHMAC 1994, p. vii | | |

 Schedule 2 (S2) — over-the-counter medicines which are restricted to supply through pharmacies or licensed sellers who are more than 25 kilometres from the nearest pharmacy.

Notably, a medicine can be classified in different schedules depending on the package size. The common analgesics — aspirin and paracetamol — are a case in point. Packages of 50 capsules are classified as S2 and, thus, can only be sold by pharmacies. In contrast, smaller packages are non-scheduled and may, therefore, be sold by general retail outlets.

In addition to scheduling medicines and poisons, the *Standards* also contains specific requirements relating to labelling, in-pharmacy access, dosage and the sale of scheduled substances.

However, the *Standards* has no legal standing as such — its implementation is determined by individual States and Territories.

Consequently, there can be differences across jurisdictions in the classification of medicines and in the controls imposed under each schedule. For example, the Commission understands that:

- Queensland legislation requires that S2 medicines be stored out of public reach and prohibits their supply to persons under the age of 18, except on prescription. In contrast, in NSW, S2 medicines may be stored on shelves, while in the ACT, no restrictions on public access within a pharmacy apply.
- Some States and Territories specify that S3 medicines be stored in the dispensary, while others require only that they be stored in a place not readily accessible to the public.

Advertising

A combination of overlapping and complex Commonwealth, State and Territory regulations and (self-regulatory) industry codes govern the advertising of medicines and pharmacy services. This sub-section briefly outlines the main State and Territory controls in this area; namely, poisons and medicines legislation, State and Territory Pharmacy Acts, and Pharmacy Board guidelines. Commonwealth regulation of advertising is described in the next section.

Advertising of medicines

State and Territory medicines and poisons legislation regulates the advertising of more potent medicines. Direct advertising of S4 and brand advertising of many S3 medicines to the public is prohibited. Manufacturers can, however, advertise these medicines to health professionals and pharmaceutical wholesalers.

Brand advertising to the public of S2 and 'excepted' S3 medicines is permitted. However, the legislation contains provisions governing the content of such advertisements. These content provisions pick up many of the requirements in the Therapeutic Goods Advertising Code.

The State and Territory advertising provisions parallel provisions in the Commonwealth Therapeutic Goods Act (see section 3.2). Any differences between the two sets of regulations are generally small. Indeed, some jurisdictions have adopted the Commonwealth regulations by reference. In essence, the Commonwealth regulations apply to medicines that are traded interstate, whereas the State and Territory regulations apply to medicines traded interstate. The State and Territory regulations may also apply to medicines traded interstate if particular provisions are more stringent than the comparable provisions in the Commonwealth regulations.

Advertising of pharmacy services

Some State and Territory pharmacy legislation imposes controls on the advertising of pharmacy services to the public. For instance, under regulation 16 of the NSW *Pharmacy (General) Regulation 1998*:

An advertisement that relates to a pharmacy or pharmacy services must not:

- a) be false, misleading or deceptive, or
- b) create an unjustified expectation of beneficial treatment or give any warranty of satisfaction, or
- c) promote the unnecessary or inappropriate use of pharmacy services, or
- d) claim or imply superiority for a pharmacist in the practice of pharmacy.

Pharmacy Boards are given discretion to interpret such controls, or to implement controls where none expressly exist under legislation. The Boards have developed guidelines (including codes of ethics) which have in the past restricted aspects of advertising and promotion.

3.2 Commonwealth regulations

The PBS

The PBS is a Commonwealth Government scheme that subsidises the cost to consumers of a wide range of medicines. The objectives of the scheme are:

• to provide access for the Australian community to necessary, cost effective medicines; and

• to secure a reliable supply at the most reasonable cost to Australian taxpayers and consumers, consistent with maintaining a sustainable pharmaceutical industry in Australia (DHFS 1998, PBPA 1998).

Over time, Government expenditure on the PBS has increased more rapidly than for other components of health care. For example, between 1992–93 and 1996–97, government expenditure increased by nearly 12 per cent a year in real terms, with a further 8 per cent real increase in 1997–98. As a share of GDP, government expenditure on the PBS has risen by some 70 per cent since the beginning of the 1990s (DHFS 1998, p. 84).

Part of this expenditure growth reflects the continuing development of new and relatively expensive drug treatments.

Nonetheless, for many years, the Commonwealth has sought to contain its expenditure on the scheme through:

- controlling prices paid to manufacturers;
- assessing the cost-effectiveness of new drug therapies relative to drugs already listed on the scheme:
- restricting the prescribing of certain highly expensive treatments;
- removing drugs used to treat less serious ailments from the scheme;
- setting subsidies on the basis of the cheapest drug in a particular drug group;
- using patient contributions (copayments) to shift an increasing proportion of costs onto consumers and, in so doing, provide them with a financial incentive to avoid unnecessary medication usage (see box 3.3);
- controlling remuneration to pharmacists for dispensing PBS drugs; and
- attempting to encourage a more efficient community pharmacy sector, through measures such as restructuring assistance and controls on new pharmacy approvals.

The measures specific to the pharmacy sector have involved the introduction of Commonwealth regulations that sit on top of State and Territory regulations.

Pharmacists' remuneration for dispensing PBS drugs

The remuneration to pharmacists for dispensing PBS drugs is determined by the Pharmaceutical Benefits Remuneration Tribunal on the basis of submissions put forward by the Commonwealth, the Pharmacy Guild and other interested parties.

The current determination is based on an agreement negotiated by the Commonwealth and the Pharmacy Guild covering the period 1995–2000.

Box 3.3 Patient contributions for PBS drugs

The Commonwealth introduced copayments for general users (in 1960) and concessional users (in 1983) to discourage unnecessary PBS drug use, and thereby to contain its expenditure on the scheme. Currently, general users pay a maximum of \$20.30 per prescription, with a maximum annual expenditure of \$620.60 for each individual or family, after which the price per prescription falls to \$3.20. Concessional users (or social security beneficiaries) pay \$3.20 per prescription, with a maximum expenditure of \$166.40 a year for each individual or family, after which PBS drugs are provided free of charge. These charges and safety net expenditures are indexed. Pharmacists are required to charge the full patient contribution for subsidised PBS drugs. (The dispensed price to general users of many drugs is below the maximum \$20.30 payment, meaning that these prescriptions attract no subsidy from the Commonwealth).

Under the current determination, the fees which pharmacists receive from the Commonwealth for dispensing subsidised PBS drugs comprise:

- a 10 per cent margin on the wholesaler's price for drugs retailing at less than \$180; a fixed amount of \$18 for drugs retailing at between \$180 and \$360; and a 5 per cent margin for drugs retailing at more than \$360;
- a composite fee made up of a dispensing fee \$4.39 for ready prepared items and \$6.27 for items mixed at the pharmacy and an administration fee of \$0.21; and
- other applicable special fees, including a loading for isolated and remote pharmacies and supplementary allowances for additional professional services (such as medication reviews in nursing homes, asthma and diabetes management, and wound care).

These fees have been set with reference to average pharmacy costs (as distinct from costs in the most efficient pharmacies). The average cost base was established at the commencement of the current agreement in 1995. Since then, the dispensing fee has been periodically increased using a formula which takes into account movements in the Consumer Price Index (CPI) and other relevant costs.

Surcharges (set by the Pharmacy Guild) apply to the dispensing of PBS drugs supplied to general users, which are priced below the maximum patient contribution

of \$20.30. These prescriptions do not attract a subsidy from the Commonwealth, meaning that consumers rather than taxpayers meet the cost of these higher charges.

Currently, the surcharges are up to \$3.35 for ready prepared items and \$3.73 for items mixed at the pharmacy. However, these surcharges are reduced if their full application would raise the dispensed price of the drug above the maximum general user contribution of \$20.30.

Discounting of patient contributions

Pharmacists are not permitted to discount consumer charges for PBS drugs that are subsidised by the Commonwealth. As discussed in chapter 4, this reduces the scope for price competition in the provision of pharmacy services.

Pharmacy location

To complement the negotiation of pharmacists' remuneration, the Commonwealth has sought to contain its expenditure on the PBS by regulating the approval of new pharmacies and relocations of existing pharmacies. These arrangements are covered in a Ministerial Determination made under the *National Health Act* 1953.

As part of its 1990–95 agreement with the Pharmacy Guild, the Commonwealth offered packages to encourage 'marginal' pharmacies to amalgamate or close. It also provided financial assistance to some pharmacies in rural and remote areas to enable them to remain viable. Further, it established the Pharmacy Restructuring Authority to administer: the approval of pharmacies to supply PBS drugs; the provision of financial assistance to encourage the closure and amalgamation of pharmacies; and the payment of an Essential and Isolated Pharmacy Allowance. As discussed in chapter 2, the restructuring incentives led to some 700 pharmacy closures and amalgamations over the life of the agreement.

The 1995–2000 agreement renews and expands on the previous agreement. Importantly, the emphasis has shifted from pharmacy closures and amalgamation to relocation. The Australian Community Pharmacy Authority (ACPA) — which replaced the Pharmacy Restructuring Authority in March 1995 — makes recommendations on applications from pharmacists concerning:

- new approvals and relocations of existing approvals. (Box 3.4 summarises the criteria applied by the ACPA);
- the payment of Isolated and Remote Pharmacy Allowances (see below); and

• the payment of supplementary allowances for additional professional services, such as providing medication reviews to patients in nursing homes. The Commonwealth provides \$4 million a year (indexed) for such services.

Box 3.4 Criteria relating to new pharmacy approvals and relocations

The criteria which the Australian Community Pharmacy Authority applies when assessing applications for new pharmacy approvals and relocations of existing pharmacies are contained in a Ministerial Determination made under the National Health Act 1953. They are basically in accordance with the current agreement between the Commonwealth and the Pharmacy Guild.

New approvals

A new pharmacy must be more than 2 kilometres from an existing pharmacy. Also there must be a 'community need' for the new pharmacy as indicated by:

- a non-mobile catchment population of over 3000 people;
- of whom at least 10 per cent are 'disadvantaged' (defined as aged persons and persons who are unemployed or receive pensions).

Relocations

A number of criteria apply to the relocation of existing pharmacies:

- Pharmacies may relocate within 1 kilometre without regard to the location of other pharmacies, provided that they have been at their current site for at least two years. The two-year requirement is aimed at discouraging 'leap frogging'.
- Pharmacies may relocate further than 1 kilometre provided: they are generally no closer than 2 kilometres to another pharmacy; and they are not leaving behind an area of 'unmet community need'. The latter criterion would normally be satisfied if there is another pharmacy within 5 kilometres of the vacated site.
- Pharmacies may relocate to shopping centres without the need to comply with the 2 kilometre rule, provided they are not leaving behind an area of 'unmet community need'. While the ACPA has discretion in approving relocations to shopping centres, the size of the centre generally determines how many pharmacies will be allowed: 1 pharmacy for centres of at least 30 shops; 2 pharmacies for centres of at least 100 shops; and 3 pharmacies if there are more than 200 shops.
- Pharmacies may relocate to private hospitals with more than 150 beds, provided they are not leaving an area of 'unmet community need'. The 2 kilometre rule does not apply in this situation.
- In 'exceptional circumstances' such as damage from fire, water, storm or earthquake, changes to occupancy provisions or redevelopment for public works, pharmacies may relocate up to 2 kilometres, without regard to the location of other pharmacies.

An Isolated Pharmacy Allowance is payable to approved pharmacies (located more than 10 kilometres from another pharmacy) to help maintain services in isolated and rural areas. It comprises a 20 per cent loading on the standard dispensing fee for ready prepared items, up to 1000 prescriptions a month.

An additional Remote Pharmacy Allowance is payable to approved pharmacies that receive an Isolated Pharmacy Allowance and that have no other approved pharmacy within 25 kilometres. Remote Pharmacy Allowances currently range from \$1120 to \$3129 a year, depending on the degree of isolation, and are indexed using the CPI.

Advertising

The Commonwealth regulates the advertising of medicines through the *Therapeutic Goods Act 1989*. As noted, the relevant provisions of the Act cover medicines that are traded interstate and generally parallel the advertising provisions in State and Territory medicines and poisons legislation. Specifically the Act:

- prohibits any advertising of S4 or S8 medicines and brand advertising of many S3 medicines to the general public;
- permits brand advertising of S2 and some S3 medicines; and
- governs the content of such brand advertising. In so doing, it incorporates a number of the requirements in the Therapeutic Goods Advertising Code.

Advertisements to the public of S2 and S3 (and unscheduled) medicines in the mainstream media must receive prior clearance — a task delegated to the Complementary Healthcare Council for complementary medicines and the Proprietary Medicines Association of Australia for the remaining medicines. Also, the *Trade Practices Act 1974* contains broad proscriptions on false or misleading advertising.

The Therapeutic Goods Act — and the parallel provisions in State and Territory medicines and poisons legislation — does not preclude pharmacists from advertising prices charged for medicines. In this regard, recent legal advice provided to the Therapeutic Goods Administration in response to concerns about price advertising by some mail-order pharmacy businesses, suggested that a simple list of product names and prices is not an advertisement under the Act. The National Co-ordinating Committee on Therapeutic Goods subsequently endorsed the notion that consumers should have access to information on prices of more potent medicines. It went on to note that these matters are expected to be considered

further in the National Competition Policy Review of medicines and poisons legislation.

The Commission's understanding is that under the Therapeutic Goods Act pharmacists could therefore:

- include information on prices charged in advertisements for S2 medicines and those S3 medicines for which brand advertising is permitted; and
- make available product price lists for S4 medicines and those S3 medicines for which brand advertising is not permitted. (Such price lists must be restricted to the product, name, pack size and price and cannot include pictorial depictions of the products, or be included in catalogues which contain depictions of other medicines).

Yet, apart from mail-order pharmacy businesses, advertising of prices charged for scheduled medicines has been largely non-existent. The possible reasons for this, and the ramifications for competition in the pharmacy market, are considered in the next chapter.

4 Benefits and costs of the regulations

A major task for the Review is to assess the benefits and costs of regulations applying to community and other types of pharmacy, and whether the underlying objectives can be achieved only by restricting competition.

As discussed in chapter 3, there are a number of rationales for the regulations including encouraging safe and effective use of medicines, promoting equitable access to services and containing expenditure on the PBS.

But, as the discussion in this chapter indicates, the effectiveness of the regulations in meeting these objectives is not always clear. Moreover, many of the regulations may impose costs on the community. In particular, restrictions on competition in the delivery of pharmacy services almost certainly increase the price of medicines and reduce consumer convenience.

In discussing the benefits and costs of the key regulations governing community pharmacy, the chapter indicates, wherever possible, whether these are likely to be significant.

However, it does not aim to provide definitive conclusions on the balance between the benefits and costs of particular regulations. The nature of some of the benefits and costs makes them difficult to quantify. Moreover, the Commission does not have access to information on the magnitude of the cost savings and other benefits that entrants to a less regulated pharmacy sector might offer consumers. In these circumstances, the Review should look to the full range of evidence submitted by interested parties.

4.1 Licensing requirements

Licensing requirements for pharmacists are intended to provide consumers with a guarantee that pharmacy services meet a minimum standard of quality and safety. The requirements complement other measures, such as codes of ethics enforced by Pharmacy Boards.

The case for licensing pharmacists centres on preventing problems that might arise in an unregulated market. A particular concern is that many consumers may not be in a good position to assess the efficacy of particular pharmacy services, or to distinguish more competent from less competent pharmacists.

Such information asymmetry is not peculiar to the pharmacy market — it characterises many markets, including those for other professional services provided by lawyers, accountants and the like.

Moreover, many of these markets appear to cope satisfactorily with the problem without the need for extensive government regulation. In some — for example, general retailing — the need for businesses to secure repeat custom from consumers makes the provision of an effective service a commercial imperative. In others, such as the market for accounting services, suppliers have dealt with the problem by implementing voluntary certification and accreditation systems.

In health care markets, however, governments are typically reluctant to rely solely on market disciplines and self-regulatory solutions. This is because of the potential for poor quality or unsafe services to impose significant human and economic costs. Thus, all developed countries have licensing requirements for pharmacists.

Of course, licensing requirements are not costless. Pharmacists will seek to recoup their costs in acquiring the necessary skills and credentials to meet the requirements by increasing prices. Moreover, licensing requirements have the potential to give owner-pharmacists a degree of market power which may allow them to increase prices further. However, this is only likely if there is a shortage of pharmacists.

Assessing whether the current licensing requirements appropriately balance these benefits and costs involves considerable judgement. That said, inter-country comparisons suggest that Australia's educational and training requirements for pharmacists are not out of step with generally less regulated markets such as the USA (see table 4.1).

Thus, as far as future reform is concerned, the issue is seemingly not whether there should be licensing, but rather whether some 'fine tuning' of the requirements would give a better balance between benefits and costs. Chapter 5 canvasses some options in this regard.

Table 4.1: Educational and training requirements for pharmacists, 1992

| Country | ntry Pharmacist qualifications | | |
|---|--|--|--|
| Australia Canada Denmark France Italy New Zealand Spain | 3 or 4 year degree + 1 year training 1 year post secondary + 4 year degree 5 year degree 6 or 9 years 5 year degree + 6 months training University degree or college diploma + 1 year training 5 year university education | | |
| United Kingdom United States | 3 or 4 year degree + 1 year training 5 or 6 years | | |

Source: Compiled from Spivey, Wertheimer and Rucker 1992.

4.2 Ownership restrictions

As noted in chapter 3, the general thrust of ownership restrictions is to prevent non-pharmacists (particularly corporations) from owning pharmacies and to limit the number of pharmacies that a pharmacist can own.

Among the rationales for these restrictions are:

- to maintain ethical and professional standards in the provision of pharmacy services;
- to provide a greater capacity to enforce professional standards; and
- to promote equitable access to pharmacy services.

However, in pursuit of these objectives, the ownership restrictions significantly reduce competition within the community pharmacy sector and, thereby, hinder the development of potentially more effective structures for delivering some pharmacy services.

Benefits of ownership restrictions

Ethical considerations

At the heart of the current ownership restrictions is the argument that non-pharmacist owners might let commercial considerations over-ride professional ethics in the 'custodianship' of medicines and the delivery of pharmacy services.

These arguments were summarised by Queensland Health in a review of the State's medical and health practitioners legislation:

- ethical and legal responsibilities make it imperative that pharmacists not be subject to the control and direction of non-pharmacists in the conduct of their profession;
- where a pharmacist owns the practice, he or she is in control of and responsible
 for all policy and management decisions. Non-pharmacist owners would have
 little or no knowledge of drugs and their associated problems and dangers; and
- if controls and management are vested in unregistered persons, there will be a reduction in ethical practices whereby social accountability will be subordinate to the profit motive (Queensland Health 1996, p. 49).

However, these arguments need to be considered in the context of related measures designed to guard against poor quality or unethical service provision, including:

- requirements that a qualified pharmacist be present at a pharmacy during business hours to oversight practices in the pharmacy, dispense medicines and provide advice and counselling to consumers; and
- pharmacy codes of ethics that provide consumers with a complaints' mechanism in instances of professional misconduct. Where the misconduct is significant, Pharmacy Boards have the power to deregister the pharmacist concerned.

With these measures in place, the issue becomes whether ownership restrictions provide any *additional* ethical and safety benefits to consumers and, if so, at what cost.

Like other businesses, success in community pharmacy depends on providing a cost-effective, quality service. The quality (and safety) of the service provided will depend, in the first instance, on the professional skills of the pharmacist. This is seemingly the case whether the pharmacist is a salaried employee or owns the business. Indeed, the Commission is unaware of evidence that, in countries such as the USA and the United Kingdom where private and corporate pharmacy have existed for many years (see table 4.2), the integrity of salaried pharmacists is compromised by their employers in ways which put consumers at risk. Thus, the question arises as to why the community pharmacy sector in Australia should be different in this respect.

Table 4.2: Restrictions on pharmacy ownership in selected OECD countries

| Country | Control on new pharmacy approvals | Ownership restrictions | | |
|----------------------------|---|---|-------------------------------------|--|
| | | Controls on multiple pharmacy ownership | Restrictions on corporate ownership | |
| Australia | Yes | Yes ^a | Yes | |
| Canada ^b | No | No | No | |
| France | Yes | Yes | Yes | |
| Germany | No | Yes | Yes | |
| Italy | Yes | Yes | Yes | |
| Spain | Yes | Yes | Yes | |
| United Kingdom | Yes | No | No | |
| United States ^c | No | No | No | |

a There are no restrictions in the ACT or the Northern Territory.

Source: Compiled from Spivey, Wertheimer and Rucker 1992.

The Review will also need to test the assumption that commercial pressures on owner-pharmacists are less than those which would be faced by non-pharmacist owners. Conceivably, the opposite could be true, given the substantial equity involvement of owner-pharmacists and their dependency on the profits of the pharmacy for much of their income.

Similar questions arise in relation to the ethical benefits from restricting the number of pharmacies that a pharmacist can own. The argument is that ownership of multiple pharmacies would weaken the professional involvement of the owner-pharmacist in the day-to-day running of each pharmacy. But again, the quality of service will depend in large measure on the skills and integrity of the pharmacist working in each pharmacy. One test that the Review could apply to this argument is whether ethical standards are lower in Queensland and South Australia, where pharmacists can own four pharmacies, than in Western Australia and Tasmania where the limit is two.

While the ethical benefits of the general ownership restrictions are debatable, the case for preventing medical practitioners from owning pharmacies seems stronger. In particular, if medical practitioners' incomes depended partly on the supply of medicines, there would be a financial incentive to increase prescribing rates, even if this were not justified on health grounds. This has apparently been a problem in Japan where medical practitioners prescribe and dispense most prescriptions (Seo

b Ontario has ownership restrictions, but these do not apply to chain pharmacies in existence before 1954.

^c Some individual States have ownership restrictions.

1994). However, the monitoring of doctors' prescribing patterns would act to constrain such behaviour in Australia.

Enforcing professional standards

A related argument for ownership restrictions is that they make it easier to enforce professional standards and to make pharmacists liable for misconduct. For instance, Phillips (1995) argues that non-pharmacist owners (such as company directors of large chain stores) would be unlikely to be held accountable for the actions of a pharmacist in one of their branches.

But, in assessing this argument, there is a need to distinguish between professional misconduct and other shortcomings in the delivery of pharmacy services, such as the inappropriate maintenance of premises. In general, professional misconduct will be the cause of most cases of serious harm to consumers. In these circumstances, Pharmacy Boards or consumers would still have the option of taking action against the pharmacist, even if he or she were not the owner of the pharmacy. For this reason, salaried health professionals in corporate and government employment often carry personal liability insurance.

Access to pharmacy services

Those supporting the current ownership restrictions claim that the entry of supermarkets and large corporate chains would lead to a rationalisation of pharmacy services, with Australia's pharmacy needs met by a smaller number of larger pharmacies. They go on to argue that one consequence would be a loss of services in some rural towns, as well as in suburban areas of the major population centres.

There seems little doubt that ownership restrictions have helped to maintain the viability of some smaller suburban pharmacies in cities and larger towns. This is notwithstanding the fact that changing consumer shopping patterns have seen suburban pharmacies under increased competition from pharmacies in the major shopping centres. In essence, the ownership restrictions will have mitigated this competitive pressure somewhat. In so doing, they will have assisted the relatively small number of urban consumers without either private transport or convenient public transport options.

In smaller rural centres, however, the overall impact of ownership restrictions on access to pharmacy services is less certain:

- It is not clear why the advent of supermarket or chain pharmacy should automatically reduce access to services in these centres. If a particular centre is not attractive to a supermarket or chain pharmacy then, subject to the usual commercial viability requirements, there is no reason why an existing independent supplier could not continue in business.
- That said, by offering a better or cheaper service to consumers, supermarket or chain pharmacies in larger regional centres might draw custom from independent pharmacies in smaller towns. If this lead to the closure of all pharmacy services in a smaller town, then some consumers in that town would be disadvantaged. This would be analogous to the outcome in suburban areas of major towns.
- On the other hand, by precluding supermarket or chain pharmacy, the ownership restrictions might, in fact, be compromising access to services in some smaller rural towns. For instance, allowing dispensaries to operate *within* supermarkets would allow retailers to spread overheads and benefit from economies of scope with the retailing of other products. In turn, this could reduce the minimum population size required to support a pharmacy service.

More generally, the Commission notes that, in looking at access issues in rural and remote areas, it is important to distinguish between the effects of ownership restrictions and the impacts of ongoing demographic changes. In particular, towns with declining populations may struggle to support pharmacy services irrespective of what happens to pharmacy ownership. The loss of services for this reason should not be construed as a harbinger of what would happen under a more liberal ownership regime.

Finally, the Commission emphasises that the corollary of any access benefits provided by the ownership restrictions is a cost to the majority of consumers. That is, reduced access for some consumers under a more liberal ownership regime would necessarily reflect the response of the majority of consumers to the availability of a better, cheaper or more convenient service. Some of the ways in which the ownership restrictions increase the cost of pharmacy services are considered in the next section.

The impact of ownership restrictions on pharmacy costs

It has been argued that, by limiting entry to the pharmacy market, the ownership restrictions give existing pharmacies the power to set their charges above competitive levels.

As noted in chapter 2, the evidence on profitability in the community pharmacy sector is dated and subject to interpretation.

But even were the Review to find conclusive evidence of sustained high profitability in the sector, it would be inappropriate to attribute this solely, or even primarily, to the ownership restrictions. Indeed, the ownership restrictions will only create scope for monopoly pricing if the number of pharmacists available to work in the sector is artificially constrained. In the Commission's view, any evidence of relatively high profitability in community pharmacy is more likely to reflect the controls on pharmacy location, the absence of widespread price advertising for more potent medicines and the prohibition on discounting patient charges for subsidised PBS drugs. These regulations/market characteristics have greatly reduced price competition in the pharmacy sector (see below).

Accordingly, the main impact of the ownership restrictions on the price/cost of pharmacy services is likely to be to inflate the cost base. Most broadly, the restrictions reduce the opportunities to draw on ideas and experience from outside the pharmacy sector on how to reduce costs, improve service quality and the like. More specifically, the restrictions impede the realisation of scale economies in the sector.

Economies of scale

Evidence from the USA suggests that economies of scale can exist in chain pharmacies up to about 80 000 prescriptions a year (Schafermeyer et. al. 1992). As noted in chapter 2, dispensing volumes in most Australian pharmacies are well below this level.

Ownership restrictions do not of themselves prevent amalgamations of pharmacies to reap economies of scale.

However, by greatly reducing access to outside equity capital, the restrictions make it more difficult to finance large scale pharmacy ventures. (Indeed, the resulting greater reliance on debt finance is likely to have increased the cost of most investments in the sector).

The relatively small scale of many Australian community pharmacies will have reduced the opportunities to introduce specialist management and retailing skills. Although it is possible for an owner-pharmacist to hire people with such specialist skills, many pharmacies will be too small to make this economic. Hence, as well as performing pharmacy functions, most owner-pharmacists undertake a range of

business tasks. Significantly, greater scope for specialisation is one of the factors driving rationalisation in many parts of the retailing sector.

The small scale of many pharmacies will also limit their capacity to spread managerial and financial overheads and to negotiate bulk discounts for drug purchases. However, as noted in chapter 2, the latter problem has been at least partially addressed through the formation of pharmacy buying groups.

Summing up

Prima facie, the case for ownership restrictions seems much less compelling than the case for licensing requirements:

- The additional service quality and safety benefits provided by ownership restrictions seem likely to be small. Similarly, only a relatively small group of consumers are likely to benefit from improved access to pharmacy services.
- At the same time, the ownership restrictions have contributed to the small scale
 of the community pharmacy sector and the increased costs of dispensing
 medicines that this entails. Also, by preventing supermarkets and other general
 retail outlets from operating pharmacies in conjunction with their other
 activities, the restrictions may have precluded the provision of pharmacy
 services in some smaller rural towns.

While the Commission has not attempted to quantify the impact of the restrictions on pharmacy costs, it notes that their significance is reflected in other regulations applying to the sector. In particular, the pharmacy restructuring program and the controls on new pharmacy approvals are directed at increasing (or at least maintaining) the scale of pharmacy operations.

4.3 Scheduling restrictions

Scheduling restrictions limiting the distribution of medicines are designed to promote the safe use of potent medicines and to guard against drug abuse.

The underlying rationale for these restrictions is that most consumers do not have sufficient information or clinical expertise to make appropriate, unassisted, self-medication decisions. The escalating nature of the restrictions in the current schedules reflects the fact that the risks to the individual and costs to the community of inappropriate use are generally higher for more potent medicines.

At the same time, scheduling restrictions impose costs. For example, the costs of advice and counselling provided to consumers of scheduled medicines, and of any monitoring of drug use, will be recouped through higher dispensing charges. In some cases, consumers may not need this advice and counselling (for example, where they are on regular medication). And, non-uniformities in scheduling restrictions across the States and Territories can increase drug labelling and packaging costs.

Yet despite such costs, virtually all developed countries consider it necessary to restrict access to at least prescription medicines. And most have in place at least one pharmacy only schedule for more potent, non-prescription medicines. The notable exception is the USA where general outlets are permitted to sell any non-prescription medicines (see table 4.3).

Moreover, were the ownership restrictions to be relaxed, the costs of Australia's scheduling requirements would fall without any loss of benefits. As discussed above, allowing general retail outlets to provide pharmacy services would almost certainly reduce costs in the pharmacy sector. Hence, the extra cost imposed on consumers by limiting the sale of scheduled medicines to pharmacies would also fall.

Against this background, the case for fundamental changes to Australia's scheduling requirements is far from clear. Rather, the more pertinent issue seems to be whether modification and/or consolidation of the current schedules would provide a better balance between benefits and costs. This issue is taken up in chapter 5.

4.4 Advertising of drug prices

As set out in chapter 3, pharmacists are legally able to advertise the prices they charge for medicines.

However, to date, price advertising of medicines restricted to sale in pharmacies has been minimal, other than by mail-order pharmacies. The absence of widespread price advertising appears to reflect at least two factors:

• The prohibition on the discounting of patient contributions for subsidised PBS drugs removes the capacity for pharmacists to compete on the basis of price in this segment of the market (see section 4.5).

• The profession appears to discourage price advertising for products for which pharmacists have a monopoly over sale. In this regard, the Commission notes the recent efforts of the profession to try to stop price advertising by the mail-order business, Pharmacy Direct.

Table 4.3: Drug classes in selected developed countries

| Country | Prescription ^a | Pharmacist ^b | Pharmacy ^c | Drugstore ^d | General sale ^e |
|---------------------|---------------------------|-------------------------|-----------------------|------------------------|------------------------------|
| Australia | ~ | ~ | ~ | | v |
| Canada ^f | ✓ | | ✓ | | ✓ |
| Ontario | ✓ | ✓ | ✓ | | ✓ |
| Denmark | ✓ | ✓ | | | ✓ |
| France | ✓ | ✓ | | | |
| Germany | ✓ | ✓g | | | ✓ |
| Italy | ✓ | ✓ | | | |
| Netherlands | ✓ | ✓g | | ✓ | |
| Sweden | ✓ | | ✓ | | ✓ |
| Switzerland | ✓ | ✓ | | ✓ | ✓ |
| UK | ✓ | ✓ ^g | | | ✓ |
| USA | ✓ | | | | ✓ |

^a Drugs available only with a prescription. Some countries have multiple classes of prescription drugs.

Source: GAO 1995

But whatever the underlying causes, the lack of price advertising has made it difficult for consumers to compare the cost of obtaining more potent medications from different pharmacies. At the same time, it has reduced the scope for pharmacies able to offer a cheaper or better value for money service to compete for customers on the basis of these attributes. The upshot has been to reduce the incentive for pharmacies to pass cost savings on to consumers, and to create scope for them to operate inefficiently without losing customers. In so doing, it has helped

b Non-prescription drugs for which a pharmacist must be involved in a sale. However, involvement may be defined as simply being on the premises when the sale is made.

^c Non-prescription drugs available only in pharmacies. The pharmacist does not have to be involved in a sale.

^d Non-prescription drugs available only in pharmacies or drugstores. In some countries, pharmacies and drugstores are distinguishable drug outlets, in that a pharmacist does not have to be employed at a drugstore.

e Non- prescription drugs available from general retail outlets.

f In Canada, the federal government classifies a drug as either prescription or non-prescription. Each province determines where the drug can be sold in that province, although, the federal government recommends whether the drug should be available outside pharmacies. Thus, three drug classes are listed at the national level in Canada.

 $[{]f 9}$ This class is known as 'pharmacy restricted' in Germany, 'pharmacy-only products' in the Netherlands and 'pharmacy medicines' in the UK. These are listed here because the requirements to sell these drugs fit the pharmacist class rather than pharmacy class.

to reinforce the inflation in pharmacy costs resulting from the ownership restrictions.

Given that the legality of price advertising has recently been confirmed, and the value to consumers of price information endorsed by the National Co-ordinating Committee on Therapeutic Goods (see chapter 3), it may well be that price advertising of more potent medicines will increase in the future. Indeed, there are signs that some community pharmacies may actively seek to compete with mail-order businesses on the basis of price. This would be an important and welcome development.

If, or as, price advertising becomes more widespread, the issue of whether the current controls on the nature of such advertising are unduly restrictive would then arise. For example, as noted in chapter 3, price advertising of S4 medicines and those S3 medicines for which brand advertising is not permitted cannot incorporate pictorial depictions. Nor can price lists for these medicines be included in catalogues which contain pictorial depictions of other medicines.

Underlying such controls is a concern that unfettered price advertising may stimulate demand for medicines and increase problems of drug misuse or abuse. Another concern is that aggressive price advertising would undermine the 'dignity' and standards of the profession.

In the Commission's view, given the existence of licensing requirements for pharmacists and industry codes of ethics, the latter argument is of limited merit.

However, the Commission accepts that uncontrolled price advertising may encourage some unnecessary use of medicines. The issue is therefore whether there is scope to liberalise the current controls so as to facilitate price competition, without compromising the health and safety of consumers. This issue is taken up in chapter 5.

4.5 Commonwealth regulations associated with the PBS

Remuneration to pharmacists for dispensing PBS drugs

As set out in chapter 3, pharmacists' fees for dispensing subsidised PBS drugs are based on an agreement between the Commonwealth and the Pharmacy Guild.

Viewed in isolation, this sort of approach may give the Commonwealth scope to secure an 'efficiency dividend' from the pharmacy sector to the benefit of taxpayers and consumers. This is particularly the case for recent agreements between the Commonwealth and the Pharmacy Guild which have provided for industry restructuring.

However, it is important to recognise that the opportunity to secure significant cost savings through negotiation may only exist because of 'fat in the system' associated with the various State and Territory restrictions on competition in the sector. To this extent, the benefits are very much 'second best'.

Moreover, the agreed average cost basis for setting dispensing fees limits the scope for the Commonwealth to achieve cost savings. It does this by reducing competitive pressures on less efficient pharmacies to either improve their productivity or cease business. At the same time, it provides windfall gains to more efficient pharmacies.

Discounting of patient contributions

The prohibition on the discounting of patient charges for subsidised PBS prescriptions has been a longstanding feature of the regulatory arrangements for community pharmacy.

At least two rationales have been advanced for the prohibition:

- the potential for discounting to precipitate rapid structural change in the pharmacy sector; and
- that lower drug prices for already heavily subsidised concessional users would weaken the price discipline on over-prescribing by doctors.

The former rationale was prominent in 1980 when the Commonwealth restored the prohibition on discounting after lifting it just two days earlier. (The initial decision to allow discounting followed recommendations to that effect in the Ralph Report (1979)).

However, it is generally preferable to tackle adjustment issues directly (see section 5.3), rather than to seek to prevent adjustment by restricting competition. In any event, restructuring in the industry during the 1990s has presumably increased its capacity to accommodate discounting.

In contrast, there is clearly a need on both economic and health grounds to discourage unnecessary prescribing by doctors. There is little doubt that, in the past,

there was a tendency for doctors to prescribe free medicines to eligible beneficiaries as a substitute for sometimes more appropriate non-drug therapies or time consuming counselling. A desire to discourage such behaviour was one of the reasons for the introduction of a charge for pensioners for PBS drugs (in return for an increase in the pension).

However, from a policy perspective, the key issue is whether the need to discourage inappropriate prescribing automatically dictates a prohibition on discounting. This is particularly the case as the prohibition is a significant impediment to competition in the single most important segment of the pharmacy market. In effect, it prevents more efficient pharmacies from competing for business by lowering their dispensing fees and passing the savings on to customers. In these terms, the effect is little different from a restriction on the advertising of drug prices.

Accordingly, chapter 5 canvasses options which would provide for discounting without removing the financial discipline on inappropriate prescribing.

Location controls

As set out in chapter 3, the Commonwealth controls the location of new pharmacies and the relocation of existing pharmacies approved to dispense PBS drugs. The intentions behind these controls are:

to ensure there is a reasonable, efficient and fair distribution of PBS dispensing points across Australia, and thereby ... help ensure that the growth of demand outlets for expensive drugs and medicines remain relatively stable, and that attendant pressure on cost growth is kept to a minimum. (NCPRP 1999, p. 24)

In terms of cost containment, the controls on new pharmacy approvals and the associated financial assistance provided to facilitate industry restructuring have had some success. As noted in chapter 2, a combination of a significant number of pharmacy closures and amalgamations and limited new approvals led to a one-third increase in the average prescription volume per pharmacy in the early 1990s.

However, the role of the relocation controls in reducing costs is far from clear. This is because relocations will not generally affect the average number of prescriptions dispensed per pharmacy.

The efficacy of the relocation controls in promoting more equitable access to pharmacy services also seems debatable. According to the review discussion paper, the controls can theoretically make it more attractive for pharmacists to stay in communities — particularly rural and regional communities — that have no

alternative pharmacy services available to them. But, as the paper goes on to point out, it is difficult to prevent commercially non-viable pharmacies from closing (NCPRP 1999, p. 26). Hence, the provisions would seemingly only promote more equitable access when they prevent a commercially viable pharmacy from relocating to an area where higher profits are available.

More generally, as a mechanism to contain budgetary costs or to promote equitable access, the location controls are very much 'second best'. As discussed in chapter 5, in a more competitive pharmacy market, the cost containment rationale for controls on the establishment of new pharmacies would become problematic. There are also more direct ways of tackling access objectives.

The second best nature of the location controls leads to a number of adverse side effects:

- The controls further restrict competition in the delivery of pharmacy services, compounding the effects of ownership restrictions and the like on pharmacy costs. As experience in other retailing areas shows, co-location of competitors is often to the benefit rather than the cost of consumers. The controls may also increase the scope for monopoly pricing of (non-PBS) medicines.
- These cost and price impacts may in turn further inflate the capital value of pharmacies. This raises the costs for potential new entrants of acquiring a pharmacy.
- The target ratios which underpin the controls are necessarily arbitrary. For example, they may prevent the establishment of pharmacies which fail to meet these ratios, even if commercial viability suggests genuine 'unmet' need. In these circumstances, consumer convenience will be reduced.
- The prescriptiveness of the relocation controls introduces a high degree of regulatory intrusion into commercial decision making by pharmacy proprietors.

The second best nature of the location controls again illustrates the importance of looking at the inter-relationships between the Commonwealth and State and Territory pharmacy regulations. One of the benefits of the alternative regulatory approaches canvassed in the next chapter would be to reduce the need for 'second layer' regulations such as the location controls.

4.6 **Concluding remarks**

In assessing the benefits and costs of the regulatory regime for community pharmacy, the need to promote the safe use of medicines and to ensure adequate access to high quality pharmacy services will continue to be fundamental objectives.

Thus, few would dispute the need for pharmacists to be licensed, or for regulations preventing unqualified staff from dispensing potentially harmful medicines. And, there are good reasons for having Pharmacy Boards or like bodies to oversee the licensing of providers and standards of practice in pharmacy.

However, the Review will need to assess whether some of the current regulations go beyond what is necessary to meet health and safety, quality and access objectives. In this regard, the discussion above suggests that the costs of some of the current restrictions on competition may well outweigh their benefits.

5 Some alternative approaches

The Commission has explored some options which would encourage greater competition in community pharmacy, while still addressing the objectives of the current regulatory regime. Of course, increasing competition is not the only way of improving outcomes. For example, improving regulatory procedures and administration can sometimes deliver significant benefits. That said, a number of other developed countries have harnessed competition to encourage the provision of better and more cost-efficient pharmacy services. For instance:

- Some countries including Canada, the Netherlands and Switzerland encourage mail-order pharmacy as a means to contain dispensing costs. Mail-order pharmacy is also expected to become more important in countries such as Germany and France (Script 1996).
- The USA, the United Kingdom and Canada allow corporate ownership of pharmacies to facilitate greater realisation of economies scale and thereby encourage the best blend of pharmacy and business management skills.
- The Netherlands and some provinces/states in Canada and the USA have experimented with market, rather than negotiated, remuneration to pharmacists for dispensing subsidised pharmaceuticals.

Were this Review to recommend continuation of the regulatory status quo, it would be important to demonstrate why these sorts of approaches would not be appropriate in Australia.

The discussion in the previous chapter suggests that the greatest impediments to efficient outcomes in the pharmacy market have been the restrictions on pharmacy ownership and the absence of widespread advertising of prices charged for more potent medicines. If there were changes in these areas, there might also be scope for the Commonwealth to relax its controls on the location of pharmacies and to rely more on the market to set pharmacists' remuneration for dispensing PBS drugs. In contrast, the restrictions on competition from State and Territory licensing and drug scheduling requirements seem broadly appropriate.

Against this background, the Commission has mapped out two broad reform options:

- a package of relatively modest changes including: some easing of ownership restrictions; fine tuning of licensing and drug scheduling requirements; changes to the basis for remunerating pharmacists for dispensing some PBS prescriptions; and modifications to the location controls. While these have been presented as a package, they could be implemented in a piecemeal fashion; and
- a 'pro-competitive' reform package involving: the abolition of most ownership controls (together with any premises requirements that prevent general retailing outlets offering pharmacy services); facilitation of price advertising by pharmacists (including an end to the prohibition on the discounting of patient charges for subsidised PBS drugs); a reduced role for the Commonwealth in determining pharmacists' remuneration for dispensing subsidised PBS drugs; and the abolition of controls on new pharmacy approvals and pharmacy relocations. (Modifications to the licensing and scheduling requirements could also be incorporated in the package.)

Box 5.1 summarises the key components of the two options.

In putting these options forward, the Commission is trying to provide the Review with some indicative benchmarks against which to assess the current arrangements. These may assist the Review's consideration of whether the current restrictions on competition are the only way of ensuring that objectives for community pharmacy are met.

5.1 Modest reforms

Less restrictive ownership controls

By relaxing the ownership restrictions, it would be possible to increase the scope for pharmacies to achieve economies of scale. Such changes could provide some cost savings and/or improve the quality of community pharmacy services, while still maintaining pharmacies as 'stand-alone' businesses.

Box 5.1 Some possible reform options for assessment

Modest reforms

Ownership

- · ease limits on the number of pharmacies owned
- allow limited forms of corporate ownership

Licensing

- · introduce graduated licensing arrangements
- liberalise recognition of overseas pharmacy qualifications

Scheduling

consider combining S3 and S2 into one pharmacy-only schedule

Dispensing fees

tender a small component of PBS dispensing (eg for nursing homes)

Controls on pharmacy location

 permit unrestricted relocation unless the Australian Community Pharmacy Authority can demonstrate that a relocation is not in the public interest

Pro-competitive reforms

Modifications to licensing and scheduling requirements, plus:

Ownership and service provision

- remove all controls on multiple pharmacy ownership
- allow ownership by non-pharmacists (including corporate ownership)
- allow general retail outlets to provide pharmacy services
- encourage mail-order pharmacy

Advertising

facilitate advertising of drug prices

Dispensing fees

- allow discounting of patient charges for subsidised PBS drugs
- leave the market to set dispensing fees, subject to a maximum cap

Controls on pharmacy establishment and location

allow unrestricted establishment and relocation of pharmacies

Easing or removing the limits on the number of pharmacies owned

One modest change would be for all States to adopt the four pharmacy ownership limit applying in Queensland and South Australia. Alternatively, all States could follow the Territories and abolish multiple ownership restrictions.

Such changes could foster the growth of small pharmacy chains with a greater capacity to employ staff with specialist management skills. Another consequence might be greater reliance on salaried pharmacists to oversee the day-to-day running of individual pharmacies. Some might see the latter development as detrimental to professional standards. However, even under the current restrictions, the employment of salaried pharmacists is commonplace. Moreover, the Commission is not aware of evidence indicating that professional standards are lower in those States and Territories with more liberal ownership regimes.

A limited form of corporate ownership

While offering the prospect of some cost savings, such changes would not address a major impediment to competition in the community pharmacy sector: namely, the virtual prohibition of corporate ownership by non-pharmacists. By reducing access to equity finance, this has contributed to the relatively small scale of pharmacy operations and thus reduced the scope to introduce specialist business skills and to spread overhead costs.

The Review will, of course, need to assess whether any restrictions on corporate ownership are necessary to ensure that professional standards are met. In this regard, the Commission observes that a range of other mechanisms designed to promote safety and professional standards — including the requirement that a pharmacist must dispense potent medicines — could continue to apply irrespective of who owns a pharmacy. Some have therefore argued that the prohibition on corporate ownership is primarily directed at maintaining pharmacies as independently owned, small businesses.

However, should the Review find there is a public benefit in preserving pharmacy as an independent retailing activity, there might still be a case for permitting corporate ownership, but with the proviso that all pharmacies operate as stand-alone businesses. This would rule out major retail chains and supermarkets operating dispensaries in the same premises as their other activities.

A similar system applies in the United Kingdom, where corporate owners have apparently purchased existing pharmacies rather than open new ones. It has also

permitted a range of pharmacy structures to exist in the market place, ranging from independent operators and chains of just two outlets to very large corporate chains. There is also significant vertical integration, with chains such as Boots and Lloyds by-passing traditional wholesalers, and some wholesalers owning and managing pharmacies (Andersen 1995). Based on this experience, even a constrained form of corporate ownership might deliver significant cost savings.

That said, a continued prohibition on general retail outlets and supermarkets offering pharmacy services would limit the potential savings in overhead costs, as well as denying consumers access to 'one stop shopping'. The Commonwealth controls on the location of pharmacies might further limit the gains by removing the option for corporate players to enter the market by opening new pharmacies rather than purchasing existing outlets.

Moreover, while relaxing the restrictions on corporate ownership would almost certainly reduce the cost of providing pharmacy services, it would not of itself ensure that these savings were passed on to consumers (or to taxpayers for medicines subsidised under the PBS). As discussed below, a market environment which facilitates price advertising is required to encourage the pass through of cost savings.

Finally, the Commission notes that the introduction of even limited corporate ownership could require changes to the powers of Pharmacy Boards to deal with misconduct in the provision of pharmacy services. In particular, the Commission is unsure whether current Board powers would allow them to deal with misconduct by a corporate owner as distinct from a pharmacist. It would be possible to rely solely on general 'business conduct' laws such as the Trade Practices Act to regulate corporate owners. However, the Review would need to consider whether this would be appropriate given the sensitive nature of pharmacy services.

Modifications to licensing requirements

Australia's educational and training requirements for pharmacists seem broadly appropriate when viewed in the context of licensing requirements in other developed countries (table 4.1).

Nonetheless, the Review might usefully consider whether some fine tuning of the requirements would lead to a better balance between benefits and costs. For example, there may be scope to more closely tailor licensing requirements to the changing role and differing functions of community pharmacists:

- The increasing availability of prepacked pharmaceuticals has reduced the pharmacist's compounding role.
- According to the pharmacy sector, the reduced emphasis on compounding has been matched by an increased emphasis on the provision of advice and counselling to consumers. In its submission to the Commission's inquiry on the pharmaceutical industry (IC 1996), the Pharmaceutical Council of Western Australia (1996) said:

The time which may previously have been spent with the ointment slab or mortar and pestle is now spent at the pharmacy counter or on the telephone discussing medication and the management of medical conditions with patients, doctors and other health professionals (p. 37).

While there are those who question the extent and usefulness of that advice (see chapter 2), it is clearly of benefit to some consumers.

Given these dual roles of dispensing medicines and counselling patients, some form of graduated licensing arrangement could be preferable to a uniform qualification for pharmacists. This might involve a basic qualification for those engaged in routine dispensing work and a higher level qualification for those engaged in counselling and advising consumers. By reducing the cost of acquiring the skills necessary to perform less complex pharmacy functions, such a system could reduce the costs of drug dispensing.

Countries like the Netherlands employ this sort of graduated approach (Spivey, Wertheimer and Rucker 1992). The Commission also notes that a graduated qualification system applies to hospital pharmacy in Australia, where there are courses for technicians lasting for about two years. These qualifications entitle the holder to perform strictly controlled, non-judgemental, mechanical and clerical dispensing tasks within hospitals (Spivey, Wertheimer and Rucker 1992). And, the National Training Course for pharmacy assistants similarly provides scope for specialisation in pharmacy functions (Pharmacy Guild 1999b).

The extent of the cost savings from graduated licensing arrangements would, however, depend on what happens to ownership restrictions. If the current ownership restrictions are maintained, then the savings would most likely be small. This is because many smaller pharmacies that are supported by the ownership restrictions could have limited capacity to employ more than one pharmacist. But if ownership regulations were significantly relaxed, the likely increase in the size of pharmacies could make the separation of routine dispensing and counselling functions viable in a greater proportion of pharmacies.

Another 'fine tuning' issue which the Review might address is whether there is scope to liberalise the recognition of overseas pharmacy qualifications, without putting consumers at risk. Particularly at times when, or in locations where, there was a shortage of Australian-trained pharmacists, this might help to contain the cost of pharmacy services.

Simplifying poisons (medicines) scheduling requirements

This Review is not specifically addressing poisons (medicines) scheduling regulations. These are being addressed in a concurrent NCP review.

However, as noted, scheduling regulations have an important impact on demand for pharmacy services and on the cost and availability of pharmaceuticals to the general public. Recommendations emerging from the review of poisons scheduling therefore have the potential to complement policy initiatives arising from this Review.

One issue is whether Australia should follow the US approach and only restrict the sale of prescription medicines (S4) to pharmacies. This would make many medicines currently listed in schedules 2 and 3 available through general retail outlets and thereby reduce their cost. Moreover, if the current ownership restrictions are retained, it would provide a convenience benefit to consumers who could purchase a wider range of medicines through general outlets.

But, the judgement in most developed countries is that some non-prescription medicines are sufficiently potent to warrant supervised provision by a qualified pharmacist. Indeed, given this concern, pharmacy-only schedules may increase the range of drugs available for self medication. That is, in the absence of such schedules, some pharmacy-only medicines might be reclassified as prescription only. This would mean that consumers needing to use them would incur the additional cost and inconvenience of a medical consultation.

This, in turn, suggests that the more pertinent policy issue is whether there are benefits from retaining two pharmacy-only (S2 and S3) schedules that outweigh the associated costs. Amongst other things, these dual schedules add to the complexity of the drug distribution system and contribute to non-uniformities in packaging and labelling requirements across States and Territories.

There is also the question of whether the classification of medicines as 'pharmacyonly' tends to be unduly restrictive. In particular, the less potent nature of some S2 medicines increases the likelihood that, at the margin, the increased cost to consumers of limiting sale to pharmacies will exceed any public health benefits. The restriction of larger packs of some common analysesics to sale through pharmacies, even though consumers can purchase unlimited numbers of smaller packs from general retail outlets, is a case in point.

Changes to the basis for remunerating pharmacists for dispensing PBS drugs

In a competitive pharmacy market, the need for Commonwealth controls on remuneration to pharmacists for PBS dispensing might be greatly reduced (see section 5.2).

But even if the current regulatory controls are retained, the Review could still consider whether there is scope for change in the remuneration framework.

One possibility would be to investigate the feasibility and effects of the Commonwealth remunerating pharmacists on the basis of best practice (most efficient) costs rather than average pharmacy costs.

In principle, this would provide cost savings to consumers and taxpayers, and sharpen the incentives for pharmacists to deliver their services efficiently. It might also allow the Commonwealth to relax or abolish the controls on new pharmacy approvals. As noted, one of the rationales for these controls is to lower average costs in the sector and thereby Commonwealth outlays for PBS dispensing.

However, this begs the question of how the Commonwealth would settle on an 'efficient' dispensing charge. Given variations in pharmacy costs and the size of markets served, there will not be a single 'efficient' dispensing price. From this perspective, the current average cost method for determining remuneration caters for some regional variation in dispensing costs. Moving away from this conceptually imperfect, but administratively feasible, approach would only be justified if the differences between average and efficient dispensing charges are significant.

One way of assessing whether this is the case, would be to 'market test' by tendering the right to dispense PBS drugs.

However, the outcomes of tender experiments in the USA (Hayman et al 1983, Curtiss 1991) and the Netherlands (BIE 1985) suggest that there would be significant problems in using competitive tenders to remunerate pharmacists for *all* PBS dispensing:

- It would be administratively complex and information intensive.
- Defining geographic areas would be a difficult task, particularly given the inconvenience for consumers if only one pharmacy in each area was able to dispense PBS drugs.
- The retention of a viable and competitive pharmacy sector would be problematic if a large part of its business was channelled to a small number of suppliers. This could lead to monopoly problems when contracts came up for renewal.

On the other hand, tendering a small component of PBS dispensing, even on a temporary basis, could provide insights into the difference between average and best practice dispensing costs without prejudicing the viability of large numbers of pharmacies. In this context, one option could be to tender for PBS dispensing to nursing homes in a particular city or jurisdiction. British Columbia and Manitoba have previously gone down this track (Gorecki 1992).

It might be argued that differences in the costs of servicing nursing home and general markets would make it difficult to draw strong conclusions about overall variations in average and best practice dispensing costs.

But, even differences in tenders submitted for a particular segment of the market could provide valuable information on variations in dispensing costs across the sector. Similarly, tendering out the delivery of pharmacy requirements in some more remote areas could provide guidance on the adequacy of isolated pharmacy allowances.

Modifications to the relocation provisions

In the absence of widespread price competition between pharmacies for scheduled medicines, and given a continuation of the current ownership controls and the average cost basis for remunerating pharmacists for dispensing PBS drugs, there may well be a case for the Commonwealth to limit new pharmacy approvals. In essence, the limits on the total number of approved pharmacies are a way of exerting downward pressure on average dispensing costs.

However, even in this 'second best' environment, the case for the relocation controls is less clear (see chapter 4).

But if the relocation provisions were to be retained, there may be scope to reduce their prescriptiveness and intrusion into commercial decision making. One option in this regard would be to permit pharmacy relocations generally, unless the Australian Community Pharmacy Authority (ACPA) could demonstrate why a relocation was not in the public interest. In effect, such a change would be tantamount to reversing the onus of proof.

This approach would give pharmacists greater capacity to establish their businesses in the most convenient location for the majority of their customers. At the same time, it would still allow the ACPA to refuse a relocation that was not in the public interest. A possible example might be a proposed relocation of a *viable* pharmacy in a small country town to a larger centre. That said, there are likely to be more direct and effective ways of promoting equitable access to pharmacy services (see section 5.3).

5.2 A pro-competitive reform package

A more comprehensive alternative would be a package of measures that would result in a similar level of competition in the community pharmacy sector as in markets for most other goods and services. At a minimum, this option would involve abolishing virtually all of the current ownership restrictions, facilitating price advertising and removing controls on pharmacy relocations.

The resulting increase in competition would offer the prospect of cost savings to consumers and taxpayers (see below). It might also permit a reduced role for the Commonwealth in setting remuneration to pharmacists for PBS dispensing and in determining the total numbers of pharmacies. Of course, such a package would need to preserve the primary controls currently in place to guard against unsafe usage of medicines and inappropriate pharmacy practice — namely licensing of pharmacists and poisons scheduling. (It could, however, embody the sort of modifications to licensing and scheduling arrangements canvassed in the previous section).

In assessing the merits of a 'pro-competitive' approach, the Review would therefore need to establish:

- whether ownership controls and regulatory impediments to price competition provide additional, and materially significant, safety and quality benefits;
- whether these restrictions on competition, together with the relocation provisions, facilitate more equitable access to pharmacy services which could not be achieved in other ways; and
- how the magnitude of any such benefits compares to the likely cost savings to consumers and taxpayers under a competitive regime.

The remainder of this chapter elaborates on what a pro-competitive reform package might entail and its possible impacts.

Abolition of most ownership controls

This option would require States and Territories to remove not only restrictions on multiple pharmacy and corporate ownership, but also any regulations (or Pharmacy Board edicts) that prevent general retail outlets offering pharmacy services. However, it would be appropriate to retain the requirement for a qualified pharmacist to be on duty in each pharmacy. This provides an important safeguard to consumers. Also, as noted in Chapter 4, there may be a case for retaining the prohibition on medical practitioners owning pharmacies. In essence, the Review would need to assess whether the monitoring of prescribing patterns would adequately counteract a possible financial incentive for over-prescribing were practitioners to own pharmacies.

The abolition of most ownership restrictions would increase the scope to draw on ideas and business skills from outside the pharmacy sector. It would also greatly increase opportunities to take advantage of economies of scale and scope in the provision of pharmacy services. The establishment of pharmacies in retail outlets (including in supermarkets) would be an important part of this process. As well as providing opportunities to realise economies of scale and scope, it would be more convenient for many consumers.

Supermarkets, and other organisations which might establish pharmacy businesses under a more liberal regime, would be in the best position to inform the Review of the potential cost savings. Suffice it to say that:

- Grocery prices in the major supermarkets are usually cheaper than in smaller independent supermarkets.
- The entry of Woolworths into petrol retailing has produced some significant price benefits for consumers, particularly those in regional areas (see, for example, Macleay 1997).
- In the USA, Canada and the United Kingdom which have more liberal ownership regimes than Australia (see table 4.2) consumers have 'voted with their feet'. Chain pharmacies in these countries have increased their market share at the expense of smaller independent pharmacies, suggesting they provide cost, quality and/or convenience benefits to consumers.

The experience with corporate chain pharmacies in countries like the United Kingdom, is similar to Australia's experience in general retailing. More liberal retail trading legislation has seen many consumers shift from smaller suburban outlets to larger shopping centres.

As in retailing more generally, a lesser role for suburban pharmacies would not adversely affect most consumers' access to pharmacy services. Indeed, the opportunity to offer pharmacy services in conjunction with other retailing activities might reduce the minimum population size required to support a pharmacy. This could be of benefit to those living in some smaller rural towns.

Nonetheless, the abolition of most ownership restrictions could adversely affect those consumers reliant on access to nearby pharmacies. This is likely to be the case even if the controls on pharmacy approvals and relocations remained in place. That is, these controls would not prevent corporate chains and general retailers acquiring existing licences in the major shopping complexes and regional centres, and using cost and convenience benefits to draw custom from suburban pharmacies and independent pharmacies in some smaller towns. Section 5.3 looks at ways of addressing such access issues.

Substitutes for conventional pharmacy services

In analysing ownership issues, the Review will need to consider the implications of the availability of substitutes for conventional pharmacy services and, in particular, mail-order pharmacy. If ownership restrictions unnecessarily inflate costs, then mail-order pharmacy may erode the market share of conventional services. In the USA, mail-order pharmacy has provided significant cost savings to consumers and, as a result, it now has a significant portion of the market (see box 5.2).

Mail-order pharmacy in Australia has, to date, been a minor segment of the market. Indeed, until recently, it was used only to provide services to consumers in remote communities. Since 1996, however, Pharmacy Direct has operated a general mail-order pharmacy business based in New South Wales.

The lack of development of mail-order pharmacy in Australia appears to have been partly a reflection of the regulatory environment. In the past, there may have been some uncertainty about the capacity of mail-order businesses to advertise their services and prices. Also, in some jurisdictions, Pharmacy Board guidelines relating to premises, face-to-face counselling and the like may have effectively precluded the establishment of mail-order businesses.

Box 5.2 Mail-order pharmacy in other countries

Mail-order pharmacy is most well developed in the USA where it has grown strongly since the early 1970s. In 1994, it accounted for over 10 per cent of the US prescription market. Canada and the Netherlands introduced the system in 1992 and Switzerland followed suit in 1995 (Script 1996). Cost containment has been the driving force behind the use of mail-order pharmacy in these countries.

Several studies have found that mail-order pharmacy is considerably cheaper than community pharmacy. For example, in the USA, mail-order has delivered drug price reductions of between 11 and 25 per cent (Wertheimer and Andrews 1995). Amongst the reasons advanced for these cost savings are that mail-order pharmacy:

- dispenses a greater proportion of generic drugs than community pharmacy. Generic drugs are significantly cheaper than brand name drugs;
- uses high volume buying power to achieve discounts from drug wholesalers. In the USA, in 1992, these discounts averaged 41 per cent for brand name drugs and 67 per cent for generic drugs, compared to an average 13 per cent discount for community pharmacies (Wertheimer and Andrews 1995); and
- achieves significant scale economies in drug handling, delivery and management.

However, given significant inter-country differences in pharmaceutical prices, caution is required in extrapolating the US experience to other countries.

While it may be possible to continue to restrict Australian-based mail-order pharmacy services — even if this involves denying consumers cost savings — controlling international services would seemingly be a much harder task. There are now companies based in the USA offering, via the Internet, to supply prescriptions anywhere in the world.

In any event, the Review might usefully examine the scope for reputable mail-order pharmacy to complement conventional pharmacy services. For example, mail-order could provide a convenient, alternative, source of medicines for the housebound and those living in some smaller country towns. (In this latter regard, it might be a vehicle for addressing any negative access impacts from deregulating ownership controls — see section 5.3). Moreover, based on Pharmacy Direct's price levels (see section 2.4), an expansion in mail-order pharmacy would offer the prospect of substantial price benefits to consumers.

Some have argued that were Australia to encourage mail-order pharmacy, it would have to address the implications of the lack of face-to-face counselling from pharmacists. There are suggestions that, in the USA, consumers have taken advantage of lower drug prices available through mail-order services and then

sought follow-up free advice from community pharmacists. And, more recently, concerns have emerged about 'unscrupulous' mail-order pharmacy businesses offering services via the Internet.

The Commission observes that regulating Internet commerce is proving a considerable challenge. One approach to address concerns in this area would be for governments and/or Pharmacy Boards to certify that particular mail-order services met the relevant regulatory and ethical requirements. A part of such a certification arrangement could be a requirement that mail-order pharmacies offer an effective telephone counselling service to supplement the written advice provided with dispensed medicines. Wertheimer and Andrews (1995) report that most US consumers consider telephone counselling to be an acceptable substitute for face-to-face counselling.

Facilitating price advertising

As noted, a feature of the community pharmacy market is that there is little advertising of prices charged for more potent medicines. The absence of such advertising — other than by mail-order businesses — has both reduced the incentive for pharmacists to compete on the basis of superior cost efficiency, and reduced the market discipline on those pharmacists providing lesser quality or more expensive services. In this regard, the Commission notes that the commencement of price advertising for legal services such as conveyancing in the early 1990s led to the availability of fees significantly below the maximum provided for in the relevant fee schedules at that time (TPC 1992).

Thus, the Commission sees it as important for the Review to test any claims that facilitating the advertising of prices of more potent medicines would entail significant risks for consumers or undermine standards in the profession. This is particularly the case as, without widespread price advertising, there is a risk that the cost savings from any freeing up of ownership restrictions will not be passed on to consumers.

As discussed in chapter 4, it appears likely that price advertising by mail-order pharmacies will sooner or later stimulate competitive advertising by shopfront pharmacies. Endorsement by governments of the validity of, and benefits from, such price advertising could help to hasten such developments.

There may also be a case for this Review — or the related review examining medicines and poisons legislation — to consider whether the current requirements

for price advertising of more potent medicines are unduly restrictive. For example, there is the question of whether the prohibition on pictorial depictions in price advertisements for S4 and some S3 medicines provides any material health and safety benefits.

Allowing the discounting of patient contributions

But even if there were no controls on price advertising, the prohibition on the discounting of patient charges for subsidised PBS prescriptions would continue to discourage price competition in this major segment of the market.

In the Commission's view, the implications of the prohibition on discounting for the cost-efficient delivery of pharmacy services make it an important issue for the Review to consider, even though it is not expressly covered by the terms of reference. If discounting was permitted, the patient contribution specified for subsidised PBS prescriptions would become a *maximum* payment.

However, any recommendation to permit discounting would have to address the concern about encouraging over-prescribing to those consumers already paying heavily subsidised prices for PBS medicines.

One way of addressing this concern could be to increase maximum patient contributions in the light of observed discounts. As well as maintaining a constraint on over-prescribing, such increases in the maximum patient contributions would allow the Commonwealth to share in the cost savings from a more competitive pharmacy market. Setting patient copayments as a fixed percentage of the dispensing fee would be another (more complex) way of diluting the impact of discounting on charges for already heavily subsidised consumers. The subsidy scheme operating in British Columbia employs this approach (see box 5.3).

Market-based remuneration to pharmacists for dispensing PBS drugs

If the Review were to find that the elements of the package described above had merit, it would then be able to consider the scope for market-based remuneration to pharmacists for dispensing PBS drugs. As previously noted, one rationale for the current regulated approach for setting dispensing fees is to compensate for the cost raising effects of the State and Territory constraints on competition in community pharmacy.

Box 5.3 British Columbia's Pharmacare program

In 1974, British Columbia introduced a universal subsidised medicines scheme — B. C. Pharmacare. The scheme uses a market approach to determine remuneration for pharmacists. The Province took this step after experiencing difficulties in settling remuneration through a negotiation process.

Under B. C. Pharmacare, each pharmacy is free to set its dispensing fee (subject to an upper limit), and therefore the price of prescriptions. All receipts have to display the dispensing fee charged.

The scheme also provides for a variable patient copayment. For the elderly, the copayment is 75 per cent of the dispensing fee. Thus, patients have an incentive to shop around for lower priced medicines (Gorecki 1992 and 1993).

Complete deregulation would see the Commonwealth relying solely on market competition to contain dispensing costs. It would therefore remunerate whatever individual pharmacists charged for dispensing subsidised PBS prescriptions.

At least in principle, this approach would:

- offer the prospect of budgetary savings by moving the basis of remuneration for dispensing from average cost towards best practice cost; and
- avoid the need for periodic negotiations on remuneration levels.

However, even in a highly competitive pharmacy market, it would be unrealistic to expect the Commonwealth to simply pay the market rate for dispensing. In particular:

- It is debatable whether such market-driven remuneration would satisfy normal accountability requirements, especially given the large amount of government expenditure involved.
- In some locations, there may be scope for pharmacies to exploit market power to raise dispensing charges above competitive norms.

To cater for these sorts of concerns, one approach would be market-based remuneration, capped at some maximum level. British Columbia's Pharmacare scheme employs this approach.

Deregulation of location controls

In a competitive pharmacy market, the need for any Commonwealth controls on new pharmacy approvals and the relocation of existing pharmacies would be debatable.

Like the arrangements for determining PBS dispensing fees, these controls are, in many respects, a 'second-best' response by the Commonwealth to the inflation in pharmacy costs associated with some of the State and Territory regulations. Hence, if these State and Territory regulations were abolished or relaxed, the cost containment rational for the location controls would largely disappear.

While the relocation provisions are also aimed at promoting more equitable access to pharmacy services, their impact in this regard is questionable. Thus, as discussed in the next section, there are likely to be much more effective ways of pursuing access objectives.

A decision to abolish the location controls would also mean an end to the inflexibilities and interference in commercial decision making that characterise the current arrangements.

5.3 Adjustment and social issues

In assessing the benefits and costs of the current regulations, the Review will need to have regard to social and adjustment concerns. It is not the Commission's role to suggest to the Review what weighting it should give these factors relative to efficiency considerations. However, the Commission wishes to draw the Review's attention to a number of issues that are likely to arise in examining the adjustment and social consequences of changes to the regulation of community pharmacy.

Adjustment effects

The sort of policy changes canvassed in the previous sections would bring about a range of adjustments in the pharmacy sector. While some less efficient pharmacies would close, others would be established to meet currently unmet demand, or to provide an improved service to customers. Some would expand or amalgamate to achieve economies of scale, while others may simply relocate to more appropriate locations. And, individual pharmacies might seek to improve their competitiveness by diversifying their product ranges or introducing cost saving measures.

Employment effects

Relaxation of ownership restrictions and regulations preventing general retail outlets offering pharmacy services would inevitably reduce the number of owner-operated pharmacies.

However, for both pharmacists and their assistants, there would be new employment opportunities with pharmacy chains and supermarket pharmacies. There would also be new opportunities for people with marketing, retailing and management skills. Under the current regulatory structure, owner pharmacists often perform these functions.

This is not to deny that the overall impact of such policy changes on employment in the pharmacy sector may well be negative. The rationalisation and growth of corporate ownership that would follow relaxation of the ownership controls would be underpinned by scope to use inputs, including labour, more efficiently. That said, experience with deregulation in other retail activities suggests that improvements in service levels might ameliorate such employment impacts. For example, the emergence of chain and supermarket pharmacies might see the extension of opening hours. This would create new employment opportunities for both pharmacists and assistants.

Loss of capital values

Policy changes that increased market competition and put a greater premium on cost-efficient service delivery would reduce the capital value of some pharmacies. Not unreasonably, those suffering a reduction in the value of their businesses might argue that this is a cost of such changes.

But, from the point of view of the community as a whole, such reductions in capital values would be an 'income transfer', rather than a true 'economic cost'. That is, the loss to pharmacists would be matched by an income benefit to consumers who would spend less on medications, and taxpayers who would outlay less on the PBS.

Nonetheless, if a reduction in the value of pharmacies was likely to cause significant hardship, or be an insurmountable barrier to achieving policy changes of benefit to the community as a whole, there *may* be a case for government to provide special adjustment assistance (see below).

Social effects

As noted in various places in this submission, one of the major arguments put against relaxation of the regulatory regime for community pharmacy is that it could reduce some consumers' access to pharmacy services.

That there would be some adverse access effects from relaxing ownership controls and the like is not in dispute.

However, relative to the likely number of beneficiaries from a more competitive pharmacy market, it seems probable that the number of disadvantaged consumers would be quite small. Indeed, it is important to recognise that for some consumers, the sort of changes to the regulatory regime canvassed in this submission could improve, rather than reduce, access to pharmacy services. In particular, scope to offer pharmacy services within supermarkets and other general retail outlets could reduce the minimum population required to support a pharmacy service.

Further, the effectiveness of the current regulations in promoting more equitable access to pharmacy services is questionable. For example, despite the ownership controls, some suburban pharmacies are finding it difficult to survive in the face of the trend for consumers to shop in major shopping complexes. Similarly, the relocation controls have not been able to sustain pharmacies in some country areas where demographic changes are reducing the customer base.

This suggests that there is a need to look at more explicit ways of meeting access objectives. Importantly, such alternatives may avoid the need to restrict competition in the delivery of pharmacy services. For example, encouraging mail-order pharmacy would be one way to improve the access to services of immobile consumers and those living in small country towns under either the current, or a less regulated, market environment. Similarly, the special dispensing allowances that help support high cost pharmacies under the current regime (see chapter 3), could be used more widely in a less regulated regime. From an economic efficiency viewpoint, subsidies would normally be the preferred means of pursuing access objectives.

Adjustment assistance

For some industries facing significant adjustment pressure from policy reforms, governments have implemented specific assistance programs.

The need for such programs will depend on the nature of the industry and its workforce, and on the significance of the adjustment problem. Hence, without a specific reform package on the table, it is not possible to indicate whether the community pharmacy sector would warrant adjustment assistance.

Nonetheless, there are a number of general considerations which will be relevant to the Review's assessments of this issue.

Often, generally available measures will be sufficient to address adjustment problems in industries undergoing structural change. These general measures include:

- labour market programs designed to provide displaced employees with the skills necessary to find alternative employment; and
- social security support.

But there may be a case for additional, more specific, measures when:

- general measures are not well tailored to a specific adjustment problem;
- adjustment has a significant regional dimension, or affects a group in the community with few alternative employment opportunities; or
- a 'circuit breaker' is required to progress a reform with significant benefits for the wider community.

Sometimes specific adjustment assistance can simply involve introducing policy changes gradually. Sometimes it can involve a special labour market program for an industry or sector. And, it can sometimes involve the provision of financial assistance to facilitate the policy change — as occurred with the pharmacy restructuring program in the first half of the 1990s.

At the same time, it is important to recognise that industry-specific adjustment assistance has drawbacks, particularly if financial compensation for business owners is involved:

- Prices paid for pharmacies leading up to, and during this review, might have been discounted in expectation of changes to the regulatory regime. If this were the case, then the provision of financial compensation would provide a 'windfall' gain to recent purchasers.
- Providing one industry with specific adjustment assistance may create
 precedents which are difficult to resist even if the circumstances of other
 industries are markedly different.

Hence, there is a need for governments to tread carefully in this area.

In the case of pharmacy, phasing in the sorts of changes outlined above would probably not be an option. And, as one of the main adjustment impacts would probably be the reduced value of some pharmacy businesses, financial assistance would almost certainly be at issue. Again, however, the Commission stresses the need to consider such matters in the context of a specific reform proposal.

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