



**Submission to the Senate  
Economics Legislation  
Committee for inquiry into the**

***National Health Amendment  
(Pharmaceutical Benefits) Bill 2015***

**June 2015**

## Consumers Health Forum of Australia

### INTRODUCTION

The Consumers Health Forum of Australia (CHF) is the national peak body representing the interests of Australian healthcare consumers. CHF works to achieve safe, quality, timely healthcare for all Australians, supported by accessible health information and systems.

This submission into the *National Health Amendment (Pharmaceutical Benefits) Bill 2015* (the Bill) draws on the experiences of our members and consumer representatives in assessing the equity and effectiveness of pharmacy sector in Australia. Under the Pharmaceutical Benefits Scheme Access and Sustainability Package (the Package), the Government will implement numerous new measures to achieve savings of \$6.6 billion over 5 years, of which \$2.9 billion will be reinvested into the pharmacy sector and the PBS.

Our submission addresses all three Schedules of the Bill and limits itself to the scope of the Bill, only the elements of the Package which require amendments to the *National Health Act 1953*. On the whole, the Bill's proposed amendments have some potential benefits however they do not go far enough to drive improvements in terms of greater competition and innovation in this sector, resulting in greater accessibility and affordability for consumers.

The Package was described by the Government as being a big win for consumers however, as our analysis shows, the bigger winners were pharmacy and the Government. While the Government has identified savings for its bottom line and greater revenue for community pharmacists, the direct consumer contribution to the fund pharmacy sector is set to increase as a proportion from 29% (\$4.8 billion) to 34% (\$8.2 billion)<sup>1</sup>. This means that general non-concessional patients will incur significantly higher out-of-pocket costs for medicines priced below the \$37.70 co-payment amount.

We are disappointed by the absence of legislative changes to the pharmacy location rules despite the recommendations that consumers do not benefit from these rules in four major reports; the Government's own [National Commission of Audit](#), [Australian National Audit Office Report 25](#) as well as the independent [Harper Competition Policy Review](#) and the Productivity Commission's [Efficiency in Health Discussion Paper](#). The restrictions placed by these rules are unnecessary and stifle competition-led improvements to aspects such as pharmacy opening-hours, price competition and consumer services. The terms of the independent comprehensive review of these location rules, pharmacy remuneration changes and wholesaler arrangements, as outlined in the 6CPA, are lacking and will not result in changes until after mid-2020.

Overall, we have welcomed the potential for some popular medicines to be cheaper for consumers as a result of the changes to PBS pricing policies and price disclosure, particularly steps to bring prices more in line with the international market, the provision of \$2.9 billion in savings for future new PBS listings and, the optional \$1 discount on PBS co-payment for prescription medicines.

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<sup>1</sup> The Agreement forecasts a 16% rise in scripts over the five years and does not account for the rise in proportion contributed by patients directly to pharmacists when purchasing low cost drugs (under \$37.70).

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### **SCHEDULE 1**

#### **Pricing Policy Changes**

The legislative changes relating to the one-off 5% price reduction to some medicines after five years and the changes to price disclosure will lower the cost of popular medicines. Consumers could benefit from these measures but this will be contingent on pharmacies passing on the savings.

Experts predict that although the price at which a medicine comes into pharmacy will be lowered due to these pricing changes, the mark-ups by pharmacists in form of the new administration, handling and infrastructure fee (AHI fee) and the additional charges for medicines below maximum co-payment will in fact result in higher out-of-pockets for some consumers.

The Government should include the evaluation of the impact of this policy on general consumer out-of-pocket costs in the scope of the Comprehensive Review outlined in the 6CPA.

#### **Location Rules**

The Bill proposes the passage of the Australian Government's Pharmacy Location Rules (Location Rules), which regulate where new pharmacies that dispense PBS prescriptions may open and where existing pharmacies, may relocate. The current location rules protect pharmacies from competition from supermarkets and other pharmacies that want to open within 1.5 kilometres of an existing pharmacy. The location rules combined with the ownership rules, stipulated in the state and territory legislation and restrict the ownership of pharmacies to pharmacists, have led to a gross monopolisation of the sector. There are more than 25,000 registered pharmacists but less than 4,000 pharmacy owners. These rules protect the high-profits of pharmacy owners and businesses at the cost of delivering better patient outcomes. CHF believes these restrictions are unnecessary and stifle competition-led improvements to aspects such as pharmacy opening-hours, price competition and consumer services.

CHF has advocated for an independent review of the community pharmacy location rules for many years and has welcomed the Minister's announcement of a comprehensive review to be completed between 1 September 2015 and 1 March 2017. However, we are concerned that the scope and terms of reference for this review appear to be determined solely by the Minister and the Guild, with no mention of consumer representation and consultation (although factsheets issued by the Guild indicate that a public process is envisaged). The public accountability of this review is important to consumers and taxpayers as funders of this \$18.9 billion agreement.

The [National Commission of Audit](#), the [Australian National Audit Office Report 25](#), the [Harper Competition Policy Review](#) and the Productivity Commission's [Efficiency in Health Discussion Paper](#) have independently concluded that the existing location rules do not benefit consumers and are anti-competitive. The Harper Competition Policy Review (commissioned by the Prime Minister and the Minister for Small Business) Report 2015 states, in its Areas for Immediate Reform section, that the current restrictions on ownership and location of pharmacies are not necessary to ensure the quality of advice and care

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provided to patients. It says, “Such restrictions limit the ability of consumers to choose where to obtain pharmacy products and services, and the ability of providers to meet consumers’ preferences”<sup>2</sup>. The Report recommends that the pharmacy ownership and location rules should be removed in the long-term interests of consumers. They should be replaced with regulations to ensure access and quality of advice on pharmaceuticals that do not unduly restrict competition.

The passage of the location rules provision will mean that no changes will be made to the location rules during the 5 year term of the Agreement ending 2020, although the review will be completed by 1 March 2017. The changes to the pricing policy and the remuneration of pharmacists must also be evaluated as part of the review to determine whether consumers are benefiting from the reduction in cost of some medicines or whether the benefit stops at the pharmacy level with consumers paying higher out-of-pockets.

The Government should appoint a skilled consumer representative on the review panel. The scope and terms of reference for the review should be agreed upon by a broader group of stakeholders including; consumer organisation such as CHF and a professional body such as the Pharmaceutical Society of Australia. The location rules clause should mention the review process and the report must be published publicly and open for consultation.

## SCHEDULE 2

### **Substitution of biosimilar medicines at the pharmacy level**

CHF does not have any objection to biosimilars being prescribed and administered if there is robust evidence to show they are clinically safe and effective. We understand the need for and support measures that contain health costs. However there is a need to always ensure these savings are not made at the expense of consumers’ well-being.

This measure has caused concern for a number of consumer organisations that represent people who have conditions that have benefitted from the advent of biologics in terms of treatment options and improved quality of life. We have attached a letter from Mr Stephen Murby, an independent and international patient expert on biosimilars, raising a range of concerns and highlighting how this approach would appear to run counter to that taken in many other countries across Europe, Canada and for many states in the USA (Attachment A).

Clearly many of the overseas trusted regulators are not convinced about the substitution issue and have taken a more cautious approach. We think initially substitution should be by the prescriber with the consent of the consumer, for both new patients and those who might be switching from a biologic. The prescribing doctor is working with their patient to optimise treatments and it would be unfortunate if they were not even aware that a biosimilar had been dispensed so would not have had a chance to discuss with the patient possible side effects and action to take in response to them.

We realise that it is the Pharmaceutical Benefits Advisory Committee (PBAC) which has indicated that it wants to allow substitution at the pharmacy level to be the default position.

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<sup>2</sup> Competition Policy Review Report March 2015, Peter Anderson, Michael O’Byrne QC, Professor Ian Harper (Chair of the Review), Su McCluskey ([http://competitionpolicyreview.gov.au/files/2015/03/Competition-policy-review-report\\_online.pdf](http://competitionpolicyreview.gov.au/files/2015/03/Competition-policy-review-report_online.pdf))

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By making it the default position PBAC is then looking for robust evidence as to why it should not be substituted. The evidence on efficacy does not of itself make that case and the restrictions on substitution internationally and here in Australia means there is limited evidence either way. There needs to be better post marketing surveillance and improved adverse events monitoring and reporting to help collect the data to ensure an informed decision is made.

As there remains continuing serious debate concerning the interchangeability of originator drugs and biosimilars, we think it is imperative that any substitution of biologic medicines is based on conclusive evidence in regards to patient safety and efficacy. Rigorous regulation of the dispensing of biosimilars and effective education of clinicians and pharmacists is vital. The issue of cost should only be considered once underpinning safety and efficacy elements are assured.

### **SCHEDULE 3**

#### **Optional discounting of co-payments by pharmacies to a maximum of \$1**

This legislation will allow pharmacies to discount the patient co-payment by a maximum of \$1. If the pharmacy chooses to offer this discount then the consumer will save up to \$1 on their out-of-pocket costs. The current maximum co-payment is \$37.70 for non-concessional and \$6.10 for concessional patients.

Even though CHF welcomes this policy as a stand-alone, we are wary of the fact that the Government has not formally withdrawn the existing proposal, from Budget 2014-15, to increase the PBS co-payment to \$42.70 (general) and \$6.90 (concessional) and increase Safety Net thresholds from its legislative program, despite public assurances from the Minister that these and the PBS Access and Sustainability measure are not linked. If the PBS co-payment and Safety Net thresholds are increased then both general and concessional patients are likely to be faced with increased out-of-pocket expenses.

The community pharmacy sector has publicly expressed its aversion to this policy change and the Guild has officially stated that it will not facilitate support for the measure. As the measure is optional and the Government has not negotiated implementation with the sector, there is great risk that it will only be taken up in areas of high pharmacy concentration where competition is at its fiercest. The measure is designed to save the Government approximately \$400 million over 5 years as consumers see a delay in the time taken to reach the safety net threshold.

The Government should work to educate consumers on the possible discount and with the sector on its implementation and uptake.

### **CONCLUSION**

The overall impact of these measures on consumers is difficult to predict and will require close monitoring and good data collection by the Government. We believe that this has been a missed opportunity to get a more sustainable, transparent, value for money and flexible agreement and reform package to accommodate evolving consumer needs.

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**Additional Information**

CHF Appraisal of the Sixth Community Pharmacy Agreement (2015-2020) and the wider PBS Access and Sustainability Package – <https://www.chf.org.au/pdfs/chf/CHF-Appraisal-of-6CPA--May-2015.pdf>

**CHF Contacts**

Leanne Wells  
Chief Executive Officer

Jo Root  
National Policy Manager

**Mailing Address**

Consumers Health Forum of Australia  
PO Box 3099  
Manuka, ACT 2603  
Australia



## **About CHF**

The Consumers Health Forum of Australia (CHF) is the national peak body representing the interests of Australian healthcare consumers. CHF works to achieve safe, quality, timely healthcare for all Australians, supported by accessible health information and systems.

CHF does this by:

- advocating for appropriate and equitable healthcare
- undertaking consumer-based research and developing a strong consumer knowledge base
- identifying key issues in safety and quality of health services for consumers
- raising the health literacy of consumers, health professionals and stakeholders
- providing a strong national voice for health consumers and supporting consumer participation in health policy and program decision making

CHF values:

- our members' knowledge, experience and involvement
- development of an integrated healthcare system that values the consumer experience
- prevention and early intervention
- collaborative integrated healthcare
- working in partnership

CHF member organisations reach Australian health consumers across a wide range of health interests and health system experiences. CHF policy is developed through consultation with members, ensuring that CHF maintains a broad, representative, health consumer perspective.

CHF is committed to being an active advocate in the ongoing development of Australian health policy and practice.