

# Chapter 1

## Introduction

### Establishment

1.1 On 11 October 2016, the Senate established the Select Committee on Red Tape (committee) to inquire into and report on the effect of restrictions and prohibitions on business (red tape) on the economy and community, by 1 December 2017, with particular reference to:

- a. the effects on compliance costs (in hours and money), economic output, employment and government revenue, with particular attention to industries, such as mining, manufacturing, tourism and agriculture, and small business;
- b. any specific areas of red tape that are particularly burdensome, complex, redundant or duplicated across jurisdictions;
- c. the impact on health, safety and economic opportunity, particularly for the low-skilled and disadvantaged;
- d. the effectiveness of the Abbott, Turnbull and previous governments' efforts to reduce red tape;
- e. the adequacy of current institutional structures (such as Regulation Impact Statements, the Office of Best Practice Regulation and red tape repeal days) for achieving genuine and permanent reductions to red tape;
- f. alternative institutional arrangements to reduce red tape, including providing subsidies or tax concessions to businesses to achieve outcomes currently achieved through regulation;
- g. how different jurisdictions in Australia and internationally have attempted to reduce red tape; and
- h. any related matters.<sup>1</sup>

1.2 On 28 November 2017, the Senate extended the reporting date to 3 December 2018.<sup>2</sup>

1.3 The committee decided to conduct its inquiry by focusing on specific areas. This interim report presents the committee's findings and conclusions about the effect of red tape on pharmacy rules (pharmacy inquiry).

### Conduct of the pharmacy inquiry and acknowledgement

1.4 The committee advertised the pharmacy inquiry on its website and wrote to a number of organisations, inviting submissions by 5 October 2017. The date was

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1 *Journals of the Senate*, No. 9–11 October 2016, pp. 290–291.

2 *Journals of the Senate*, No. 73–28 November 2017, p. 2314.

subsequently extended to 9 November 2017. In total, the committee received nine submissions, which are listed at Appendix 1.

1.5 The committee held a public hearing in Canberra on 27 November 2017. The witnesses who appeared before the committee are listed at Appendix 2.

1.6 The committee thanks the organisations and individuals who made submissions and who gave evidence to assist the committee with its pharmacy inquiry.

### **Scope of the report**

1.7 Chapter one provides broad background information to set the regulatory context for the pharmacy inquiry. Chapter two then examines some of the evidence presented to the committee, which may be drawn upon in the committee's final report.

### **Regulatory framework for the community pharmacy sector**

1.8 The Commonwealth, states and territories regulate the community pharmacy sector. Their responsibilities are as follows:

#### ***Commonwealth regulation***

1.9 Australia's overarching National Medicines Policy aims to improve positive health outcomes for all Australians.<sup>3</sup> The policy has four central objectives, including 'timely access to the medicines that Australians need, at a cost individuals and the community can afford'.<sup>4</sup>

1.10 The Australian Government aims to achieve this objective through the Pharmaceutical Benefits Scheme (PBS) and the Repatriation Pharmaceutical Benefits Scheme (RPBS), which provide subsidised 'pharmaceutical benefits' to all eligible Australians.<sup>5</sup> In 2016–2017, these subsidies amounted to nearly \$11.3 billion,<sup>6</sup>

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3 Department of Health, 'National Medicines Policy', <http://www.health.gov.au/nationalmedicinespolicy> (accessed 15 February 2018).

4 Department of Health, 'National Medicines Policy Document', <http://www.health.gov.au/internet/main/publishing.nsf/Content/national-medicines-policy> (accessed 15 February 2018). The other three objectives are: medicines meeting appropriate standards of quality, safety and efficacy; quality use of medicines; and maintaining a responsible and viable medicines industry.

5 Part VII of the *National Health Act 1953* (Cth).

For further information on the Pharmaceutical Benefits Scheme, see: Department of Health, 'Pharmaceutical Benefits Scheme', <http://www.health.gov.au/PBS> (accessed 15 February 2018).

For further information on the Repatriation Pharmaceutical Benefits Scheme, see: Department of Veterans' Affairs, 'RPBS', <https://www.dva.gov.au/tags/rpbs> (accessed 15 February 2018).

6 Department of Health, *Annual Report 2016–17*, p. 138.

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and were paid to approximately 5665 community pharmacies,<sup>7</sup> which primarily deliver the benefits, as well as other professional health services.<sup>8</sup>

### ***State and territory regulation***

1.11 The states and territories regulate various aspects of community pharmacy, for example: who may practise pharmacy; who may own/operate a pharmacy; and who may sell/dispense certain types of medicine.

1.12 Across jurisdictions, there are differences in the structure and content of legislative and regulatory schemes, as well as the types of regulatory bodies. Some areas where there is regulatory variation are: pharmacy premises; pharmacy ownership; medicines distribution and storage; and prescription and dispensing of restricted medicines.<sup>9</sup>

### ***Community Pharmacy Agreements***

1.13 Since 1990, the Australian Government has entered into five-year agreements with the Pharmacy Guild of Australia (Community Pharmacy Agreement (CPA)). The most recent CPA is the Sixth Community Pharmacy Agreement (6CPA) that expires on 30 June 2020.<sup>10</sup>

1.14 The 6CPA outlines three key funding elements: community pharmacy remuneration; the Community Services Obligation; and community pharmacy programs.<sup>11</sup> It also encompasses a range of additional matters, including the Review of Pharmacy Remuneration and Regulation (King Review) and the Location Rules (referred to as the Pharmacy Rules in this inquiry).<sup>12</sup>

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7 Department of Health, *Submission 7*, p. 4; Keith Tracey-Patte, Assistant Secretary, Systems Branch, Provider Benefits Integrity Division, Department of Health, *Committee Hansard*, 27 November 2017, p. 23.

8 Department of Health, *Submission 7*, p. 4, which described community pharmacies as 'an integral part of Australia's health care system'.

9 King, S., Watson, J. and Scott, W., *Review of Pharmacy Remuneration and Regulation*, Interim Report, Prepared for the Department of Health, June 2017, pp. 115–119, [http://www.health.gov.au/internet/main/publishing.nsf/content/7E5846EB2D7BA299CA257F5C007C0E21/\\$File/interim-report-final.pdf](http://www.health.gov.au/internet/main/publishing.nsf/content/7E5846EB2D7BA299CA257F5C007C0E21/$File/interim-report-final.pdf) (accessed 15 February 2018).

10 Australian Government, *Sixth Community Pharmacy Agreement*, 2015, <http://www.pbs.gov.au/general/pbs-access-sustainability/signed-sixth-community-pharmacy-agreement-commonwealth-and-pharmacy-guild.pdf> (accessed 15 February 2018).

11 Further information on these funding elements can be found at: Department of Health, 'Sixth Community Pharmacy Agreement', <http://www.pbs.gov.au/info/general/sixth-community-pharmacy-agreement> (accessed 15 February 2018).

12 Australian Government, *Sixth Community Pharmacy Agreement*, 2015, clause 8 and sub-clause 7.2, <http://www.pbs.gov.au/general/pbs-access-sustainability/signed-sixth-community-pharmacy-agreement-commonwealth-and-pharmacy-guild.pdf> (accessed 15 February 2018).

1.15 The Pharmacy Rules set out location-based criteria for the premises from which 'approved pharmacists' can supply pharmaceutical benefits. The criteria are broadly categorised as relating to either the expansion/contraction/relocation of an existing pharmacy<sup>13</sup> or the establishment of a new pharmacy.<sup>14</sup> Although the Pharmacy Rules expire at the same time as the 6CPA,<sup>15</sup> the Australian Government is currently seeking to extend them beyond 30 June 2020.<sup>16</sup>

1.16 In 2016–2017, the King Review examined one of the key funding elements—community pharmacy remuneration—and the regulation of pharmacy and pharmacy distribution.<sup>17</sup> An interim report was released on 22 June 2017<sup>18</sup> and the final report has been presented to the Australian Government for its consideration and response.<sup>19</sup>

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13 Items 121–124 in Part 1 of Schedule 1 of the National Health (Australian Community Pharmacy Authority Rules) Determination 2011 (PB 65 of 2011).

14 Items 130–136 in Part 2 of Schedule 1 of the National Health (Australian Community Pharmacy Authority Rules) Determination 2011 (PB 65 of 2011).

15 Subsection 90(3C) and section 997 of the *National Health Act 1953* (Cth); Australian Government, *Sixth Community Pharmacy Agreement*, 2015, clause 7, <http://www.pbs.gov.au/general/pbs-access-sustainability/signed-sixth-community-pharmacy-agreement-commonwealth-and-pharmacy-guild.pdf> (accessed 15 February 2018).

16 Schedule 5 of the National Health Amendment (Pharmaceutical Benefits—Budget and Other Measures) Bill 2017; Commonwealth of Australia, *Budget Measures: Budget Paper No. 2, 2017–2018*, p. 115, [http://www.budget.gov.au/2017-18/content/bp2/download/bp2\\_expense.pdf](http://www.budget.gov.au/2017-18/content/bp2/download/bp2_expense.pdf) (accessed 15 February 2018).

17 For further information on the five terms of reference, see: 'Review of Pharmacy Remuneration and Regulation', <http://www.pbs.gov.au/reviews/pharmacy-remuneration-and-regulation/review-of-pharmacy-remuneration-and-regulation-terms-of-reference.pdf> (accessed 15 February 2018).

18 Department of Health, 'Review of Pharmacy Remuneration and Regulation', <http://www.health.gov.au/pharmacyreview> (accessed 15 February 2018).

19 Penny Shakespeare, First Assistant Secretary, Technology Assessment and Access Division, Department of Health, *Committee Hansard*, 27 November 2017, p. 21.