



**Australian Government**

**Department of Health**

**Secretary**

Mr Gerry McNally  
Committee Secretary  
Senate Select Committee on Red Tape

by email: [redtape.sen@aph.gov.au](mailto:redtape.sen@aph.gov.au)

Dear Mr McNally

**The effect of red tape on pharmacy rules**

Thank you for your letter of 14 September 2017 inviting the Department of Health to make a submission to the Senate Select Committee on Red Tape inquiry into the effect of red tape on pharmacy rules.

Please find attached the Department's submission which focuses on the objectives and background of the Pharmacy Location Rules and how they operate.

I trust this information will assist the Senate Red Tape Committee in its considerations.

Yours sincerely

Glenys Beauchamp

31 October 2017



**Australian Government**

**Department of Health**

# SENATE INQUIRY ON THE EFFECT OF RED TAPE ON PHARMACY RULES

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**Submission by the Department of Health**

**October 2017**

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## Executive Summary

The Pharmaceutical Benefits Scheme (PBS) provides timely, reliable and affordable access to necessary medicines for Australians.

One of the objectives of the PBS is that all Australians should have reasonable access to medicines, regardless of their capacity to pay for them, 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 accessing PBS medicines.

To ensure the delivery of PBS medicines is efficient and equitable, pharmacies are approved in respect of particular premises, to supply PBS medicines.

Since the signing of the First Community Pharmacy Agreement (CPA) in 1990, the location of pharmacies to supply PBS medicines has been regulated through a legislative instrument made by the Minister for Health. The legislative instruments (the Location Rules) have reflected consensus reached between the Government and the Pharmacy Guild of Australia (the Guild), representative of the owners of the majority of community pharmacies, through Community Pharmacy Agreements.

Access to pharmacies supplying PBS medicines is key to improving the health of all Australians. The network currently has approximately 5,600 approved community pharmacies, which are well distributed throughout urban, rural and remote regions of Australia.

The continued regulation of pharmacy locations assists in meeting the Government's objectives in relation to the delivery of timely access to medicines that Australians need, at a cost individuals and the community can afford.

The objectives of the Location Rules are consistent with the broad objectives of national health policy, in particular the National Medicines Policy<sup>1</sup> which has timely access to medicines as one of its four key pillars.

## Background

Creating a world-class health system is a Government priority. Ensuring Australians have access to medicines when they need them is central to this. The Location Rules are in place to enable a suitable geographic spread of pharmacies supplying PBS medicines while providing ongoing assurance and certainty for pharmacies, particularly in rural and remote regions of Australia.

### National Medicines Policy

The PBS is part of the broader National Medicines Policy. The aim of the National Medicines Policy is to improve health outcomes for all Australians through their access to and wise use of medicines.

The National Medicines Policy has the following four central objectives:

- timely access to the 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.

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<sup>1</sup> *National Medicines Policy 2000*, Commonwealth of Australia 1999

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

The PBS facilitates access to certain prescribed medicines by subsidising costs to patients.

PBS medicines are supplied to patients through a retail network of community pharmacies.

The PBS and the Repatriation Pharmaceutical Benefits Scheme (RPBS, targeted at eligible veterans, war widows/widowers, and their dependants) are primarily delivered through Australia's network of approximately 5,600 approved community pharmacies. The majority of Government PBS/RPBS payments (\$10.8 billion in 2015-16<sup>2</sup>) are made to community 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 including:

- prescription medicines, including those subsidised by the PBS; and
- non-scheduled and over-the-counter medicines.

Pharmacists employed in the community pharmacy sector deliver a range of Government funded and medication related services such as dose administration aids, diabetes services and medication reviews, and provide professional advice to consumers on the safe and effective use of medicines.

### **History of the Location Rules**

In 1985 there were just under 5,500 pharmacies in Australia. An enquiry conducted by the Pharmaceutical Benefits Remuneration Tribunal (PBRT) in 1988 found that there was marked inconsistency in the location of pharmacies and the network of community pharmacies supplying PBS medicines.

It found that many urban areas had clusters of pharmacies while rural and remote communities had relatively poor access, with significantly lower pharmacy to population ratios. Some rural and remote communities experienced distance barriers to access community pharmacies, which made it difficult or expensive to access PBS medicines. This contributed to poorer health outcomes for rural and remote Australians than for those in urban or near-urban areas.

At that time, remuneration arrangements for community pharmacy included an "economy of scale factor"<sup>3</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.

Following changes to pharmacy remuneration by the PBRT, the First CPA was signed in 1990, which set out a new remuneration framework. This was accompanied by the introduction of Location Rules, and resulted in industry restructuring that would lower pharmacy numbers and encourage greater efficiency, profitability and economies of scale in individual pharmacy businesses.

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<sup>2</sup> The 2016-17 expenditure will be released in the Department's Annual report which will be available by 31 October 2017

<sup>3</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. This was designed to support small pharmacies.

In the First CPA, the Location Rules were primarily focused on the relocation of pharmacies, with strict requirements for the establishment of a new pharmacy, including that the proposed pharmacy needed to be at least five kilometres from the nearest approved pharmacy. The First CPA enabled two policy objectives to be met: winding back what was then considered unsustainable growth in PBS remuneration, and, via the introduction of the Location Rules, rationalising and reducing numbers of relatively inefficient pharmacies.

Subsequent five year agreements, including the current Sixth CPA (from 2015 to 2020), have maintained the Location Rules.

In the May 2017 Federal Budget, Agreement was made to vary the Sixth CPA. That Agreement variation was underpinned by shared principles of:

- **stewardship** of the health system and a shared responsibility for its ongoing sustainability, in particular a shared responsibility for the stewardship of the PBS;
- **partnership** in the delivery of the National Medicines Policy;
- **stability and certainty** of the Government's investment in the medicine supply chain, and the timely availability of medicines to all Australians through a well-distributed community pharmacy network; and
- **integrity** of Australia's world class health system, including patient safety and high value clinical care.

That Agreement recognises the pivotal role of the community pharmacy sector in delivering medicines to Australian patients and the key role that it plays in the primary health care team. It includes a commitment by Government to the continuation of the Location Rules beyond the life of the Sixth CPA by amending the relevant sections of the *National Health Act 1953* (the Act) to remove the sunset clauses that would have seen the Location Rules expire at the end of the Sixth CPA.

### **Location Rules**

There are currently seven provisions in the Location Rules that relate to the establishment of a new pharmacy and three that relate to the relocation of an existing pharmacy.

To apply for approval, an application must be made through the Department of Human Services for referral to the Australian Community Pharmacy Authority (the Authority). The Authority meets ten times a year to consider applications and to make recommendations as to whether an application should be approved. The Authority cannot override the requirements of the Location Rules and can only recommend an application be approved if it is satisfied that all of the requirements of the Rule, under which the application was made, have been met.

### **Reviews of the Location Rules**

There have been a number of reviews which have assisted in informing amendments to the Location Rules over the years. The most recent review is the Review of Pharmacy Remuneration and Regulation which commenced in 2015, and considered the role of Location Rules in supporting access to medicines in Australia.

The Review's Interim Report was released in June 2017 for consultation. The final report has now been delivered to Government. The Government is considering the review report and will release the report and respond to it in due course.

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

The community pharmacy network is the distribution mechanism for PBS medicines. Without a well distributed network of pharmacies, consumers in rural and remote areas may experience barriers to accessing pharmacies and PBS medicines. As was the case before the First CPA, it can then be difficult or expensive for some consumers to access prescription medicines, which is counter to the National Medicines Policy. This also results in poorer health outcomes for rural and remote Australians than for those in urban or near-urban areas.

A well distributed network of approved community pharmacies that closely matches the demographic distribution of the Australian community is important to facilitate timely access to the supply of medicines subsidised under the PBS, as well as a range of pharmacy services that form part of the Sixth CPA.

The Location Rules facilitate access to PBS medicines by approved pharmacies for all sectors of the community. This is of significant value in terms of delivering safe and reliable health care services. As Australia's population ages, a broad geographic spread of pharmacies will be important to meet the needs of older Australians.

## **Objective of Government Action**

For over 26 years, the regulation of the location of pharmacies, through the Location Rules, has been an integral component of the CPAs between the Government and the Guild.

Ensuring Australians have access to medicines when they need them is central to the Government's commitment to the health system. It is therefore important that any regulatory intervention in the community pharmacy network is consistent with the goals of reasonable access and efficient and equitable access to PBS medicines.

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

### **Geographical spread**

This element of access is primarily addressed through the Location Rules which requires that any new pharmacy must be in an area of demonstrated community need as well as a minimum distance from existing pharmacies.

### **Reasonable trading hours**

This element of access is primarily addressed through the Act which requires that an approval cannot be granted to a pharmacist to supply PBS medicines unless the pharmacy will be accessible to members of the public at times that are reasonable (generally taken to mean at least normal business hours).

### **Physical accessibility**

This element of access is primarily addressed through the Location Rules which requires that the pharmacy premises must be accessible to members of the public and not restricted to certain classes of the community (e.g. patients of a hospital or medical centre).

## Impact Analysis

### Numbers of approved pharmacies

In 2016 The University of Adelaide published a report on the geographic spread of pharmacies in Australia. The report compared pharmacies in 1990, prior to the introduction of the Location Rules and in 2014. The report was released on the University of Adelaide’s website and is titled *Geographic Access and Spatial Clustering of Section 90 Pharmacies – 1990 to 2014: An Exploratory Analysis* <http://www.adelaide.edu.au/hugo-centre/research/projects/#2016-geographic-access>

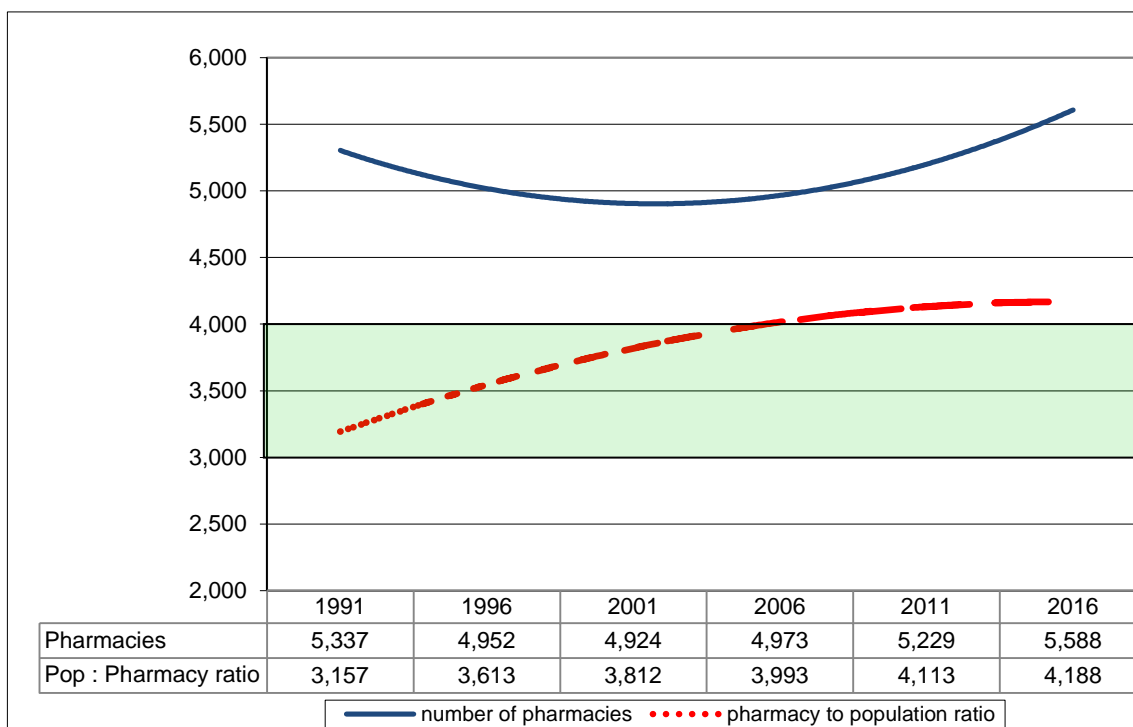
Prior to the introduction of Location Rules, there were 5,579 pharmacies in Australia, with a pharmacy to population ratio of 1:2,476<sup>4</sup>. Many pharmacies were clustered, mostly in urban areas. Conversely, there were some areas with few or no pharmacies. In addition, there were a number of relatively inefficient pharmacies which were primarily in commercially attractive urban areas.

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<sup>5</sup>.

The number of pharmacies declined through until the commencement of the Third CPA in 2000 (see **Table 1**). During the five years of the Fourth CPA, to 2010, there was a steady rise in the number of pharmacies; however the increase had not kept pace with the growth in population (see **Table 1**). To address this, the Location Rules were significantly relaxed from 18 October 2011. Over the term of the Fifth CPA, there was a considerable increase in the number of pharmacies.

The Location Rules continue to influence the number and distribution of pharmacies. New pharmacies can only be established where both the community need criteria and distance requirements of the Location Rules are satisfied.

**Table 1: Number of approved pharmacies and pharmacy to population ratio from 1991 to 2016<sup>6</sup>**



<sup>4</sup> The University of Adelaide: Geographic Access and Spatial Clustering of Section 90 Pharmacies – 1990 to 2014: An Exploratory Analysis 2016

<sup>5</sup> Department of Human Services - approved pharmacists data (unpublished)

<sup>6</sup> Department of Human Services – approved pharmacists data (unpublished); ABS - census population



Since 30 June 2013 the pharmacy to population ratio in rural localities has been better than the pharmacy to population ratio in urban localities<sup>7</sup>. As at 30 June 2016, the pharmacy to population ratio in rural localities was 1:3,615, while the pharmacy to population ratio in urban localities was 1:3,884<sup>8</sup>. This information lends weight to the conclusion that the Location Rules are facilitating a pharmacy network that is well distributed across urban and rural areas.

The restriction on the relocation of existing pharmacies has continued. In general, pharmacies are able to relocate within the local area for which they are approved (up to one kilometre from the existing premises) provided they had been at those premises for at least two years. The two year restriction does not apply if the pharmacy is relocating within the same town, or within a small shopping centre, large shopping centre, large medical centre or private hospital.

The number of applications considered by the Authority in recent years is shown in **Table 2** below. The reduction in the number of applications from 2012/13 onwards, coupled with the increase in the number of new pharmacies recommended for approval since the introduction of the relaxed Locations Rules on 18 October 2011, shows that the changes have made it much easier for new pharmacies to be established.

**Table 2: Applications for approval considered by the Authority<sup>9</sup>**

FINANCIAL YEAR	2010/2011	2011/2012	2012/13	2013/14	2014/15	2015/16	2016/17
APPLICATIONS	471	567	391	381	328	387	362

## Competition Assessment

It should be noted that the Location 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).

The Location Rules provide the ability to deliver the main components of the CPA to a greater number of 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.

## Conclusion

It is Government policy that all Australians should have reasonable access to PBS medicines and pharmaceutical services which are delivered efficiently and affordably.

PBS medicines are important in treating illness and can also play a role in preventing illnesses. The accessibility 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 Location Rules.

<sup>7</sup> ABS census population divided by the number of approved pharmacies by Pharmacy Access/Remoteness Index of Australia (PhARIA) area - Urban being PhARIA 1 and rural PhARIA 2-6

<sup>8</sup> Productivity Commissioner: Report on Government Services (RoGS)

<sup>9</sup> Department of Health: Community Pharmacy Application Registration data (unpublished)

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 intervention was necessary to ensure that PBS medicines were efficiently and equitably available to all Australians. That policy objective was realised through the introduction of the Location Rules.

This approach to achieving the desired policy outcome has been supported by successive Governments as a key component of the CPAs which address the delivery of PBS medicines and professional pharmacy services and programs.

The Location Rules support a well distributed geographical spread of pharmacies in Australia. The Location Rules ensure that the community pharmacy sector remains viable and able to meet consumers' needs throughout Australia, including (and especially) in rural and remote areas, while also allowing competition between pharmacies. These factors are important to achieving the objectives of the Community Pharmacy Agreement, National Medicines Policy and the PBS more broadly.