



Australian Government  
Department of Health

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# POST-IMPLEMENTATION REVIEW

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**Amendments to the *National Health Act 1953* to extend the  
Pharmacy Location Rules to 30 June 2015**

# Table of Contents

<b>Purpose of the Post-Implementation Review</b>	<b>4</b>
<b>Executive Summary</b>	<b>4</b>
<b>Background</b>	<b>5</b>
National Medicines Policy (NMP) .....	5
The Pharmaceutical Benefits Scheme (PBS) .....	5
Community pharmacy .....	6
Community Pharmacy Agreements.....	6
Location Rules under the Fourth and Fifth Agreements .....	8
Reviews of pharmacy location arrangements .....	9
The Wilkinson Review (2000)	9
Productivity Review of National Competition Policy Reforms (2005)	10
Department of Health and Ageing and Guild Joint Review (2005)	10
Urbis Review (2010)	11
International comparison .....	11
<b>Problem</b>	<b>11</b>
Why do we need a well-distributed and viable network of pharmacies?.....	11
<b>Objective of Government Action</b>	<b>12</b>
Geographical spread.....	12
Reasonable trading hours.....	12
Physical accessibility.....	13
<b>Impact Analysis</b>	<b>13</b>
Numbers of approved pharmacies .....	13
Extension of the Rules (2010).....	14
Community Pharmacy impacts.....	15
Costs	15
Benefits	15
Consumer impacts .....	16
Costs	16
Benefits	17
Medicines Industry impacts.....	17
Government impacts .....	17
Costs	17
Benefits	17
Outcome .....	18
<b>Competition Assessment</b>	<b>18</b>
<b>Consultation process</b>	<b>20</b>
What are the views of those parties?.....	21
<b>Other options</b>	<b>21</b>
Option 1: Targeted easing of the existing Rules.....	22
Description of measure	22

Who would be affected?	22
Effects on existing regulation and regulatory authorities	22
Likely benefits and costs	22
Option 2: Remuneration Based Incentives .....	22
Description of measure	22
Who would be affected?	23
Effects on existing regulation and regulatory authorities	23
Likely benefits and costs	23
Option 3: Complete Deregulation .....	24
Description of measures	24
Who would be affected?	25
Effects on existing regulation and regulatory authorities	26
Benefits and costs	27
<b>Subsequent amendments to the Rules (2011)</b>	<b>27</b>
Who was affected? .....	28
Effects on existing regulation and regulatory authorities .....	28
Benefits and costs .....	28
<b>Conclusion</b>	<b>29</b>

## Purpose of the Post-Implementation Review

Australian Government agencies are required to undertake a Post-Implementation Review (PIR) when regulation, with more than a minor machinery of government impact, is introduced without a regulation impact statement. A PIR is required to examine:

- the problem the regulation was intended to address;
- the objective of government action;
- the impacts of the regulation; and
- the effectiveness of the regulation in meeting its objectives.

This PIR is required because no Regulation Impact Statement (RIS) was developed at the time of the decision to extend the operation of the [Pharmacy Location Rules](#) (the Rules). This document is the PIR for the *Health Legislation Amendment (Australian Community Pharmacy Authority and Private Health Insurance) Bill 2010* (the Amendment Bill).

Consultation is also required as a part of a PIR. However, since the extension of the Rules in 2010, a review of the Rules has been completed and amendments were made in October 2011. While those amendments are not within scope of this PIR, the consultation that was undertaken as a part of that review process is directly relevant to this PIR.

## Executive Summary

The locations of pharmacies in Australia, approved by Government to supply medicines subsidised under the Pharmaceutical Benefits Scheme (PBS), are determined through the application of Pharmacy Location Rules (the Rules).

The Rules have existed since 1990 when the first (five-year) Community Pharmacy Agreement was signed between the Australian Government and the Pharmacy Guild of Australia.

The Amendment Bill had the effect of extending, under the *National Health Act 1953* (the Act), the operation of the Rules and the operation of the Australian Community Pharmacy Authority (the Authority) for the term of the Fifth Community Pharmacy Agreement (Fifth Agreement) until the end of June 2015.

The extension of the Rules, for the term of the Fifth Agreement, was to ensure Australia continues to maintain a viable and sustainable network of community pharmacies approved to supply PBS medicines and pharmacy health services funded under the Fifth Agreement.

This PIR examines the issue of whether the continued regulation of pharmacy locations, through the extension of the Rules, is detrimental to pharmacy businesses and consumers. It also examines the question of whether, if the Rules no longer existed, it would be detrimental to the objectives of Government in relation to the delivery of timely access to medicines that Australians need, at a cost individuals and the community can afford.

The PIR concludes that the policy objectives of the Rules are consistent with the broad objectives of national health policy, in particular, the National Medicines Policy which has timely access to medicines as one of its four key pillars. In addition, there is a net benefit to the retention of the Rules, particularly for consumers in rural and remote areas, although it is acknowledged that further easing of the Rules may have additional benefits.

Subsequent amendments to the Rules were made in October 2011 as a result of a 2010 review of the Rules held under the Fourth Community Pharmacy Agreement (the Urbis Review). While relevant to this review, the decision to introduce those amendments is not within scope of this PIR and the amendments did not require a RIS.

## Background

### **National Medicines Policy (NMP)**

Medicines in Australia are provided within the context of the NMP which is a co-operative endeavour to bring about better health outcomes for all Australians, focusing especially on people's access to and quality use of medicines. It was launched in December 1999 with whole of Government support. The NMP has the following central objectives:

- timely access to medicines that Australians need, at a cost individuals and the community can afford;
- medicines meeting appropriate standards of quality, safety and efficacy;
- quality use of medicines; and
- maintaining a responsible and viable medicines industry.

The NMP functions within the context of wider public health strategies and policies including:

- The National Strategy for Quality Use of Medicines;
- The National Primary Health Care Strategy;
- The National Preventative Health Strategy; and
- The National Health and Hospital Reforms.

### **The Pharmaceutical Benefits Scheme (PBS)**

The PBS provides access to necessary medicines, at a cost that individuals and the community can afford. The PBS is a key part of the Australian health system.

Through the PBS, the Australian Government (the Government) seeks to ensure a cost effective delivery of medicines. Government investment in the PBS is significant, amounting to around 16 per cent of annual health expenditure and 0.7 per cent of gross domestic product in 2011-12. Patient co-payments complement government payments.

Consistent with the NMP, one of the objectives of the PBS is that all Australians should have reasonable access to prescription medicines, regardless of their capacity to pay or where they live. Because of the nature of the demographic and geographic distribution of the Australian population, some members of the community have more difficulty than others in obtaining reasonable access to health services, including the supply of PBS medicines.

The PBS and its sister programme targeted at veterans, the Repatriation Pharmaceutical Benefits Scheme (RPBS), are primarily delivered through Australia's network of over 5,000 approved pharmacies. The majority of Government PBS/RPBS payments (about \$9 billion in 2011-12) are made to those pharmacies. The PBS and RPBS programmes are intended to make prescribed medicines affordable and accessible for all Australians. (*Unless otherwise noted – future references to the PBS include the RPBS*).

## **Community pharmacy**

The community pharmacy sector, as the delivery mechanism for PBS medicines and related professional pharmacy services, is an integral part of Australia's health care system.

For most Australians, the community pharmacy is their shopfront for a range of medicines and health care products such as:

- prescription medicines, including those supplied through the PBS, and over-the-counter medicines available only from pharmacies; and
- non-scheduled and over-the-counter medicines, healthcare and other products, such as cosmetics, that are also available from other retail outlets.

In addition, the community pharmacy network is a mechanism used to deliver a range of broader health services to the Australian community, funded under Community Pharmacy Agreements. Pharmacists employed in the community pharmacy sector deliver a range of Government funded and medication related services such as clinical interventions, dose administration aids, diabetes services and medication reviews, and provide professional advice to consumers on the safe and effective use of medicines.

## **Community Pharmacy Agreements**

The Community Pharmacy Agreements are five-year agreements signed between the Australian Government and the Pharmacy Guild of Australia (the Guild). The first agreement was signed in 1990 and there have been five agreements since that time.

The First Agreement (1990-1995) was reached against a background where:

- an enquiry conducted by the Pharmaceutical Benefits Remuneration Tribunal (PBRT) in 1988 had indicated that pharmacists were being remunerated considerably more than the cost of dispensing;
- remuneration arrangements for community pharmacy included an "economy of scale factor"<sup>1</sup> which meant that if average prescription volumes decreased, the remuneration per prescription increased. This served as a disincentive for pursuing efficiencies through growth in pharmacy size; and
- the overall pharmacy to population ratio in Australia was, at the time, considered high compared to other developed countries.

Further, at the time of the introduction of the first iteration of the Rules in 1990, there was concern about the unevenness of the distribution of pharmacies. The enquiry conducted by the PBRT noted that many areas had pharmacies located within 10 metres of each other, 25 per cent of pharmacies were within 100 metres of another pharmacy and 62 per cent were within 1 kilometre of another pharmacy.

In contrast, consumers in rural and remote areas had relatively poor access, with a significantly lower pharmacy to population ratio. Some rural and remote consumers experienced distance barriers to access to pharmacies, which made it difficult or expensive for consumers to access needed prescription medicines. This contributed to poorer health outcomes for rural and remote Australians than for those in urban or near-urban areas.

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<sup>1</sup> The "economy of scale factor" refers to a feature of remuneration at the time, whereby dispensing remuneration reduced with increasing volume. That is, the greater the number of prescriptions that a pharmacy dispensed, the lower the average payment per medicine dispensed. It was believed that this encouraged small and inefficient pharmacies.

To address these issues in a way that would minimise the potential for conflict between parties, the Government and the Guild agreed to set out a new remuneration framework. This was coupled with Rules ensuring a more rational distribution of pharmacy services, resulting in industry restructuring that would lower pharmacy numbers and encourage greater efficiency, profitability and economies of scale in individual pharmacy businesses.

In the First Agreement, the Rules were primarily about the relocation of pharmacies, with strict requirements for the establishment of a new pharmacy, including that the proposed pharmacy needed to be at least 5km from the nearest approved pharmacy. In the short term the First Agreement enabled two major policy objectives to be met: winding back of what was then considered unsustainable growth in PBS remuneration, and, via the introduction of the Rules, rationalising and reducing numbers of relatively inefficient pharmacies, in cooperation with the Guild.

The Second Agreement (1995-2000) sought to consolidate the remuneration structure and efficiency gains of the first. This agreement separately maintained pharmacy location restrictions, both in terms of satisfying a community need criteria to establish a new pharmacy, and to satisfy primarily distance-based criteria for relocated pharmacies.

The Third Agreement (2000-2005) reduced the emphasis on prescription based remuneration arrangements and modified the Rules governing the location of pharmacies. The requirements for both new and relocated pharmacy approvals were relaxed, particularly in rural and remote areas. Financial incentives to establish new pharmacies in rural locations were also introduced.

Under the Fourth Agreement (2006-2010), the major changes to the Rules were the introduction of new provisions to facilitate the relocation of pharmacies into large medical centres, as well as small and large shopping centres (to recognise changing retail trends to smaller community shopping centres). There was also improved flexibility to allow the relocation of an existing pharmacy into single pharmacy towns and high growth single pharmacy urban areas.

**The Fifth Agreement (2010-2015)** took effect from 1 July 2010 and will operate until 30 June 2015. The Fifth Agreement recognises that community pharmacy is an integral part of the infrastructure of the health care system in its role in primary health care through the delivery of the PBS and related professional pharmacy services.

The Fifth Agreement provides \$15.6 billion over the life of the Agreement (as set out in Table 1 below) for more than 5,000 community pharmacies for dispensing PBS medicines, providing pharmacy programmes and services, and for the Community Services Obligation (CSO) arrangements with pharmaceutical wholesalers. It provides funding to retain services that enhance patient medication management including a focus on improving quality use of medicines by Aboriginal and Torres Strait Islander peoples. The commitment to supporting rural pharmacies and the rural pharmacy workforce is maintained, and research is being commissioned on evidence-based best practice in quality pharmacy services.

**Table 1: Funding for elements of the Fifth Community Pharmacy Agreement**

<b>Element</b>	<b>\$m</b>
Pharmacy remuneration (includes dispensing fee, pharmacy and wholesale mark-up, extemporaneously prepared and dangerous drug fees, premium free dispensing incentive and electronic prescription fee)	13,771.6*
Programs and services	386.4
Additional Programs to support patient services	277.0
Community Service Obligation	949.5
<b>Total</b>	<b>15,384.5*</b>

\*Estimates variations in January 2011 and 2013 increased this amount by \$286.4 million to \$14,058.0 million. The revised total is now \$15,670.9 million.

The Agreement ensures that pharmacists receive fair and adequate remuneration for the pharmaceutical benefits that they supply under Part VII of the Act so that:

- a stable environment is created for community pharmacy, enabling it to remain viable and to participate in the continuity of care for all Australians;
- positive health outcomes are attained by the Australian community through the efficient delivery of patient-focused professional services and programmes; and
- there is a network of accessible and viable community pharmacies throughout Australia including in rural and remote areas.

#### **Location Rules under the Fourth and Fifth Agreements**

Under the Fourth Agreement, detailed objectives for the Rules were established. These objectives remain under the Fifth Agreement. The specific objectives of the Rules are to ensure:

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

The Rules under the Fourth Agreement were determined by the then Minister for Health and Ageing in 2006. The 2006 Rules addressed the establishment of new approved pharmacies and the relocation of existing approved pharmacies. In essence, the requirements for the establishment of new pharmacies were that:

- in urban areas, new pharmacies needed to be 1.5 km from the nearest pharmacy, and located in an area with a catchment of at least 3,000 residents and containing at least one general practitioner; and
- in rural locations, the pharmacy needed to be 10 km from the nearest pharmacy.

For the relocation of an existing approved pharmacy the requirements included:

- for a long distance relocation, the pharmacy needed to be 1.5km from the nearest approved pharmacy;



- for short distance relocations, pharmacies could relocate up to 1km from the existing location or if they were relocating within in a shopping centre, large medical centre or private hospital as defined in the Rules (subject to certain time restraints and exceptions);
- for relocations between 1km and 1.5km, the pharmacy needed to move to a location that was 500m from all pharmacies that were more than 1km from the original premises;
- for a relocation to a small shopping centre (defined as one large supermarket and at least 15 other commercial establishments), the pharmacy needed to be at least 500 metres from the nearest approved pharmacy;
- for a relocation to a large shopping centre (defined as one small supermarket and at least 30 other commercial establishments), there were no distance restrictions;
- for a relocation to a large medical centre (one that operated at least 70 hours per week and had one or more prescribing medical practitioners at the centre for at least 70 hours each week, and a total of at least eight full-time equivalent general practitioners, the pharmacy needed to be at least 500m from the nearest approved pharmacy;
- for a relocation to a private hospital (with a minimum number of 150 beds), there were no distance restrictions; and
- for a relocation to a rural town with only one approved pharmacy, the town needed to have at least four full-time equivalent general practitioners and a catchment of 8,000 people and the proposed pharmacy needed to be 200 metres from the existing pharmacy.

The Rules under the Fourth Agreement were extended under the Fifth Agreement. This was done on the understanding that an independent review of the Rules had commenced (the Urbis Review) and amendments to the Rules to enhance the efficiency and effectiveness of the Rules were to be implemented following consideration of the outcomes of the review. Those amendments, which came into effect on 18 October 2011, are outlined in the Urbis Review discussion below.

### **Reviews of pharmacy location arrangements**

Since 2000, a number of reviews have considered the appropriateness, effectiveness and efficiency of the Rules - the *Wilkinson Review* (2000), the *Productivity Review of National Competition Policy Reforms* (2005) and the *Department of Health and Ageing and Guild Joint Review* (2005).

As part of the Fourth Agreement, the Government and the Guild agreed to undertake a review of the Rules prior to the expiry of the Agreement on 30 June 2010. This review, the *Urbis Review* (2010), is the most recent independent review of the Rules.

#### *The Wilkinson Review (2000)*

The National Competition Policy Review of Pharmacy chaired by Warwick Wilkinson AM (the Wilkinson Review) was established in June 1999. It was a mechanism enabling the Commonwealth, States and Territories simultaneously to meet their National Competition Policy obligations to review their respective legislation regulating the operation of the pharmacy industry and pharmacy professional practice.

The Wilkinson Review reported in February 2000. It found that the Rules:

- helped maintain a stable and sustainable local pharmacy market and minimum market saturation;
- facilitated the placement of new and relocated pharmacies in localities where there was a genuine community need for pharmacy services; and
- kept pressure on growth in Government expenditure on the PBS to a minimum.

It also found that:

- while some form of restriction on the number of pharmacies dispensing PBS medicines should be retained, there may be more 'competition friendly' mechanisms for keeping overall pharmacy numbers to a level consistent with community need;
- existing regulation of approvals of new pharmacies was placing significant restrictions on competition; and
- if other remuneration-based measures to encourage more efficient and better distributed pharmacies proved to be impractical, existing regulation should be reformed.

The findings and recommendations of the Wilkinson Review were taken into account by the Government when reformed regulation for pharmacy location was negotiated as part of the Third Agreement.

*Productivity Review of National Competition Policy Reforms (2005)*

In February 2005, the Productivity Commission reported on its Review of National Competition Policy Reforms. It found that, in the area of pharmacy regulation, restrictions potentially impose increased costs on consumers, taxpayers and the wider community. It also observed that previous reviews had not been able to fully explore the linkages among the different regulations and recommended that a new and broader review of pharmacy restrictions should take place in 2008, in time to inform the renegotiation of the subsequent Community Pharmacy Agreement in 2010. It also observed that there may still be opportunities for some beneficial changes to be implemented as part of the Fourth Agreement (2005-2010).

*Department of Health and Ageing and Guild Joint Review (2005)*

As part of their commitments under the Third Agreement, the Department of Health and Ageing and the Guild conducted a joint review of pharmacy location provisions in preparation for the Fourth Agreement (2005). The review sought to:

- evaluate the benefit of the existing pharmacy location arrangements, taking account of relevant policy objectives;
- identify any significant anomalies in the application and administration of the Rules, and consider alternatives to remedy any anomalies; and
- report on alternative arrangements taking account of relevant policy objectives and transitional issues.

The review received submissions from interested parties and a consultant was engaged to assist with the analysis.

The report of the joint review recommended that there be a continued targeted easing of the existing Rules to provide greater flexibility to respond to community need for pharmaceutical services and for changes to the existing Rules to address administrative difficulties and anomalies.

The report identified a number of anomalies and administrative difficulties in the existing Rules that had resulted in a limited ability to address unforeseen or unique circumstances or leave the Rules open to interpretation and challenge. It suggested possible solutions to address these problems and also identified several areas where more flexibility could be introduced to improve access to pharmacy services in some settings and communities. The majority of these suggestions were incorporated into the Rules which were in effect under the Fourth Agreement and were extended under the Fifth Agreement.

### *Urbis Review (2010)*

The Urbis review focused on the efficiency and effectiveness of the operation of the Rules and the report proposed several issues for consideration. These addressed a number of concerns that had been raised in the review including difficulties regarding the definition and interpretation of the catchment criteria and the need to respond to emerging health care sector reforms to co-locate pharmacies with other health services. It also addressed the development, over a number of years, of a “black market” in the trading of pharmacy approval numbers.

The full report of the Urbis Review, which includes a description of the consultation process, can be located [here](#).

Following the publication of the 2010 Urbis review report on the Department’s website on 26 November 2010 and further consultation with key stakeholders, amendments to the Rules were introduced with effect from 18 October 2011. Through a targeted easing of existing regulations, the simplified Rules:

- converted the majority of relocation rules to new pharmacy rules. The relocation of an existing pharmacy was no longer required to establish a pharmacy in shopping centres, large medical centres, private hospitals and one-pharmacy towns. This made it easier and cheaper to establish a pharmacy in such circumstances and provided greater flexibility to respond to community need;
- simplified the catchment criteria by the introduction of an objective test based on existing services and attractions;
- abolished three Rules which either had fulfilled their intended purpose and were no longer required, were confusing to applicants and not widely used, or were not achieving the desired outcomes; and
- relaxed the requirements to establish a pharmacy in a large medical centre to better address emerging health care delivery models.

The changed Rules also extended the existing restriction on pharmacies operating within supermarkets and addressed, to a significant extent, the unintended market for, and value of, pharmacy approvals.

### **International comparison**

As in Australia, the pharmacy sector is regulated in many other nations. While the framework and extent of regulation varies between countries, the location (or ‘establishment’) of pharmacies is a common feature of pharmacy regulation. Internationally, debate over the regulation of pharmacy sector and markets has continued for some years. The varying approaches to the regulation of the pharmacy sector are discussed in [Attachment A](#).

## **Problem**

### **Why do we need a well-distributed and viable network of pharmacies?**

The community pharmacy network is the distribution system for the PBS. If the pharmacy network, left unaided, cannot deliver reasonable access for all Australians, as was the case immediately prior to the commencement of the First Agreement, then some regulatory intervention in the market is needed to ensure that medicines are available (to all Australians) efficiently and equitably through the PBS.

Without a well distributed network of pharmacies, consumers in rural and remote areas would experience distance barriers to access to pharmacies. As was the case before the First Agreement, it can then be difficult or expensive for consumers to access needed prescription medicines, which is counter to the key pillars of the NMP. This also results in poorer health outcomes for rural and remote Australians than for those in urban or near-urban areas.

The Government is interested in a well distributed network of approved community pharmacies that closely matches the demographic distribution of the Australian community which, in addition to the supply of medicines subsidised under the PBS, can deliver a range of pharmacy services that form part of the Fifth Agreement.

In delivering these services, along with the supply of PBS medicines, the incidence of medicine misadventure is minimised. This provides better health outcomes for individual patients and also reduces the impact on the broader health system, e.g. less presentations to emergency departments following misuse of medicines. This is a key mechanism through which the Government meets the timely access and quality use of medicines objectives of the NMP.

The Rules are also inextricably linked to the other elements that form part of the Community Pharmacy Agreements. By including the Rules as an element of the negotiations, the Australian Government is able to reach agreement on a range of other identified and targeted policy objectives which provide enhanced health programs and services to the community, as well as delivering important savings to the Government to ensure the sustainability of the PBS (including the ability to list new and innovative drugs on the PBS as they become available).

## Objective of Government Action

For the past 23 years, the regulation of the location of pharmacies, through location Rules, has been, and continues to be, an integral component of the Community Pharmacy Agreements between the Government and the Guild.

The Government is seeking to ensure that any regulatory intervention in the community pharmacy network is consistent with the goals of reasonable access; efficient and equitable delivery of medicines; and ensuring competition between pharmacies is only restricted to the extent justified by this need.

Whilst 'access' is not defined in the Act or the Rules, the Department considers there are three main elements to community access to PBS medicines. These are the *geographical spread* of pharmacies throughout Australia, *reasonable trading hours* for approved pharmacies and the *physical accessibility* of pharmacy premises by members of the community.

### Geographical spread

The purpose of the Rules is to provide a suitable geographical distribution of accessible pharmacies which includes rural and remote regions of Australia. The distance requirements in the Rules serve to improve the geographical spread of pharmacies in areas of demonstrated community need, whilst reducing the unnecessary clustering of pharmacies.

The last time there was no regulation of pharmacy location in Australia was in 1989/90 and the situation at that time has been described earlier.

### Reasonable trading hours

This element of access is primarily addressed through section 90 (3D) of the Act which means that an approval cannot be granted to a pharmacist to open or operate an approved pharmacy unless the

delegate is satisfied that the pharmacy will be accessible to the public at times that are reasonable (generally meaning at least the normal business hours).

### **Physical accessibility**

This element of access is primarily addressed through item 211(b)(ii) of the Rules which requires that the pharmacy premises must be accessible to members of the public at large and not restricted to certain classes of the community.

## **Impact Analysis**

### **Numbers of approved pharmacies**

Prior to the commencement of the First Agreement in 1990, there were 5,609 pharmacies in Australia, with a pharmacy to population ratio of 1:2,974. Between 1990 and 1995 there were 630 pharmacy closures and 64 amalgamations, resulting in a decrease of 665 pharmacies in Australia, to just below 5,000.

Many pharmacies were clustered in few, and mostly urban areas. Conversely, there were some areas with few or no pharmacies. In addition, there were a number of relatively inefficient pharmacies which were primarily in commercially attractive urban areas. There was also a concern that the pharmacy to population ratio, at that time, was too high compared to other developed nations. As the Rules evolved in successive Agreements, a ratio of approximately 1:3,000 to 1:4,000 was deemed appropriate.

The number of pharmacies remained relatively stable from 1995 through until the commencement of the Fourth Agreement on 1 July 2006. At that time, there were 4,973 approved pharmacies, including 4,142 in urban localities and 831 in rural localities. During the Fourth Agreement, to 30 June 2010, the number of pharmacies steadily increased with a net increase of 116 approved pharmacies in urban localities and 77 in rural localities.

As at 30 June 2012 there were a total of 5,241 approved pharmacies in Australia - see Table 2.

**Table 2: Number of PBS approved pharmacies in Australia from 2005/06 to 2011/12**

<b>Year</b>	<b>Urban</b>	<b>Rural</b>	<b>Total</b>
2005/06	4,142	831	4,973
2006/07	4,158	818	4,976
2007/08	4,172	833	5,005
2008/09	4,188	858	5,046
2009/10	4,212	876	5,088
2010/11	4,258	908	5,166
2011/12	4,286	955	5,241

From 2006 to 2012, the number of urban pharmacies increased by 3.5 per cent, while the number of rural pharmacies increased by 17.3 per cent.

Consequentially, the number of pharmacies increased at a slower rate than the population from 1995 to 2010. Since that time, the increase in the number of pharmacies has been greater than the rate of population growth. At 30 June 2012 the pharmacy to population ratio was 1:4,328. This

information lends weight to the conclusion that the Rules are facilitating a pharmacy network that is well-distributed.

### Extension of the Rules (2010)

No changes were made to the Rules between the Fourth Agreement and the Fifth Agreement.

The Rules continued to influence the number and distribution of pharmacies. New pharmacies could only be established where both the community need criteria and distance requirements of the Rules could be satisfied. This restricted the number of approvals for pharmacies as the opportunities to meet the requirements for a new pharmacy were limited (as there are only two rules under which a new pharmacy could be established).

This impacted most heavily on those pharmacists wishing to enter into pharmacy ownership. If pharmacists were not able to identify an opportunity to establish a new pharmacy, they may have chosen to purchase a pharmacy (or a pharmacy approval number) to relocate to their desired premises. The relative scarcity of pharmacies or approval numbers for sale drove up the value of the pharmacies and approval numbers in some cases.

The restrictions on the relocation of existing pharmacies were also continued. In general, pharmacies were able to relocate up to one kilometre from their existing premises as long as they had been at those premises for at least two years. Further, existing pharmacies could relocate any distance over one kilometre provided that the proposed premises were at least 1.5 kilometres from the nearest approved premises. These opportunities did not apply, in some circumstances, if the pharmacy had previously been relocated into a shopping centre, large medical centre or private hospital as defined under the Rules. Those pharmacies that had been established in rural towns were not able to relocate out of the town.

The number of applications considered by the Authority in recent years is shown in Table 3 below. For a number of reasons, there are often multiple applications for the same or similar location.

**Table 3: Applications for approval considered by the Authority**

APPLICATIONS	2009/2010	2010/2011	2011/2012
<b>RECOMMENDED</b>			
Relocations	221	218	219
New	60	78	101
<b>Subtotal</b>	<b>281</b>	<b>296</b>	<b>320</b>
<b>NOT RECOMMENDED</b>			
Relocations	51	81	84
New	68	94	163
<b>Subtotal</b>	<b>119</b>	<b>175</b>	<b>247</b>
<b>TOTAL</b>	<b>400</b>	<b>471</b>	<b>567</b>

The community pharmacy sector, consumers, the medicines industry, large retailers who had previously expressed an interest in operating pharmacies in supermarkets and the Government are all affected by the continuation of the Rules.

## Community Pharmacy impacts

### *Costs*

The compliance costs imposed by the Rules are relatively small. There are no application fees or other charges for a pharmacist to apply for or obtain an approval. Applicants need to take the time to collect the evidence required to include with an application, but most of this involves the provision of documents and information that would normally be collected as part of establishing or relocating the pharmacy.

There is the need to provide some additional evidence for some Rules, including the requirement to demonstrate that distance requirements or the community need indicators (catchment population or services) are met. While most applicant pharmacists prepare and submit their own applications, a significant number (approximately 40 %) choose to employ agents (broker or solicitor) who provide a service to co-ordinate and submit applications. In addition, approximately 10 % of applicants obtain a surveyor's report as evidence to support the distance requirements of their application. Not all of these costs would be incurred in the absence of the Rules, but some administration requirements would remain in order to participate in the PBS. Some applicants also engaged town planners to help complete their application.

These different approaches result in a wide spread of costs involved in preparing an application. It is estimated that these costs can vary from as little as \$260 for a pharmacist prepared application to approximately \$6,500 for an application involving the use of a broker/solicitor and requiring the use of a surveyor. When considering the estimated number of applicants using the variable approaches and costs, the estimated average cost per application is approximately \$2,300. The overall annual compliance cost to community pharmacy is approximately \$1.074 million<sup>2</sup>.

In addition, some applicants choose to apply to the Administrative Appeals Tribunal or the Federal Court to overturn the recommendations of the Authority. This is a voluntary decision by the pharmacists involved. Whilst this incurs costs for both parties, they are not considered to be compliance costs imposed by the establishment of the Rules.

The Urbis Review noted that the Authority process was considered by a number of applicants to be unnecessarily lengthy. For some pharmacists this increased lag time meant that PBS-related revenue could not be earned while operating costs continued.

With the Rules remaining in place between the Fourth and Fifth Agreements, opportunities for new pharmacies to be established remained limited. In addition, as noted previously, the Urbis Review (2010) found that the rising cost of purchasing a PBS approval continued to limit opportunities for many pharmacists looking to purchase a pharmacy. The impacts of the restriction on competition are discussed further in this PIR.

### *Benefits*

In maintaining the Rules to ensure all Australians have access to PBS medicines, there is a level of protection of the asset values of existing pharmacies. The existing community pharmacy sector is

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<sup>2</sup> Costs calculated based on the 471 applications considered by the Authority in 2010/11 and an estimate that 60 per cent would be prepared by the business owner and the remaining 40 per cent by either a pharmacy broker or solicitor. Assumptions include; a) individual applicants time being costed at the Pharmacy Manager award rate as per the Pharmacy Industry Award 2010; an estimated 10 hours at an hourly rate of \$500 for a Senior Associate when a solicitor is used; c) an estimate of brokers fees at \$5,000 per application; d) approximately 10 per cent of applications involving a registered surveyor at an estimated cost of \$1,500.

able to plan, invest and operate with a relatively high level of certainty in terms of the number of competitors in their markets while the Rules are in place. While the Rules provide a level of protection from new entrants to the market, the relocation options do not prevent pharmacies from clustering together to some degree over time, although there are restrictions on relocation imposed by the Rules.

No pharmacies were forced to close or relocate at the time of the original introduction of the Rules in 1990, so some areas with a high number of pharmacies have retained high numbers. Additionally, the Rules allow for some pharmacies to relocate, up to 1km, every two years. This means that there are some areas with a high number of pharmacies (some of which may have more pharmacies than was the case in 1990 prior to the introduction of the Rules) with the result being an increase in competition between the pharmacies.

The Urbis Review also noted that the “majority of previous applicants involved in the review noted that the application process was relatively straight forward.”

The removal of the Rules would likely result in a significant reduction in the capital value in community pharmacies thereby impacting on the current pharmacy owners as small business operators. Arguably, this could require some readjustment assistance to the sector from the Government if reforms were to be pursued.

### **Consumer impacts**

The immediate impact of extending the Rules was negligible. Consumers continued to have widespread access to PBS medicines across Australia. The extension of the Rules did not change the PBS co-payment arrangements. There was no change to the number of pharmacies or the cost to consumers for the medicines, retail items and services they were accessing through the community pharmacy network.

#### *Costs*

In May 2010, the Consumers Health Forum (CHF) issued its “Analysis of the Fifth Community Pharmacy Agreement” information paper. The paper included statements about the Fifth Agreement generally as well as some specific to the Rules. The section on Location Rules stated:

“Consumers had mixed views about the location rules. Some felt strongly that the rules should be removed or loosened, to allow for increased competition between pharmacists. Others, however, argued that removing the location rules could result in less profitable pharmacies closing, particularly in rural and remote areas.

The location rules will continue unchanged at this stage. However, a review of the location rules is currently underway. CHF has been consulted as part of this review, and provided input on the broad range of consumer views.”

The costs to consumers of extending the Rules includes that in some areas there would be reduced numbers of pharmacies than may be the case without the existence of the Rules, which may result in less competition. This may be more evident in urban areas than rural and remote areas. This would be most noticeable in the potential higher prices for some products sold in pharmacies, particularly non-PBS, pharmacy-only medicines. Some costs are also experienced by consumers in relation to the Rules due to delays experienced by applicants during the Authority approval process. For consumers this can mean a longer period without access to pharmacy services.



### *Benefits*

From the CHF paper mentioned above, it is stated that:

“On the whole, CHF is pleased with the final version of the Fifth CPA. While the Fifth CPA provides for \$1 billion in savings over the five years of the Agreement, the proportion of program funding going to Patient Focused Services has increased from 53 per cent to 78 per cent. These services will include an ongoing focus on medicines management, including through Medicines Use Reviews.

Key initiatives to protect continued consumer access to PBS medicines will continue unchanged or largely unchanged, including the Community Service Obligation Pool and the Location Rules.”

The Rules continue to benefit consumers through the improved geographical distribution of pharmacies. This is particularly the case in rural areas (refer to Table 2). Since the introduction of the Rules, there has also been a greater geographical spread of pharmacies in urban areas than would have likely been the case in the absence of the Rules.

### **Medicines Industry impacts**

The market for prescription pharmaceuticals in Australia is relatively static and the location of pharmacies does not impact on that market to any significant extent. Should the Rules have been discontinued, it is anticipated that the impact on the medicines industry would have been negligible.

### **Government impacts**

#### *Costs*

The cessation of the Rules could have represented a save of approximately \$10-15 million dollars in decreased costs. This estimate includes Government costs to administer the Rules, legal costs of handling appeals against decisions of the Authority for both Government and pharmacists as well as regulatory costs incurred by pharmacists to lodge applications. If the Rules were discontinued, there could be significant costs in implementing any incentives or other measures that may be established to ensure the desired geographical distribution of pharmacies currently achieved by the Rules.

#### *Benefits*

The Government, with the advice of the Authority, continued to administer the Rules for PBS purposes. The Authority and related machinery in the then Department of Health and Ageing and the Department of Human Services (Medicare) were retained. There were no immediate changes to the existing regulations relating to the Rules and the Authority's role and functions did not change.

Retaining the pharmacy location arrangements without any change maintained the existing benefits to the Government and the Australian community of the Rules. While this cannot be measured as a part of the PIR, it is logical to assume that the greater spread and availability of medicines and services would lead to fewer presentations to emergency departments of hospitals by patients with medical misadventure.

In an environment where professionals of all kinds, and particularly health professionals, are difficult to attract to rural areas, the maintenance of the Rules contributed to accessibility of medicines and services in these areas. The ratio of pharmacies to population in Australia has been estimated at 1:4,094, and overall, there is not much difference between the ratio in urban areas and non-urban areas.

**Table 4: Australia 2011 Pharmacy to Population Ratio<sup>3</sup>**

Australia	Urban (PhARIA <sup>4</sup> 1)	Non-Urban (PhARIA 2-6)
1:4,094	1:4,082	1:4,148

While this ratio varies internationally, Australia is not dissimilar to comparable countries. One international study<sup>5</sup> gives figures of the following magnitude:

**Table 5: International comparison Pharmacy to Population Ratio<sup>6</sup>**

	Pharmacy: Population Ratio
Canada	1:4,000 (1998)
France	1:2,000 (2000)
Germany	1:4,000 (2001)
Netherlands	1:10,000 (2000)
Norway	1:9,500 (2002)
United States	1:5,000 (2000)

A report in 2004 indicates that following deregulation in Norway, the pharmacy to population ratio had changed to 1: 8,600 which suggests that deregulation did not greatly impact access to pharmacies.<sup>7</sup>

### Outcome

In reaching the Fifth Agreement, the Government decided to extend the term of the Rules and the Authority for a further five years to 30 June 2015. This was done in the understanding and expectation that further easing of the arrangements would occur following the Urbis Review. Subsequent amendments to the Rules were agreed and then determined by the then Minister for Health and Ageing.

On balance, it appears that there has been a net benefit to the extension of the Rules from the Fourth Agreement, given the positive (or neutral) impacts for consumers, community pharmacy, government and the medicines industry. In particular there is evidence suggesting that benefits gained from the Rules in the Fourth Agreement have at least been maintained in the Fifth Agreement.

## Competition Assessment

One of the main impacts of the Rules is the restriction on competition imposed by the Rules. The Rules restrict competition by limiting the:

- number of businesses in the market; and
- range of businesses in the market.

<sup>3</sup> Department of Health and Ageing - Report on Government Services 2012.

<sup>4</sup> PhARIA is the Pharmacy Accessibility/Remoteness Index of Australia which is a pharmacy specific measure of remoteness of Australian localities which is designed to facilitate the equitable distribution of financial assistance for rural and remote pharmacies and used to determine the eligibility and payment levels for rural allowances and programs

<sup>5</sup> The Regulation of Pharmacies in Six Countries: Report prepared for the Office of Fair Trading, E Mossialos MD PhD & M Mrazek PhD, LSE Health & Social Care and the European Observatory on Health Care Systems, Office of Fair Trading, 2003

<sup>6</sup> Department of Health and Ageing - Report on Government Services 2012.

<sup>7</sup> On course towards more correct use of medicine, Medicinal Product Policy, Report No 18 to the Storting (2004-2005)

The consequence of such a restriction can be less competition (and potentially higher consumer costs, reduced access and reduced choice for consumers).

In addition, the Rules do not prevent the establishment of a pharmacy in any location. Medicines can be dispensed from unapproved pharmacies; however these do not attract PBS subsidies and the Government does not have a role in determining their location. Pharmacists can and do establish pharmacy businesses at any suitable site (providing they meet the requirements of the relevant State and Territory laws which apply to all pharmacies).

At the time the Fifth Agreement was being negotiated, a pharmacy that comprised 70 per cent PBS subsidised business against 30 per cent non-PBS subsidised business (eg: over the counter medicine, cosmetics) was highly likely to be viable. Policy initiatives such as Expanded and Accelerated Price Disclosure (EAPD), coupled with the emergence of new business models, such as large discount pharmacy models, suggest this may no longer be the case. These new business models appear to be significantly less reliant on PBS income with a corresponding increase in non-PBS income streams. With the impact of EAPD, it is likely as drug subsidies drop that reliance on PBS income will continue to be reduced. In this environment it is entirely feasible that a non-PBS dispensing pharmacy is, in fact, a viable business, and there are no restrictions on opening a non-PBS dispensing pharmacy.

Demand for prescription medicines is relatively stable and therefore, for a large part of pharmacy income, increased competition in the form of more pharmacies would not grow the market. Nor would it lead to a better distributed, more accessible pharmacy network. In terms of prescriptions for PBS medicines, any new pharmacies would be competing with existing pharmacies within a limited market. Further, an approval of a pharmacist relates to the supply PBS medicines only.

The price paid to pharmacies for dispensing PBS medicines is the same for all approved pharmacies regardless of the location of the pharmacy or the Rules. The cost to consumers/patients for those medicines is set by the Government under the PBS and for the most part is fixed through co-payment arrangements determined under the Act.

Pharmacist services are an area of potential competition and differentiation between pharmacies. However they are not of themselves sufficient to generate income that offsets the costs of their provision, and the Rules play a role in maintaining sufficient volumes of prescription throughput to partially support quality use of medicines activities and the provision of other services by pharmacists. In this regard, economies of scale play a role: larger pharmacies have greater capacity to absorb the costs of providing these professional services.

It is not possible at this time to measure the effects of these competing factors. It might be expected that increased competition would result in reduced prices for a range of products, including medicines, in those geographical areas which can support an increased number of pharmacies. This may be offset in part by increasing prices and lower service levels where pharmacies do not have sufficient prescription volumes to match the commercial arrangements of the higher turnover pharmacies.

Anecdotal evidence (such as advertising by some pharmacy chains) indicates that there is significant competition in medicine prices, including for items that cost less than the general (or concessional) co-payment amounts, and for non-prescription and over the counter medicines.

In addition, there have been recent reports of increasing pharmacy bankruptcies across Australia. While there is likely to be a range of factors involved in these bankruptcies, one that has been cited is the increased competition from nearby pharmacies.

The Rules may reduce access to pharmacies for consumers, particularly the case for consumers in urban areas. This is demonstrated by the fact that, before the Rules, pharmacies were clustered in

mostly urban areas, and the Rules have reduced this clustering. However, it is unlikely that this effect would be significant, as the intent and operation of the Rules is to ensure that close clustering – for example, pharmacies within 10-500 metres of other pharmacies – is minimised.

The extension of the Rules also continued the restriction which prevents an approved pharmacy from being directly accessible from within a supermarket. While there are many pharmacies located in a very close proximity to supermarkets, the Rules prevent an approved pharmacy from being established within a supermarket.

In addition, State and Territory Government regulations effectively restrict ownership of pharmacies to pharmacists, limit the number of pharmacies which may be owned by each pharmacist and also prevent a pharmacy from operating within a supermarket.

There is an opportunity cost for the community in that the larger retailers/supermarkets are not permitted to enter into the market to supply PBS medicines. These retailers are denied the opportunity to trade in the PBS medicines market.

If approved pharmacies were permitted within supermarkets there may be the potential for increased access (both in terms of geographical location and trading times) to PBS medicines in some areas. However, it is likely that supermarkets would not operate these pharmacies at the full range of opening hours.

The restriction on competition may lead to higher prices for consumers and higher profits for existing pharmacies due to the restriction on the number of pharmacies able to enter the market. However, this is not the case for non-pharmacy only medicines (ie. those medicines that do not require a prescription such as paracetamol, as there is no restriction on the businesses who can offer these products). In the case of PBS medicines, it has been shown through the implementation of EAPD that significant competition does exist in the PBS market as many drugs are heavily discounted.

It therefore can only be argued that the restriction on supermarkets may deny additional access points for consumers to access PBS medicines as the Rules reduce the opportunity for these businesses to participate in the market.

The Rules also reduce the ability for pharmacies to respond to changes to the geographic distribution of demand. The relocation restrictions mean that a pharmacy has to wait two years before they can move locations, except where there are exceptional circumstances. If the geographic distribution of demand changes, pharmacies cannot promptly respond to this change.

While there is significant competition between pharmacies, particularly in urban and regional areas, it is not free market competition. The Rules provide the ability to deliver the main components of the Community Pharmacy Agreement to all communities throughout Australia, rather than just those communities in an area where pharmacists might view it as desirable to set-up their business. Logically, the level of commercial competition between pharmacies will depend on the number of pharmacies in a particular area.

## **Consultation process**

Prior to the negotiation of the Fifth Agreement, the then Department of Health and Ageing initiated an extensive consultation process with a broad range of stakeholders. This process included meetings, discussions and submissions from pharmacist representative organisations and associations, pharmaceutical manufacturers, the CHF, the National Prescribing Service, pharmacy

academics and students associations and international government agencies responsible for pharmaceutical services, as well as other Australian Government agencies. In sum the organisations consulted provided views across the range of consumer, pharmacy and Government stakeholders.

The extension of the Rules under the Act was linked to the timeframe for negotiating the Fifth Agreement.

### **What are the views of those parties?**

Pharmacy owners are represented by the Guild. The Guild did and continues to represent over 90 per cent of pharmacy proprietors. The Guild was the party with which the Government negotiated the Fifth Agreement, and its members' views were taken into account by the Guild in those negotiations.

In the public interest, both Agreement parties expressed a commitment, through the negotiating process, to respond positively to the outcomes of the Urbis Review of the Rules by relaxing the regulations restricting competition in the community pharmacy industry.

The CHF paper informed the Government about consumer views on the content and implementation of the Fifth Agreement. The CHF was, on the whole, pleased with the final version of the Fifth Agreement including the continuation of the Rules. It noted that it had been consulted and provided a broad range of consumer views as part of the Urbis review.

The report and findings of the Urbis review represented the views of stakeholders. There were findings regarding potential amendments to the Rules, the operation and administration of the rules and the communication of information concerning the Rules and the application processes.

These findings were largely addressed in the amendments to the Rules or in changes to the administration process which addressed identified issues which were outside the content of the Rules.

Submissions to previous reviews suggested that any type of regulatory intervention placed restrictions on consumer choice and restricted competition in the sector which in turn inflates the capital value of pharmacies.

## **Other options**

There are other options/alternative approaches in relation to the determination of pharmacy location for the supply of PBS medicines. Presented below are three alternative approaches:

- Targeted easing of the existing Rules;
- Remuneration-based incentives and disincentives; and
- Complete de-regulation.

In addition, there have been other options previously considered such as a tendering process for the delivery of PBS medicines and pharmacy services, where the lowest cost tender which provided the desired range of goods and services would be the successful provider.

At the point of negotiating the Fifth Agreement, none of the alternate approaches were preferred to the continuation of the Rules, particularly given the agreement to amend the Rules (if it was warranted), following the completion of the Urbis Review.

## **Option 1: Targeted easing of the existing Rules**

### *Description of measure*

Under this option, the restrictions of the Rules would be further relaxed to provide greater opportunity to establish new pharmacies. Such amendments would address emerging or ongoing issues and provide greater flexibility to respond to community need for access to PBS medicines. They would also take into account the changing business environment and health care policy priorities, such as the trend towards smaller suburban shopping centres with large supermarkets as anchor tenants or the move towards co-locating primary health care services.

### *Who would be affected?*

*Government:* Potential amendments would allow for the Rules to better align with wider and emerging Government health policies such as the GP super clinic model. The amendments may also allow for the simplification and greater objectivity of some elements of the Rules. This in turn could reduce the number and costs of legal challenges against the decisions of the Authority. The Government, with the advice of the Authority, would continue to administer the (amended) Rules for PBS purposes.

*Community Pharmacy:* Amended rules would be likely to provide increased opportunities for more pharmacists to enter the market, thus providing greater competition in areas which could sustain an increase in the number of pharmacies, whilst avoiding unnecessary clustering and thus mitigating risks of an unviable pharmacy network. The potential for more flexible and less complex Rules would simplify the application process for pharmacists.

*Consumers:* The impact on consumers would largely depend on where they live. In areas with an identified community need for additional pharmacies, there would likely be an increase in the number of pharmacies, facilitating greater access to PBS medicines. This would see an increase in the level of competition in some communities whilst still promoting a geographical spread of pharmacies, including facilitating the entry of new pharmacies in rural and remote areas. This would most likely not cause any detrimental impact on the access to quality use of medicines services.

### *Effects on existing regulation and regulatory authorities*

An amendment to the Act would be required to extend the Rules for the life of any renegotiated Community Pharmacy Agreement. The Authority's role and functions would not change, however, there would be some change to the specific requirements of the Rules against which applications were assessed. The introduction of simpler Rules could make them easier to administer and reduce the complexity of the Authority's decision making process.

### *Likely benefits and costs*

Further easing of the restrictions in the Rules would be likely to result in more pharmacies in commercially attractive areas, and provide increases in competition in some areas as more pharmacies entered the market. Less complex and subjective Rules could reduce the cost to the Government if there was a subsequent decrease in the number of appeals against the Authority's decisions. However, more subjective Rules would provide greater avenues for legal challenges through variable interpretation or intent.

## **Option 2: Remuneration Based Incentives**

### *Description of measure*

Remuneration-based incentive and disincentive schemes could provide an alternative to an easing of the existing Rules. Under such a scheme the location of pharmacies would be influenced by differential dispensing fees or targeted incentives, based on areas of over or under supply.

While the exact payment mechanisms may vary, one option may be to set a base dispensing fee and then adjust it:

- up for defined areas where it is considered that there is an undersupply of pharmacists (i.e. the pharmacy to population ratio for the locality is too low against an agreed measure); or
- down for defined areas where it is considered that there is an oversupply of pharmacists.

Pharmacies in areas of equilibrium in terms of their pharmacy to population ratio would receive neither a loading nor a penalty.

Differential dispensing fees could be applied generally (i.e. to all pharmacies in the defined area), or selectively (for example, to pharmacies establishing themselves in the defined area after a commencement date). The introduction of new pharmacies in an area may impact on the income for existing pharmacies as well as impacting on any differential dispensing fee. There would be issues also as to whether selectively applied fees and related determining criteria may be seen as a consistent treatment of all PBS approved pharmacies receiving Government remuneration.

#### *Who would be affected?*

*Government:* A differential dispensing fee regime could meet the Government's reasonable access objectives for pharmacy services. There may be overall costs or savings depending on how the fees were implemented, and there would be differential income received by pharmacies. This income differential would influence pharmacists' location decisions. It would be difficult to assess the appropriate payment levels to produce the desired existing or new distributional patterns.

This option would also require a significant investment to rebuild the pharmacy claiming system within the Department of Human Services (Medicare) to enable such variable payments and to potentially accommodate frequent adjustments of differential dispensing fee payments at individual pharmacy level.

*Community Pharmacy:* Differential remuneration would influence pharmacy business planning and purchasing decisions, by making the incentive or disincentive of dispensing income a factor in the pharmacy's turnover calculations. If the pharmacy was in, or moved to an area where its PBS derived income was increased or penalised because of its location, then that financial incentive or disincentive would affect a proprietor's decision to remain at, or move to, a given pharmacy site.

*Consumers:* If a differential fee model was introduced, people using pharmacies in relatively crowded local pharmacy markets would be likely to see little or no difference in terms of their access to services, although their choice of service providers may be reduced. In less well-served areas, local consumers may see more pharmacies appearing to meet local needs as pharmacists moved their businesses to take advantage of remuneration incentives.

#### *Effects on existing regulation and regulatory authorities*

Legislation and statutory instruments enabling the regulation of pharmacy location for PBS approval purposes would lapse or may need to be repealed. The Authority, as the body whose main responsibility is applying those regulations, would be abolished as the market would essentially be left to adjust without Government intervention.

#### *Likely benefits and costs*

If calculated appropriately, PBS pharmacist remuneration arrangements could meet two objectives: promoting reasonable access to community pharmacy services, and providing direct incentives to pharmacies to maintain and enhance their overall efficiency and effectiveness as both professional service providers and as commercial businesses.

Differential dispensing fees, if incentives were set at an appropriate level, could be genuine factors in persuading all pharmacy proprietors to think about the location of their pharmacies as a part of maximising the return on their investments. If any pharmacy wished to trade in an over serviced area, under this approach it would have to accept the consequences of that decision for its PBS income, which for most pharmacies is their single largest source of turnover.

It would be consistent with the Government's desire to ensure reasonable access to pharmacy services and an effective national PBS distribution network. It would be expected that at least some pharmacies would cease trading in over serviced areas and move to locations where they could maximise their income.

On the costs side, there would be a high degree of administrative complexity to overcome. The Government would likely find this alternative highly problematic, particularly from an implementation perspective. Some of the potential problems would include:

- the process of defining geographic areas would be difficult and require extensive and detailed pharmacy practice and demographic information to be held by Government;
- the process for determining the price variation among regions may be problematic, particularly given the lack of Commonwealth data on location-specific pharmacy performance;
- other relevant criteria may be needed to be defined (e.g. an area with a high proportion of elderly residents may need more than an average number of pharmacies to service its needs);
- the assessment of areas of undersupply or oversupply may be problematic for pharmacists on or near the border of a region (for example, a pharmacist might find that by moving a short distance, such as across a road, they change regions). In effect, new forms of strategic behaviour by pharmacists would replace the existing manipulation of the Rules.
- it would be necessary to put in place a process for reviewing the status of regions and implementing any changes to remuneration that resulted from such reviews;
- the Act does not allow the Government to unilaterally vary pharmacists' PBS remuneration and so either the Act would need to be changed to allow this, or the determination of remuneration for different regions would have needed to be negotiated as part of a future Community Pharmacy Agreement.

It would also be very difficult to estimate in advance the level of fees required to achieve desired distributional results. There would be risks, and relative uncertainty, both for Government and the pharmacy sector.

Beyond this, there would be many pharmacists (those in areas considered to be over serviced) who would potentially experience reductions in their income, and this may occur for both efficient and inefficient operators. In practice an attempt to introduce a system of this kind would be difficult and controversial, and would likely result in considerable dispute with the community pharmacy sector.

### **Option 3: Complete Deregulation**

#### *Description of measures*

Under this option there would be no Government regulation of the number or location of pharmacies approved to dispense PBS medicines. The regulatory regime would revert to that which existed prior to the First Agreement (i.e. the Secretary of the Department of Health would determine applications for pharmacy approvals without reference to the Authority or any Rules). In practice this previously meant that anyone who met minimum requirements (being a pharmacist, and having a Pharmacy Board approval) was approved.



*Who would be affected?*

*Government:* The Government would no longer directly determine the location of pharmacies under location Rules.

*Community Pharmacy:* Pharmacies would be able to make commercial decisions in response to market conditions and consumer demand. Numbers of new pharmacy approvals would be likely to increase with a return to a clustering of pharmacies in attractive locations, as existed prior to the First Agreement. There would be a likely decline in pharmacies in less populated areas, including rural and remote localities.

The removal of the Rules would be likely to result in a significant reduction in the capital value in community pharmacies thereby impacting on the owners of the more than 5,000 pharmacies. The pharmacy sector may seek some financial assistance from the Government if complete deregulation were to be pursued.

Further, changes to the Rules that resulted in more pharmacies may lead to more frequent pharmacy closures and an increased turn-over of pharmacies in some areas. This also has the potential for increased costs to the Commonwealth as, once medicines have been delivered to pharmacies, the Commonwealth incurs some costs, regardless of whether they are ever supplied to consumers/patients under the PBS. Closures of pharmacies with stock on hand could, therefore, also result in unproductive supply costs for the Commonwealth.

*Consumers:* Market forces would dictate the location of pharmacies based on a pharmacist's judgement of commercial viability. It would be difficult to predict the benchmark that would apply for such commercial decisions and therefore the number and type of communities that may lose or gain access to services as a result.

Consumers in urban areas may see more competition in terms of number of pharmacies than may otherwise be the case. Depending on other circumstances, they may see some reduction in prices for some PBS medicines priced under the patient co-payment level and for non-scheduled and over-the-counter drugs, healthcare and other products, such as cosmetics, that are also available from other retail outlets.

Where such clustering did occur consumers may see a greater number of smaller, less profitable pharmacies, which may lead to a decrease in the number of professional services offered and therefore a decrease in medicine management for some consumers.

Consumers using pharmacy services in relatively well serviced areas may see reductions in the number of pharmacies (as pharmacies would be free to move to locations with less competition). However, they would be likely to still have reasonable access to services.

Consumers using pharmacies in less attractive locations (for example, rural and remote areas and some urban areas) would be likely to lose access to these services if pharmacies clustered towards more attractive urban settings around large business and shopping precincts.

*Medicines Industry:* Medicine suppliers compete for business to supply pharmacies. Increased competition in the pharmacy sector may result in increased pressure by pharmacies on suppliers to reduce their prices for medicines.

This may increase the effect of Government EAPD mechanisms. Prices paid by pharmacies for medicine under competition are frequently below the reimbursement levels paid to pharmacists under the PBS, as suppliers discount to pharmacists in pursuit of market share. EAPD arrangements under the PBS collect data on actual prices paid by pharmacists for medicines, which are used to

calculate an average disclosed price which will then become the PBS reimbursement price. Through this mechanism PBS reimbursement levels are set closer to actual market prices.

Conversely, the clustering of pharmacies may lead to the reverse effect. The clustering of pharmacies may lead to smaller pharmacies with reduced economies of scale for purchasing and distribution which would lower the discounts offered by wholesalers. The lack of discounts would impact on the price disclosure programmes and reduce the savings to the Government through EAPD and increase the Governments expenditure on the PBS.

If increased pharmacy competition leads to further downwards pressure on medicine prices, then price disclosure arrangements may also reduce PBS reimbursement rates further. The degree to which this may occur is likely to be relatively small as price disclosure arrangements are already designed to bring medicine prices to approximate the volume weighted average market value.

*Taxpayers and the Government:* Because Government underwrites the costs of a large part of the PBS, including the cost of medicines and their delivery, the efficiency of pharmacy may affect the Government's fiscal position. Without the Rules in place the following could occur:

- greater competition between pharmacies could drive increased pharmacy efficiency, reducing pressure on future PBS pharmacy remuneration payments;
- increased pressure on medicine prices may result in reduced PBS medicine reimbursement costs although this would be likely to be small;
- changes in geographical access and associated costs, with other measures likely to be required to ensure access to pharmacy services in rural areas;
- less capacity within pharmacies to deliver quality use of medicines services and related programmes may lead to higher overall costs, either from greater demand for remuneration for these activities or, in their absence, higher costs elsewhere in the health system such as increased number of presentations at hospital emergency departments for medicine misadventures; and
- pharmacy business models could be pushed in non-medicine and dispensing related directions.

A significant increase in the number of pharmacies to which the pharmaceutical wholesalers need to deliver would raise the cost of delivery to pharmacies. In turn, the costs incurred by wholesalers would increase with the result likely to be either a request for increased funding from the Commonwealth for the cost of participating in the Community Service Obligation programme or some wholesalers not participating<sup>8</sup>.

#### *Effects on existing regulation and regulatory authorities*

Legislation and statutory instruments enabling the regulation of pharmacy location for PBS approval purposes would lapse or need to be repealed. The Authority, as the body whose main responsibility is applying those regulations, would be abolished as the market would be left to adjust without Government intervention.

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<sup>8</sup> The Community Service Obligation (CSO) Funding Pool, was introduced under the Fourth Agreement in recognition of the additional costs faced by some pharmaceutical wholesalers in providing the full range of PBS medicines to pharmacies in a timely fashion. The aim of the CSO Funding Pool is to ensure there are arrangements in place for all Australians to have access to the full range of PBS medicines, via their community pharmacy, regardless of where they live and usually within 24 hours. Under these arrangements, payments are provided directly to eligible wholesalers who supply the full range of PBS medicines to any pharmacy, usually within 24 hours, and that meet compliance requirements and service standards. These payments are over and above those made directly to pharmacists to cover the costs of supply from the wholesaler

### *Benefits and costs*

Deregulation would give primacy to market signals as the driver of entry and location decisions. It would therefore provide pharmacists with the freedom to choose where they wished to compete for business and let them make commercial judgements about where they wished to locate in response to consumer demand.

Complete deregulation would result in service instability in the sector as some pharmacists would take the opportunity to relocate to more attractive areas with higher profit potential.

In the short term, the effects may not be substantial because:

- pharmacists are usually locked into leases - while these can be broken, this would likely be at significant cost;
- relocation involves forsaking any existing goodwill that a business may have; and
- there would be a natural degree of uncertainty in the marketplace, with many pharmacists waiting until the dust had settled to see what a liberalised marketplace looked like before making consequent decisions.

However, in the longer term, the market would likely change in a number of ways under deregulation:

- in urban areas it is possible that there would be a move by pharmacies to shopping centres and into supermarkets thereby abandoning traditional community-based locations in some suburbs; and
- there would likely be a decline in the number of pharmacies in rural and remote regions and less attractive urban areas.

With no Rules there would be excess entry into some areas (i.e. the number of pharmacies would be greater than necessary). Simple duplication of services (for example, the location of two pharmacies next to each other) would not be welfare-enhancing given the limited degree of service differentiation and price competition that currently exists. However, the risk of excessive access is limited because it is likely that if the market could not sustain more than one pharmacy at the location they would face an incentive to merge, close or relocate.

It should be noted that there are some industry concerns that the dominance of some pharmacy chains, which do not offer some of the Government's quality use of medicine services and programmes, may mean a lack of pharmacy services in some areas. While there are many consumers/patients who do not require these services, under this option there may be a negative impact on the health of those consumers/patients who do require such services, and potentially increased costs to the health system overall.

## **Subsequent amendments to the Rules (2011)**

Following the Urbis review and further consultation with key stakeholders, further amendments to the Rules were introduced in October 2011. These changes reflected a further targeted easing of the Rules.

The simplified Rules:

- converted the majority of relocation rules to new pharmacy rules. This made it easier and cheaper to establish a pharmacy in shopping centres, medical centres, private hospitals and

single pharmacy towns. This provides greater flexibility to respond to community need for pharmaceutical services.

- addressed the unintended market and value of approvals through a number of changes, in addition to converting the majority of relocation rules to new pharmacy rules. This reduced the cost of purchasing an existing pharmacy.
- simplified the catchment criteria by the introduction of an objective test based on existing services and attractions. This in turn reduced the complexity and potential costs for applications.
- relaxed the requirements to establish a pharmacy in a Large Medical Centre to better address emerging health care delivery models.

The changed Rules also extended the existing restriction on pharmacies operating within supermarkets.

These amendments did not require a Regulatory Impact Statement (RIS) and the full impacts of these changes will not be addressed in this PIR (RIS reference 12520). However, the amended Rules are relevant to this PIR insofar as they were the result of an extensive review and consultation process and they addressed some of the negative impacts seen through the continued operation of the Rules from the Fourth Agreement.

### **Who was affected?**

*Government:* The Government, with the advice of the Authority, continued to administer the Rules for PBS purposes.

*Community Pharmacy:* The changes to the Rules introduced more opportunities to establish new pharmacies which provides for greater levels of competition. The changes also greatly decreased the value of an approval which could impact the purchase cost for pharmacists wishing to enter into pharmacy ownership by purchasing an existing approved pharmacy. The trade in pharmacy approvals for relocation purposes has effectively ceased.

*Consumers:* The impact on consumers was largely dependent on where they live. In some areas it is likely that there was an increase in the number of pharmacies and the level of competition in the community. Consumers have generally benefited because converting relocation rules to new approvals has offered greater incentives to pharmacies to move to areas of community need and reduced the cost of establishing a pharmacy.

### **Effects on existing regulation and regulatory authorities**

Consistent with previous iterations of the Rules, a new ministerial determination which set out the revised provisions was drafted and then signed by the Minister. The Authority was retained to consider applications under the Rules.

### **Benefits and costs**

Converting the majority of the Rules to new approvals has driven increases in competition as more pharmacists enter the market and the costs to establish a new pharmacy have been reduced considerably. This has resulted in a significant increase in the number of pharmacies recommended for approval, particularly in small shopping centres and single pharmacy towns.

In line with contemporary health care models, this conversion to new approvals, combined with the relaxed requirements for the Large Medical Centre Rule, has resulted in a significant increase in the number of pharmacies open in large medical centres.

The changes have also simplified the application process for pharmacists and improved the flexibility of the Rules. The revised catchment criteria has provided an objective assessment of catchment

which does not require detailed demographic analysis as was sometimes the case in the past. Pharmacies located in facilities (shopping centres, medical centres and private hospitals) are able to relocate freely within those facilities.

In addition, there have been reduced costs of litigation (for all parties) associated with challenges to decisions involving the subjective catchment criteria.

## Conclusion

The need to ensure that all Australians have access to Government-subsidised PBS medicines and pharmaceutical services which are delivered efficiently and affordably is ongoing.

PBS medicines are important in treating illness and can also play a role in preventing illnesses. The ready availability of PBS medicines is therefore a significant determinant of people's health and should be available to those Australians who require them, regardless of where they live. It is this principle of access to PBS medicines which underpins the operation of the Pharmacy Location Rules.

The pharmacy network, left to market forces alone up to 1990, did not deliver reasonable access to PBS medicines for all Australians. At that time, the Government decided that some form of regulatory intervention in the market was necessary to ensure that PBS medicines were efficiently and equitably available to all Australians. This policy objective was realised through the Rules.

This approach to achieving the desired policy outcome has been supported by successive Governments as a key component of the Community Pharmacy Agreements which address the delivery of PBS medicines and professional pharmacy services and programs as an integral part of the Australian health system.

Given these factors and the broader issues relevant at the time of the negotiation of the Fifth Agreement, the Government decided it was prudent to continue with the existing arrangements, that is using the Rules, to maintain the desired policy outcome and to further the objective of better access to PBS medicines, particularly for persons living in rural and remote areas.

Based on the impact analysis undertaken as part of this PIR, it is recognised that imposing restrictions on pharmacy locations may come at the cost of erecting a barrier to entry to the PBS subsidised pharmacy market. Generally, for the various stakeholders, the cost impacts of retaining the Rules (as they were through the Fourth Agreement in 2010) would appear to be:

- possibly reduced geographical access to pharmacies in urban areas;
- the potential for higher cost of non-PBS medicines, reflected in higher profits to existing pharmacists; and
- an administrative impost for pharmacists who want to relocate or expand.

In addition, the retention of the Rules may continue to have a negative impact on the entry of new pharmacies into the market place given the limited number of options available to owners to establish these pharmacies (only two rules permit the establishment of new pharmacies) and a negative impact on the entry of new pharmacy owners (ie first time owners) due to the increasing value of what is seen to be a limited (or capped) number of pharmacy approvals numbers within Australia.

From an administration perspective, the application process may continue to encounter issues, including legal challenges, associated with assessments of a pharmacies catchment area, specific distance requirements and related matters.

(Note: these issues were significantly addressed in the 2011 amendments to the Rules)

Regardless of these impacts, there is certainly evidence to suggest that the retention of the Rules will maintain the reasonably well-distributed geographical spread of pharmacies in Australia. The Rules ensure that an accessible and commercially viable network of pharmacies exists throughout Australia, including (and especially) in rural and remote areas, while also ensuring there is increasing competition between pharmacies in the market place. These factors are important to achieving the objectives of the Fifth Agreement, NMP and PBS more broadly.

It should also be noted that, if the restrictions imposed by the Rules were relaxed too broadly, there is a distinct possibility that:

- the more rapidly deregulated environment may skew the access to community pharmacy services, as pharmacists could be expected to favour more lucrative locations;
- such a situation could jeopardise the geographical distributional improvements achieved through previous Agreements and adversely impact on consumer access to medicines; and
- the viability of at least some suburban and regional pharmacies providing reasonable access to older and less mobile pharmacy consumers may be reduced as these pharmacies are often relatively small and localised, and less able than some of their competitors to realise economies of scale.

In addition, if the Rules were abolished altogether, an alternative approach to ensure appropriate community access to PBS medicines would be required. While other methods are available to Government to achieve the objective of an appropriate geographical distribution of pharmacies supplying PBS medicines, the specific outcomes of adopting such other methods are unclear and may be more costly and administratively complex than the current system.

On this basis, it is the conclusion of this PIR that, while there remains a net benefit to consumers and pharmacy owners from the retention of the Rules from the Fourth Agreement, additional benefits can be achieved. These benefits, particularly in relation to consumers and in the government administration of the Rules, could be realised through the targeted easing of the Rules along the lines of those outlined in Option 1 above.

## Summary - International Regulation of Pharmacies

An international comparison of regulation in the pharmacy sector undertaken in 2003 by the United Kingdom Office of Fair Trading<sup>9</sup> indicated no consistent pattern in regard to the regulation of the location of new pharmacies for the range of developed countries which it examined. The location of new pharmacies was found to be restricted in a number of countries (eg the United Kingdom and France) but not in others (eg Germany and the United States).

The UK Office of Fair Trading study found that the pharmacy network was better distributed in the group of 3 countries with requirements around the establishment of new pharmacies, with clustering of pharmacies around profitable urban locations being an issue in each of the 3 countries without such requirements. The study indicated that deregulation of pharmacy numbers and location leads to significant growth in the sector but mainly in urban areas, with the extent of overall growth dependent on the degree of pharmacy provision prior to deregulation.

A 2006 study of the regulation of community pharmacy in Europe commissioned by the Pharmaceutical Group of the European Union<sup>10</sup> similarly found that deregulation led to an increase in the number of pharmacies but primarily these were clustered in profitable urban areas with existing pharmacies. The study also found:

- the extent of professional counselling of patients by pharmacists and the uptake of professional or cognitive pharmacy services tended to be higher in the more regulated countries; and
- a lack of evidence of lower prices in the unregulated countries across 15 “blockbuster” Over the Counter pharmaceutical products examined.

On the other hand in the United Kingdom, which allows the establishment of pharmacies in supermarkets, the UK Office of Fair Trading study found evidence of lower prices in supermarket chains compared with community pharmacies in regard to a range of pharmaceutical products where they compete. In addition a “mystery shopping” study undertaken by the UK consumer magazine *Which* in 2004 of the quality of pharmacist advice in supermarkets and community pharmacies (and replicated in Australia for community pharmacies by *Choice* magazine) found that the quality of advice was poorer in community pharmacies in both the United Kingdom and Australia than in large chain pharmacies and supermarket pharmacies in the UK<sup>11</sup>.

The 2006 European Union study also noted that the bulk of member states have implemented rules for the establishment of new pharmacies, including around location, but the nature of these rules varied considerably.

The study looked at the impact of the regulatory arrangements in the pharmacy sector of six member countries over the period 1995-2005, including the arrangements for the establishment of new pharmacies. Three of the countries – Ireland, the Netherlands and Norway – were found to have liberal regulatory regimes and no location restrictions on the establishment of new pharmacies.

The remaining countries – Austria, Finland and Spain – were found to have a high level of regulation of the pharmacy sector, as in Australia, with strict rules governing the introduction of new pharmacies which sought to ensure their location in areas of definite public need.

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<sup>9</sup> The Control of Entry Regulations and Retail Pharmacy Services in the United Kingdom, Office of Fair Trading, 2003

<sup>10</sup> Community Pharmacy in Europe, Lessons from Deregulation – Case Studies, Commissioned by the Pharmaceutical Group of the European Union, Vienna, February 2006.

<sup>11</sup> See Review of the Commonwealth Pharmacy Location Rules, The Allen Consulting Group, 19 May 2005, pages 39 to 40.

For example, in Austria the establishment of a new pharmacy needed authorisation by the relevant regional authority. The statutory requirements included that:

- a general practitioner had his/her practice in the same municipality,
- a minimum distance of at least 500m between the new pharmacy and the nearest existing pharmacy,
- the number of persons who continued to be supplied by adjoining pharmacies was not to fall below 5500 as a result of the new pharmacy,
- if there was a dispensing doctor within 4 kilometres, 5500 people were required to be supplied by the new pharmacy, and
- minimum room and space requirements for the new pharmacy be met.

Before the introduction of a new Pharmacies Act in Norway in 2001, which relaxed previous restrictions on locations and ownership of pharmacies, it had generally been accepted that there was an undersupply of community pharmacies. Following the changes, average opening hours increased, and the number of pharmacies increased quickly.<sup>12</sup>

However, while the increase in the number of pharmacies changed the population to pharmacy ratio, the new pharmacies were not spread evenly across the population. Rather, these tended to cluster in densely populated urban areas, often in locations where pharmacies already existed, especially in the capital Oslo and surrounding areas. From 2001 to 2005 there was a 35% increase in the number of community pharmacies. By contrast, special arrangements were put in place to ensure that pharmacy services were maintained in rural areas. An agreement between the Norwegian Ministry of Health and pharmacy chains meant that no pharmacies in rural areas were to be closed. However, there was little or no increase in the number of rural pharmacies. By 1 January 2005, 199 of the 434 municipalities in Norway did not have a community pharmacy, which is 9 less than before the pharmacy changes.

A further impact of the deregulation in Norway was that three large retail players enhanced their market share and grew more dominant in the market, accounting for around 85% of the market with the remaining 15% comprising independent and hospital pharmacies. These three large retailers were also vertically integrated through ownership with their wholesalers, and controlled the majority of the wholesaler/distribution market. At the time that the changes were assessed, independent pharmacies had to purchase their medicines through the pharmacy chain wholesalers.

A Study which looked at the impact of pharmacy deregulation in Iceland found that, within two years of deregulating the pharmacy establishment rules, there was a 67% increase in pharmacy numbers in metropolitan areas and a 17% increase in other areas. By 2004, the Iceland Pharmacy market was dominated by two pharmacy groups.<sup>13</sup>

At a European Workshop held in Brussels (2008), a number of member states reported on their experiences in de-regulation of location restrictions. These members observed increases in the numbers of pharmacies in both rural and urban areas. In 2006, Italy undertook a partial deregulation which has led to an increase in the number of pharmacies, reduction in medicines prices and better quality outcomes to patients.<sup>14</sup>

Conversely, in February 2009, the Government of Sweden submitted a proposal to re-regulate the pharmacy market, ending the monopoly provider's (Apoteket AB) exclusive rights to retail pharmacy

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<sup>12</sup> On course towards more correct use of medicine, Medicinal Product Policy, Report No 18 to the Storting (2004-2005)

<sup>13</sup> Anel, A. *Deregulating the pharmacy market: the case of Iceland and Norway*. The Swedish Institute for Health Economics, 2005.

<sup>14</sup> *Workshop on 'Access to High Quality Pharmacy Services'*, European Commission, Brussels, October 2008



trade. The aim of the reform was to create conditions for more pharmacies with longer opening hours, and included measures to ensure all premises must have a qualified pharmacist on site. At the time, there was an average of 10,000 people for every pharmacy. It was believed that increased competition in the pharmacy market would lead to better opening hours, lower prices and better service.<sup>15</sup> The proposal involved the ‘liberalisation of the Rules on owning and operating a pharmacy’. Central to the reform is that new players will be required to negotiate on purchase prices of pharmaceutical products. State owned pharmacies will be transitioned into privately owned arrangements.

These international examples highlight the complexity in managing reforms that fundamentally influence competitive behaviour. While overseas research finds that regulation of the location of pharmacies can affect their productivity, there are also some findings that deregulation may have drawbacks for individual pharmacists, such that compensatory schemes for individual pharmacists may be warranted, and measures to ensure access to medicines in remote areas may be necessary. It is noted that under the Fifth Community Pharmacy Agreement, Australia currently provides support for rural pharmacy and this support may need to increase in the absence of the Rules.

The following table lists the varying regulation of pharmacies in 13 nations. (Ltd indicates restrictions in limited circumstances)

**Table: Comparison of Community Pharmacy Restrictions**

Restrictions on	Australia	New Zealand	Italy	United States	United Kingdom	Ireland	Norway	Iceland	Canada	France	Netherlands	Germany	Denmark
<b>Non-pharmacist ownership for dispensing NHS/PBS or equivalent</b>	Yes	Ltd	Yes	No	No	No	Ltd	No	No	Yes	No	Yes	Yes
<b>Location of pharmacies</b>	Yes	No	Yes	No	Yes	No	Ltd	No	No	Yes	No	No	Yes
<b>No. of pharmacies per owner</b>	Yes	Yes	Yes	No	No	No	Yes	No	No	Yes	No	Yes	Yes

<sup>15</sup> Proposal to the Council on Legislation on reform of the pharmacy market, Government Offices of Sweden, 2009.