The Senate

Select Committee on Red Tape

Effect of red tape on health services

Interim report

March 2018

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Recommendation 2

2.27 The committee recommends that the Department of Health investigate the merits of allowing private health funds to fund out-of-hospital care.

Recommendation 3

2.28 The committee recommends that the Australian Government review cost drivers for private health insurance, to identify and better manage their ongoing effect on the cost of private health insurance.

Recommendation 4

2.30 The committee recommends that the Australian Government consider ceasing regulation of the prostheses market, apart from maintaining standard consumer protection.

Recommendation 5

2.52 The committee recommends that the Australian Government, through the Council of Australian Governments, streamline the identifiers issued to healthcare practitioners for practice purposes.

Recommendation 6

2.60 The committee recommends that the Australian Government, through the Council of Australian Governments, develop a standard template and associated guidelines, including reasonable timeframes, to streamline ethics and governance approval processes for clinical trials across Australia.

Recommendation 7

2.67 The committee recommends that the Australian Government place licensing requirements for the supply, ownership and operation of diagnostic imaging equipment on the agenda for consideration by the Council of Australian Governments.

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.[1]

1.2 On 28 November 2017, the Senate extended the reporting date to 3 December 2018.[2]

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 health services (health services inquiry).

Conduct of the health services inquiry and acknowledgement

1.4 The committee advertised the health services inquiry on its website and wrote to a number of organisations, inviting submissions by 22 January 2018.

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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.

The committee continued to accept submissions received after this date. In total, the committee received 11 submissions, which are listed at Appendix 1.

1.5 The committee held a public hearing in Canberra on 9 February 2018. The witnesses who appeared before the committee are listed at Appendix 2.

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

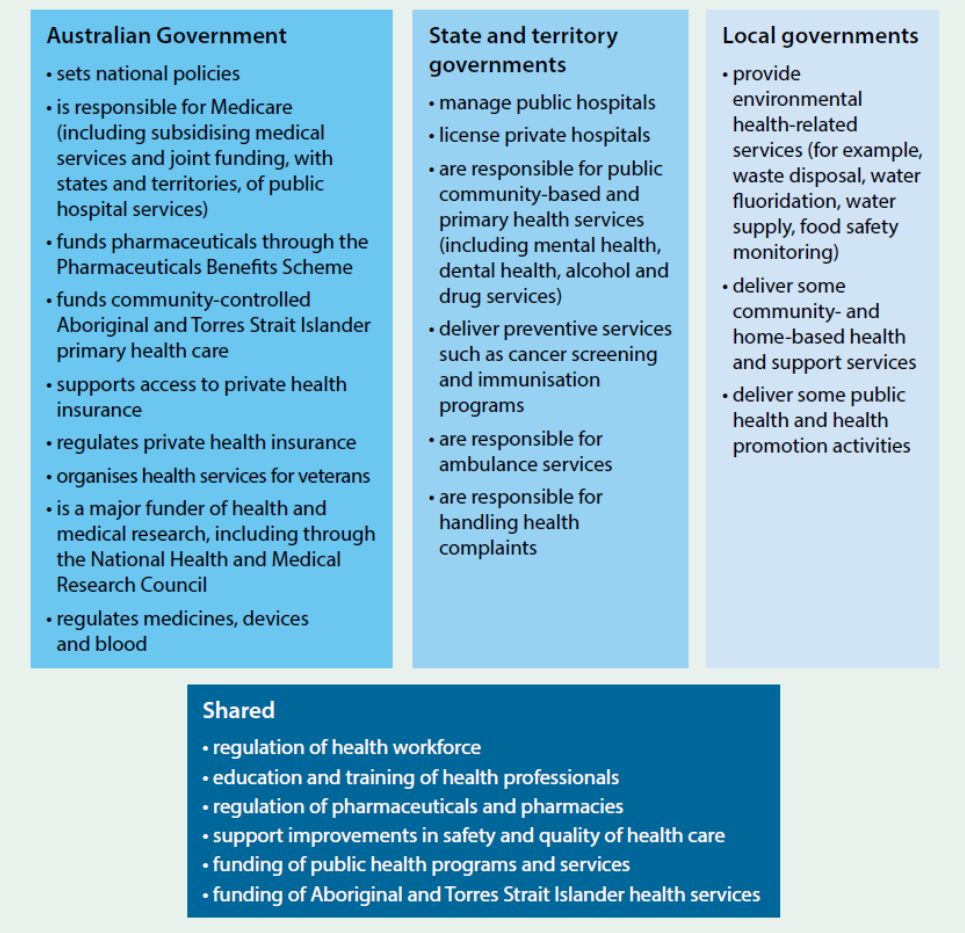
Scope of the report

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

Regulatory framework for health services

1.8 The health services inquiry encompasses Commonwealth, state, territory and local government responsibilities. Accordingly, there are a number of regulatory regimes upon which submitters and witnesses could comment. In this report, the committee focussed primarily upon Commonwealth responsibilities. Figure 1 illustrates the responsibilities of each level of government.

Figure 1.1: Government responsibilities, Australian health system



Source: Australian Institute of Health and Welfare, Australia's Health 2016, 2016, p. 24.

Australian Government responsibilities

1.9 The Department of Health (Department) has a diverse range of responsibilities which reflect a common purpose—better health and ageing outcomes for all Australians.[3] In total there are 10 outcomes including: access to medical and dental services; primary health care; private health; and health infrastructure, regulation, safety and quality. Specific agencies—such as the Australian Commission on Safety and Quality in Health Care and the National Health and Medical Research Council—are responsible for a further 20 outcomes in the Health portfolio.[4]

Regulatory Reform Agenda

1.10 In 2013, the Australian Government introduced the Regulatory Reform Agenda (Agenda): to reduce the burden of regulation across government; to coordinate red tape reduction efforts; and to set clear expectations that regulation should not be the default option for government policy makers.[5]

1.11 Key elements of the Agenda include:

- cutting regulatory compliance costs to businesses, community organisations and individuals by at least $1 billion a year;
- requiring all major regulatory decisions to be informed by a Regulation Impact Statement (RIS) that sets out the benefits/costs of regulation;
- introducing the Regulatory Burden Measurement framework to calculate the regulatory costs of current/proposed policies or regulation;
- undertaking an assessment of the regulatory burden imposed by the Commonwealth stock of regulation; and
- introducing the Regulator Performance Framework for over 80 regulatory authorities, to encourage regulators to:
    - reduce regulatory burden;
    - communicate clearly with stakeholders;
    - take risk-based and proportionate approaches to regulation;
    - operate efficiently and transparently; and

3 Department of Health, 'About us', https://beta.health.gov.au/about-us (accessed 22 March 2018)

4 Department of Health, 'Portfolio Outcomes', Outcomes 3 and 5–7, http://www.health.gov.au/internet/main/publishing.nsf/Content/health-portout.htm (accessed 22 March 2018).

5 Department of the Prime Minister and Cabinet, 'Regulatory Reform Agenda: Key Achievements (as at December 2015)', https://www.pmc.gov.au/regulation/australias-approach-regulatory-reform/regulatory-reform-agenda-key-achievements-december-2015 (accessed 22 March 2018).

- undertake continuous improvement.[6]

Performance under the Regulatory Reform Agenda

1.12 By 31 December 2015, the Australian Government reported having made decisions to reduce regulation compliance costs by $4.8 billion.[7] Of this total, the Department reported it had achieved net savings of $249 million, with significant reductions in red tape, notwithstanding the introduction of new regulation.[8]

1.13 The Department of the Prime Minister and Cabinet (PMC), which is responsible for coordinating the regulatory policy priorities across all portfolios, has not published up-to-date information for 2016, 2017 or 2018.[9] The Department was not able to advise its regulatory savings since 2015, instead referring the committee to PMC.[10]

1.14 In addition to regulatory savings, the Department advised that it continually tests the relevance and effectiveness of existing regulation, and explores opportunities to reduce red tape.[11] A major deregulatory measure was the 2015 *Review of Medicines and Medical Devices Regulation*. This review focussed on the regulatory framework and processes of the Therapeutic Goods Administration.[12]

1.15 As part of best practice regulation, the Department also conducts regulatory impact analysis in the form of RISs.[13] In 2014–2015, six statements were developed, however it is not clear from the Department's website if any RISs have been developed since 2015.[14]

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6 Department of the Prime Minister and Cabinet, 'Regulatory Reform Agenda: Key Achievements (as at December 2015)', https://www.pmc.gov.au/regulation/australias-approach-regulatory-reform/regulatory-reform-agenda-key-achievements-december-2015 (accessed 22 March 2018).

7 Australian Government, *Annual Red Tape Reduction Report*, 2015, p. 1, https://www.pmc.gov.au/sites/default/files/publications/2015_annual_red_tape_reduction_report.pdf (accessed 22 March 2018).

8 Department of Health, *Submission 11*, p. 1.

9 Department of the Prime Minister and Cabinet, 'Regulatory Policy Coordination', https://www.pmc.gov.au/regulation/regulatory-policy-coordination (accessed 22 March 2018).

10 Sharon Appleyard, First Assistant Secretary, Office of Health Protection, Department of Health, and Gillian Shaw, Assistant Secretary, Office of Health Protection, Department of Health, *Committee Hansard*, 9 February 2018, p. 27.

11 Department of Health, *Submission 11*, p. 1.

12 Department of Health, 'Expert Review of Medicines and Medical Devices Regulation', http://www.health.gov.au/internet/main/publishing.nsf/Content/Expert-Review-of-Medicines-and-Medical-Devices-Regulation (accessed 22 March 2018).

13 Department of Prime Minister and Cabinet, 'Best Practice Regulation', https://www.pmc.gov.au/regulation/best-practice-regulation (accessed 22 March 2018).

14 Department of Health, 'Regulation Impact Statements', http://www.health.gov.au/internet/main/publishing.nsf/Content/regulation-impact-statements (accessed 22 March 2018).

Chapter 2

Key issues

2.1 Regulation has an important role in protecting the quality, safety and efficiency of health services. However, regulation can be costly and burdensome. The Department of Health (Department) aims to ensure that regulation within the Health portfolio remains efficient and fit-for-purpose.[1]

2.2 However, submitters and witnesses described how health regulation does not always conform to the Regulatory Reform Agenda, being sometimes costly, excessive, ineffective and outdated. Consequently, red tape is adversely affecting health services, providers and consumers.[2] The Australian Dental Industry Association (ADIA) submitted, for example:

> Red tape invariably leads to increases in treatment costs, limitations on the variety of treatment options, and the restriction of the growth, sustainability, international competitiveness, and job creation capacity of industry.[3]

2.3 This chapter discusses some of the issues raised with respect to:

- the effect of red tape on the Australian economy;
- specific areas of burdensome and duplicative red tape;
- the need for harmonisation in certain areas; and
- the *Review of Medicines and Medical Devices Regulation*.

Effect of red tape on the Australian economy

2.4 Submitters and witnesses highlighted the important role of their sectors in the Australian economy, and argued that red tape is impeding competition, growth, viability and efficiency, with subsequent effects for the provision of high quality health care to Australian consumers.

2.5 Roche Products Pty Ltd (Roche) submitted that the pharmaceutical industry's contribution to research in Australia is important for investment and jobs. In 2015, for example, investment in active clinical trials was over $1 billion, which supported a minimum 6,900 highly skilled jobs.[4] However, there is significant competition in clinical research within the Asia-Pacific region and Australia is not as competitive as it could be:

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1 Department of Health, *Submission 1*, p. 1.

2 For example: Medical Oncology Group of Australia, *Submission 5*, p. 1; Royal Australian College of General Practitioners, *Submission 10*, p. 1.

3 Australian Dental Industry Association, *Submission 7*, p. 2.

4 Roche Products Pty Ltd, *Submission 1*, Attachment 1, p. 1.

> It is concerning that the opportunity for Australia to lead the Asia Pacific region in clinical trials continues to elude us. Persistent challenges are research costs, red tape around study start-up and slow recruitment.[5]

2.6 Day Hospitals Australia submitted that private stand-alone day hospitals are a growing part of the health system. Increasingly, patients are choosing to have surgical, diagnostic and medical treatment as day patients, rather than in overnight hospitals. Further, 'the sector delivers a safe, quality, low risk, cost effective care option for consumers'.[6] However, Day Hospitals Australia cautioned:

> There are significant challenges to running a day hospital in the current legislative, regulatory and accreditation environment. Some of these conditions imposed on the day hospital sector severely impact financial viability and thus provision of services to patients.[7]

2.7 The Royal Australian College of General Practitioners (RACGP) and the Medical Oncology Group of Australia (MOGA) argued that general practitioners (GPs) and oncologists unnecessarily spend a large amount of time on management and administration. Both indicated that this expenditure burdens doctors and could be better spent on the delivery of health services.[8] For example, RACGP submitted:

> The removal of red tape, or streamlining processes, would reduce the amount of time GPs and other clinical staff spend on administration, allowing more time to deliver safe, high-quality health services.[9]

2.8 The Australian Dental Association (ADA) claimed that dental practices are subject to a much higher level of regulatory oversight than medical GPs. Its submission conservatively estimated compliance costs at $397 million in 2016 ($84 400 per practice), which typically affects small businesses:

> Regardless of the type of red tape that currently exists in the dental sector, dentists are required to spend more time and resources to ensure compliance with red tape. This burden of compliance makes dentists less likely to be innovative and entrepreneurial; not to mention they will be less able to treat more patients. Similarly, the time and resources required to navigate and comply with red tape will lead to higher costs of care for patients. These barriers in turn are the hardest to overcome by the disadvantaged. In some instances, people could be dissuaded from undertaking a career as a health practitioner due to the regulatory burden. Ultimately, this is not in the public interest.[10]

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5 Roche Products Pty Ltd, *Submission 1*, Attachment 1, p. 2. Also see: Medicines Australia, *Submission 9*, p. 2.

6 Day Hospitals Association, *Submission 2*, p. 6.

7 Day Hospitals Association, *Submission 2*, p. 6.

8 Medical Oncology Group of Australia, *Submission 5*, pp. 1–2; Royal Australian College of General Practitioners, *Submission 10*, p. 1, which estimated 20 per cent of general practitioners' time was spent in management and administration.

9 Royal Australian College of General Practitioners, *Submission 10*, p. 1.

10 Australian Dental Association, *Submission 6*, pp. 5–6. Also see: p. 1 and Annexure A.

2.9 Private Healthcare Australia (PHA) presented the view of private health funds that, in 2015–2016, contributed $14.9 billion (8.8 per cent) of health expenditure.[11] It emphasised the integral role of private health insurance (PHI) in Australia's healthcare system, but argued that indexation and other changes to the PHI rebate are decreasing affordability and participation. It contended that a continuation of this trend:

> …will exacerbate an affordability crisis in PHI that will have flow-through impacts on the public sector in key areas of non-emergency surgery waiting lists, mental health and dental care. A 'tipping point' has been reached for the sector.[12]

Committee view

2.10 The committee is concerned that various healthcare professionals continue to experience red tape that significantly affects their business and the services that they can provide to healthcare consumers. As indicated in chapter one, the Australian Government has not published savings in the Health portfolio for a couple of years. This lack of transparency does not assist the committee in assessing recent efforts to reduce red tape.

Recommendation 1

2.11 The committee recommends that the Australian Government publish without delay the red tape reduction reports for 2016 and 2017.

Specific areas of burdensome and duplicative red tape

2.12 Submitters and witnesses described specific areas of burdensome and duplicative red tape that are of concern to their industry. The committee also received information that businesses are affected by ineffective regulation. For example, the Pharmaceutical Society of Australia outlined several red tape issues associated with the PBS Safety Net, the PBS authority system, and the lack of an electronic prescribing and electronic prescriptions system.[13]

2.13 The following sections discuss red tape issues associated with the Health Technology Assessment (HTA) process and PHI reforms.

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11 Australian Institute of Health and Welfare, *Health expenditure Australia, 2015–2016*, 2017, Tables 3.1 and 3.2, p. 23, https://www.aihw.gov.au/getmedia/3a34cf2c-c715-43a8-be44-0cf53349fd9d/20592.pdf.aspx?inline=true (accessed 22 March 2018).

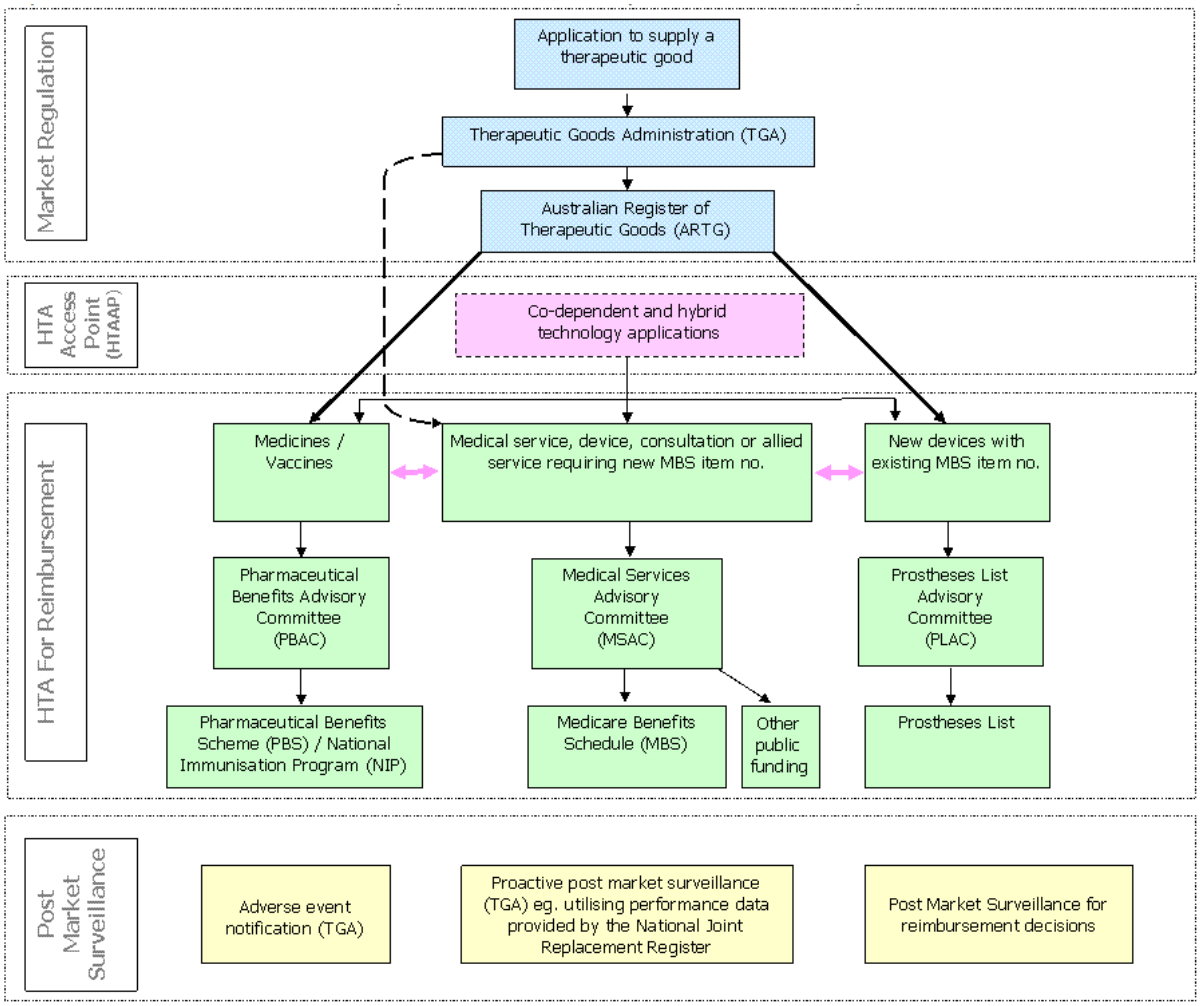
12 Private Healthcare Australia, *Submission 8*, p. 2. Also see: Evaluate, *The Relative Efficiency of the Private Health Insurance Rebate v. Direct Public Health Expenditure*, 1 August 2017, https://www.privatehealthcareaustralia.org.au/wp-content/uploads/Evaluate-Report-Relative-Efficiency-of-PHI-Rebate-versus-Direct-Public-Health-Expenditure-1Aug2017.pdf (accessed 22 March 2018), which highlighted the financial benefits of a strong system of private health insurance.

13 Pharmaceutical Society of Australia, *Submission 4*, pp. 4–7. Also see: Medical Oncology Group of Australia, *Submission 5*, pp. 1–2; Day Hospitals Association, *Submission 2*, p. 4.

Health Technology Assessment process

2.14 The HTA process informs decisions about the registration of health technologies and the Australian Government's subsidisation of the costs of health-related goods and services (for example, listing on the Pharmaceutical Benefits Scheme (PBS)).[14] There are four HTA agencies with discrete functions, and complex and inter-dependent relationships.[15] The current HTA processes for market entry and reimbursement processes are shown in Figure 1 below.

Figure 2.1: HTA processes for market entry and reimbursement processes



Source: Department of Health, Health Technology Assessment (HTA) overview, http://www.health.gov.au/internet/hta/publishing.nsf/Content/commonwealth-1, accessed 22 March 2018.

14 Department of Health, 'Health Technology Assessment (HTA), http://www.health.gov.au/internet/hta/publishing.nsf/Content/home-1 (accessed 22 March 2018).

15 Department of Health, 'HTA Policy Framework', http://www.health.gov.au/internet/hta/publishing.nsf/Content/policy-1 (accessed 22 March 2018).

2.15 Medicines Australia acknowledged steps undertaken by the Australian Government to streamline HTA processes and expedite access to some high priority medicines. Its submission expressed support also for the new Provisional Approval pathway process that will facilitate the registration of new prescription medicines.[16]

2.16 However, Roche argued that the HTA process for PBS listing is unnecessarily complex and lengthy, and denies timely access to affordable medicines:

> There are opportunities to reduce the number of submissions and resubmissions to the Pharmaceutical Benefits Advisory Committee (PBAC) for reimbursement of new medicines, which can delay patient access to new treatments. Whilst there have been commitments and progress made by the Government and Department of Health to streamline the process and implement different pathways for submissions, it is imperative that the system is made fit-for-purpose.[17]

2.17 David Pullar, Head of Government Affairs and Public Policy at Roche, said that Australia's 'assessment process is generally viewed as one of the fastest in the world' (17 weeks). However, Mr Pullar indicated that this reputation does not match the reality:

> An analysis of new cancer drug submissions from 2010 to 2016 found that no more than 50 per cent of recommendations were ever positive, meaning that most medicines required resubmissions and took around two years to list after being approved by the [Therapeutic Goods Administration (TGA)]. In the meantime, patients have to pay out of pocket or not access the medicines at all. We're currently ranked 17 out of 20 developed countries for access to new medicines. Because of the fixed assessment cycle, a medicine that's rejected can't be resubmitted for another four months, then recommended another four months after that. Yet in practice, after the first submission price is often the outstanding issue. This could easily be handled by an out-of-session negotiation rather than a comprehensive dossier assessment, which is what's currently required.[18]

Committee view

2.18 The committee notes that the Australian Government, in consultation with stakeholders, is currently progressing reforms to HTA processes. The committee suggests that assessment processes associated with listing new medicines on the PBS, or through other funding arrangements, be considered as part of this reform.

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16 Medicines Australia, *Submission 9*, p. 4. The Therapeutic Goods Amendment (2017 Measures No. 1) Bill 2017 was passed by the Parliament on 15 February 2018. Also see: Australian Dental Industry Association, *Submission 7*, p. 4.

17 Roche Products Pty Ltd, *Submission 1*, p. 1. Also see: Attachment 2.

18 David Pullar, Head of Government Affairs and Public Policy, Roche Products Pty Ltd, *Committee Hansard*, 9 February 2018, p. 1. Mr Pullar noted that Roche Products Pty Ltd is working with the Australian Government to introduce more flexibility into the HTA process: pp. 1–2.

Private health insurance reforms

2.19 In 2017, the Australian Government announced a package of PHI reforms.[19] PHA welcomed these reforms which it anticipates will 'put downward pressure on premiums and make it easier for consumers to choose and use their health insurance'. PHA added that further reform is necessary to address inflationary dynamics and 'correct regulatory settings currently constraining the industry from evolving to meet the needs of modern consumers'.[20]

Out-of-hospital care

2.20 Dr Rachel David, Chief Executive Officer of PHA, indicated that one of the most frustrating red tape issues is the prohibition against health funds funding out-of-hospital care. Dr David contended that this prohibition is no longer practical or appropriate:

> It is quite possibly the stupidest way you could run a health fund. If someone has cancer these days, they have their surgery in hospital; we can cover them for the out-of-pocket for that; but they get the rest of their care—their chemo, pathology, imaging—out of hospital. We can't cover the co-payment—it's against the law. That means that people, even though they have private health insurance, are faced with this huge out-of-pocket cost. Pregnancy and obstetrics: can we cover for management of the pregnancy? No, only the birth. We can't cover out-of-hospital admissions or consultations with a psychiatrist in private, but we can cover someone to be admitted to hospital and have the same consultation there. If they're admitted to hospital, that's $1,000 a day. If they have a consultation in a doctor's room, it's $300. This is what is forcing premiums up. It is absurd.[21]

Prostheses List

2.21 In October 2017, the Australian Government announced that the minimum benefits payable by private health insurers for devices on the Prostheses List would be reduced from 1 February 2018, with further reductions in August 2018 and February 2020. The reductions are expected to reduce expenditure on prostheses and lower PHI premium increases.[22]

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19 Hon Greg Hunt MP, Minister for Health, 'Major reforms to make private health insurance simpler and more affordable', media release, 13 October 2017, http://www.health.gov.au/internet/ministers/publishing.nsf/Content/health-mediarel-yr2017-hunt106.htm (accessed 22 March 2018).

20 Private Healthcare Australia, *Submission 8*, p. 2. Also see: pp. 7–18.

21 Dr Rachel David, Chief Executive Officer, Private Healthcare Australia, *Committee Hansard*, 9 February 2018, p. 25. Also see: Private Healthcare Australia, *Submission 8*, pp. 14–16.

22 Department of Health, 'The Prostheses List', http://www.health.gov.au/internet/main/publishing.nsf/content/health-privatehealth-prostheseslist.htm, and 'Private health insurance reforms: Prostheses List benefit reductions', http://www.health.gov.au/internet/main/publishing.nsf/content/private-health-insurance-reforms-fact-sheet-prostheses-list-benefit-reductions (both accessed 22 March 2018).

2.22 PHA argued that further reform could be directed toward more savings and increased transparency in the medical devices supply and benefit system.[23] For example, Dr David said there is a popular view in the PHI industry that the Australian Government should transition away from fixing prices in this area. Instead:

> We need to transition to a shared purchasing arrangement that is separate from Commonwealth intervention so that a market is able to operate where there is some reference pricing to real market prices in Australia and around the world. There are transparency measures that are implemented by the existing regulators, like the ACCC, that look at the rest of the retail market.[24]

2.23 The committee heard that such a transition would be difficult, as there are vested interests militating against change.[25] The committee notes however that the Australian Government and the Medical Technology Association of Australia have signed an agreement to improve access to innovative medical technology and the affordability of medical devices for consumers holding PHI. An element of this commitment is to establish:

> …an industry working group by 31 March 2018 to develop a revised framework for benefit setting and benefit review, reflecting use of health technology assessment including evaluation of value, cost-effectiveness and innovation; use of post-market review and the operation of competitive markets in the Australian context.[26]

2.24 The committee recognises that the Australian Government is currently working toward stabilising the cost of items on the Prostheses List, which will occur over the next five years.

PHI rebate

2.25 Dr David also drew attention to cost drivers that she argued continue to increase the cost of premiums:

> The reality is that health fund premium increases are going up in lockstep with demand for health care, and it's because health funds are paying for more health care that premiums go up. This is the effect of the baby boom population now moving through the health system and starting to become unwell. The effect is also being felt on the public hospital side, as their

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23 Private Healthcare Australia, *Submission 8*, pp. 16–18.

24 Dr Rachel David, Chief Executive Officer, Private Healthcare Australia, *Committee Hansard*, 9 February 2018, p. 22. Dr David also commented that price fixing has incentivised a large number of medical devices where there was no clinical benefit: p. 23. Also see: Private Healthcare Australia, *Submission 8*, pp. 16–18.

25 Dr Rachel David, Chief Executive Officer, Private Healthcare Australia, *Committee Hansard*, 9 February 2018, p. 22.

26 See: Department of Health, 'Private Health Insurance-Prostheses', http://www.health.gov.au/internet/main/publishing.nsf/content/health-privatehealth-PLAC (accessed 22 March 2018), for the agreement between the Australian Government and the Medical Technology Association of Australia.

> costs have been going up by seven to eight per cent over the same time frame and very consistently. Without addressing those underlying cost drivers and removing every dollar of waste, inefficiency, inappropriate care and payments on the supply side, we are not going to be able to really bring the cost of premiums down.[27]

Committee view

2.26 The committee accepts that it would be beneficial to consumers if PHI were to cover the cost of out-of-hospital care. Such cover might also assist in reducing the cost of PHI premiums as consumers receive care in the primary care setting, rather than the secondary (or acute) setting. The committee suggests that it might be useful for the Department of Health to further explore this issue.

Recommendation 2

2.27 The committee recommends that the Department of Health investigate the merits of allowing private health funds to fund out-of-hospital care.

Recommendation 3

2.28 The committee recommends that the Australian Government review cost drivers for private health insurance, to identify and better manage their ongoing effect on the cost of private health insurance.

2.29 The committee is not convinced that either consumers or industry players are benefiting from government intervention in the prostheses market. Assuming product safety and efficacy are confirmed, a free market would seem likely to result in reduced costs and better patient outcomes.

Recommendation 4

2.30 The committee recommends that the Australian Government consider ceasing regulation of the prostheses market, apart from maintaining standard consumer protection.

Duplicative regulation

2.31 Medicines Australia submitted that regulators must coordinate with one another, particularly where there is a risk of jurisdictional overlap. By way of example, its submission cited overlap between the TGA and the Australian Competition and Consumer Commission (ACCC): 'potential inconsistent regulatory approaches must be avoided in order to reduce the risk of unnecessary red tape'.[28]

2.32 ADIA expressed particular concerns with the ACCC's involvement in certain (teeth-whitening) product supply issues. ADIA argued that this involvement creates

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27 Dr Rachel David, Chief Executive Officer, Private Healthcare Australia, *Committee Hansard*, 9 February 2018, p. 21. Also see: Private Healthcare Australia, *Submission 8*, pp. 21–23, which cautioned against removing the rebate on extras, which covers, for example, preventative dental care (53 per cent, $2.6 billion each year).

28 Medicines Australia, *Submission 9*, p. 5.

regulatory inconsistencies and compliance challenges, as states/territories already regulate according to the Poisons Standard.[29] ADIA submitted:

> The lack of clarity and certainty that has arisen from this unjustified regulatory duplication subjects industry to the costs of additional regulatory burden, limits treatment options available to healthcare professionals, and undermines the Australian Government's efforts to support the Council of Australian Government's (COAG) development of nationally consistent standards.[30]

2.33 The ACCC has a regulatory role in teeth-whitening products as a consumer good, whereas the TGA has a regulatory role in respect of therapeutic goods that contain medicines or poisons.

2.34 The ADA raised for consideration a different example of regulatory duplication. ADA submitted that its regulatory body, the Dental Board of Australia (DBA), requires dentists and dental practitioners to comply with professional infection control guidelines in order to renew their registration each year.[31] At the same time, governments impose additional infection control requirements:

> These different sets of rules, imposed by different tiers of government entities and jurisdictions, effectively duplicate requirements that form part of every registered dental practitioner's scope of practice as set by the regulator.[32]

2.35 Dr Carmelo Bonanno, Vice President of the ADA, described the situation as one of 'bombardment', where national registration requirements should suffice.[33] In his view, self-regulation is more appropriate given the dental industry's expertise and high levels of professional communication:

> We have our own version of the standards and we actually put out our own infection control manual, which is the only up-to-date infection control guideline for dental practitioners…we have an infection control committee. The membership of the committee are some of the best minds in dentistry, who are up to speed with the latest infection control issues and advances. Therefore, we're able to have a document that is a live document. We can

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29 Also see: Australian Dental Association, *Submission 6*, pp. 5–6, which referred to regulatory inconsistencies in respect of some teeth-whitening products.

30 Australian Dental Industry Association, *Submission 7*, p. 10.

31 Australian Dental Association, *Submission 6*, p. 4, which argued that annual renewal of registration creates an administrative burden that could be eased if triennial renewal were implemented.

For further information on annual renewal of registration, see: Dental Board of Australia, 'Registration Renewal', http://www.dentalboard.gov.au/Registration/Registration-Renewal.aspx (accessed 22 March 2018).

32 Australian Dental Association, *Submission 6*, p. 2.

33 Dr Carmelo Bonanno, Vice President, Australian Dental Association, *Committee Hansard*, 9 February 2018, p. 13.

> amend it and any time we like and it is available to all of our members at any time.[34]

2.36 Dr Bonano told the committee that practice accreditation (with similar duplication) might shortly become compulsory, meaning that government regulation might shortly increase for the dental industry.[35]

Department response

2.37 A departmental officer advised that both the ACCC and TGA have roles with respect to teeth-whitening products. However, the committee heard that the regulatory inconsistency raised by ADIA has now been addressed, with the ACCC having 'withdrawn its statement from its website'.[36]

Committee view

2.38 The committee agrees that duplicative/inconsistent regulation should be avoided, as it creates unnecessary red tape burdens. The committee notes that the Regulatory Reform Agenda requires a whole-of-government effort toward red tape reduction. In fulfilling this agenda, the committee encourages all departments and agencies to be aware not just of their regulatory environment but also those with which they interact.

2.39 In relation to guidance around infection control, the committee is not convinced that there is a need for government regulation in this area. Information presented to the committee suggests that the highest possible national standards for dental practice can and are being addressed by the profession.

Need for harmonisation in certain areas

2.40 Submitters and witnesses commented that there is a lack of uniformity in some Commonwealth, state and territory regulation. For example, Day Hospitals Association identified variable licensing and accreditation requirements as problematic for its members.[37] The Pharmaceutical Society of Australia commented that legislative arrangements need to be harmonised for the regulation of medicines.[38]

2.41 The following sections focus on three specific areas—digital technologies, clinical trials, and diagnostic imaging equipment—which the committee heard need to be harmonised in the interests of healthcare providers and consumers.

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34 Dr Carmelo Bonanno, Vice President, Australian Dental Association, *Committee Hansard*, 9 February 2018, p. 14.

35 Dr Carmelo Bonanno, Vice President, Australian Dental Association, *Committee Hansard*, 9 February 2018, p. 13. Also see: Australian Dental Association, *Submission 6*, p. 3.

36 Dr Larry Kelly, First Assistant Secretary, Medicines Regulation, Department of Health, *Committee Hansard*, 9 February 2018, p. 30.

37 Day Hospitals Association, *Submission 2*, pp. 5–6.

38 Pharmaceutical Society of Australia, *Submission 4*, pp. 14–16.

Digital technologies

2.42 Some submitters and witnesses contended that red tape in the provision of health services could be significantly reduced with up-to-date digital technologies. For example, the RACGP indicated that GPs' non-patient care workload is increased by:

- many processes and administrative tasks not being modernised with the introduction of new technologies; and
- secure electronic communications not being the preferred and default method of communication between health services, government agencies and general practices.[39]

2.43 Dr Nathan Pinskier, Chair, RACGP Expert Committee, eHealth and Practice Systems, argued that the lack of interoperable government automated and integrated systems to manage key information capture and data transfer is a key cause of red tape in general practice:

> This is equally true at both the Commonwealth and state or jurisdictional level. Many of the administrative tasks that GPs are required to undertake to support direct-care delivery and to allow patients to access additional care or services can be improved and modernised through the better use of technology, which should be a core consideration of the government's digital transformation requirements. General practice is predominantly electronic at both an administrative and a clinical level, yet it interacts with a healthcare world that still relies heavily on paper and faxes. To state the obvious, this is out of step with the massive changes that have occurred in other sectors of the economy.[40]

2.44 Part of the problem appears to be the need for secure communications that support the National Privacy Principles. Dr Pinskier indicated that 'the government hasn't actually chosen a standard for its own sector, federally or at a state level'.[41] He suggested that the data transfer standards created by My Health Record could be enhanced to significantly reduce red tape:

> The My Health Record is in itself not a communications tool; it's a repository of information that can be accessed as and when appropriate. What we need to do is to build on those standards to ensure that they are embedded into what we call provider-to-provider communication or point-to-point communication. So if a patient goes to hospital, when the patient's discharged, rather than a letter or a fax, I would get an electronic

39 Royal Australian College of General Practitioners, *Submission 10*, pp. 2–3.

40 Dr Nathan Pinskier, Chair, RACGP Expert Committee, eHealth and Practice Systems, Royal Australian College of General Practitioners, *Committee Hansard*, 9 February 2018, p. 10.

41 Dr Nathan Pinskier, Chair, RACGP Expert Committee, eHealth and Practice Systems, Royal Australian College of General Practitioners, *Committee Hansard*, 9 February 2018, p. 11.

> message directly into my inbox. That would significantly reduce red tape and improve healthcare delivery.[42]

2.45 Dr Bonanno agreed that there is a need to securely access and transfer digital information in order to effectively treat patients.[43] MOGA similarly submitted:

> A common, shared infrastructure for the storage, archiving and retrieval of digital records is recommended. This would assist in addressing delays in patient treatment and management, potential complications and in reducing patient risk nationally. Despite a substantial amount of Federal funding having been committed to Australia's eHealth system a more targeted and comprehensive Government-led approach is needed.[44]

2.46 In another example of digital red tape, Dr Pinskier drew attention to the registration and management of healthcare professionals. He described a 'bizarre' situation where professionals are issued with multiple identifiers for practice purposes, and queried why these identifiers could not be streamlined:

> There's a whole lot of bureaucracy. Just to register a doctor in the system in my practice takes 15 forms. That is 15 forms to complete just to get the doctor into the system. I have provided these to Medicare, the department, the digital healthcare agency and other organisations. Everyone says, 'Yes, that's terrible,' but nothing ever gets done about it. We have a great opportunity as part of the digital transformation and the current review of Medicare's claims and payments back-end processes to streamline all this and reduce it down to the minimum number of numbers that we need to run an efficient and effective system.[45]

Department response

2.47 A Department representative advised that harmonisation of health regulation is an ongoing matter: 'there would not be a single [Australian Health Ministers

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42 Dr Nathan Pinskier, Chair, RACGP Expert Committee, eHealth and Practice Systems, Royal Australian College of General Practitioners, *Committee Hansard*, 9 February 2018, p. 12.

43 Dr Carmelo Bonanno, Vice President, Australian Dental Association, *Committee Hansard*, 9 February 2018, p. 12. Also see: Dr Nathan Pinskier, Chair, RACGP Expert Committee, eHealth and Practice Systems, Royal Australian College of General Practitioners, *Committee Hansard*, 9 February 2018, pp. 12–13, who commented on variation in electronic capabilities in the healthcare sector, and p. 13, where state/territory requirements for 'wet' (non-electronic) signatures were noted.

44 Medical Oncology Group of Australia, *Submission* 5, p. 3. Also see: Day Hospitals Association, *Submission 2*, pp. 4–5, which commented on the compliance burden of having to provide data more than once.

45 Dr Nathan Pinskier, Chair, RACGP Expert Committee, eHealth and Practice Systems, Royal Australian College of General Practitioners, *Committee Hansard*, 9 February 2018, p. 17.

Advisory Council] meeting where there isn't an issue that involves some degree of harmonisation…between the regulatory approaches'.[46]

2.48 In response to the concerns identified by RACGP, the officer said that 'Australia has arguably got the most contemporary and best piece of legislation to enable a national digital health effort'. He conceded however that there is still a lot of work to be done:

> It's complex. Some of it is about legislation; some of it is about regulation; a lot of it is about change management. Also a lot of it is making sure all the different parts of the healthcare system are able to target their investments around a common legislative and hopefully standard-setting framework that enables their investments to deliver the necessary benefits to them, their businesses and ultimately to patients.[47]

2.49 To illustrate the argument, an officer described various levels of responsibility and internal/external roles associated with the transition to electronic signatures, concluding:

> It's a joint piece of work that needs to be put together in relation to the jurisdictions and how their different legislative frameworks work and then the alignment with the National Health Act to ensure that we have a mechanism that people can roll out nationally.[48]

Committee view

2.50 Digital technology is a critical concern for GPs, who are the backbone of primary health care. The committee recognises that governments are progressing *ad hoc* reform in this area. However, the committee notes that the Department did not provide any specific information on its achievements to date; for example, how far discussions might have progressed in relation to secure communications. The committee suggests that the Department could do more to inform stakeholders of its efforts, milestones and outcomes in this area.

2.51 On a different matter, the committee cannot perceive any logical reason why healthcare practitioners should require multiple identifiers for practice purposes. As part of digital reform, the Australian Government should streamline these identifiers to reduce the red tape burdens that they create.

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46 Mark Cormack, Deputy Secretary, Health Financing Group, Department of Health, *Committee Hansard*, 9 February 2018, p. 27. Mr Cormack cited the Electronic Recording and Reporting of Controlled Drugs system initiative as an example of current Council of Australian Governments' discussions: p. 28.

47 Mark Cormack, Deputy Secretary, Health Financing Group, Department of Health, *Committee Hansard*, 9 February 2018, p. 29.

48 Rachel Sierant, Director, Electronic Medication Management Section, Department of Health, *Committee Hansard*, 9 February 2018, p. 29. Ms Sierant added that an electronic prescribing working group has been established through the Australian Health Ministers' Advisory Council and is activing working on this digital reform.

Recommendation 5

2.52 The committee recommends that the Australian Government, through the Council of Australian Governments, streamline the identifiers issued to healthcare practitioners for practice purposes.

Clinical trials

2.53 Submitters and witnesses stated that regulatory variation adversely affects competition and investment in clinical trials in Australia, as well as consumer access to new medicines. Roche, Medical Technology Association of Australia and Medicines Australia all agreed that there is a need for greater national consistency, including in the area of ethics approval.[49]

2.54 Helen Aunedi from Roche explained that 'the issue here is the national coordination of human research ethics committees'. Although some committees work well, there is 'huge variation' which causes unnecessary difficulties for sponsors of clinical trials, particularly when they involve multiple sites and institutions. Ms Aunedi emphasised that streamlining and harmonising processes is about 'putting patients first; the quicker we can start a trial, the quicker we can get access to treatment for our patients'.[50]

2.55 The committee heard that there have been numerous attempts to harmonise the state-based ethics approval processes (including by the National Health and Medical Research Council).[51] However, Medicines Australia indicated however that reform is taking too long: 'we would support measures to further expedite their overdue implementation'.[52]

2.56 Witnesses described a range of options that have been considered. For example, Mr Pullar referred to mutual recognition and consistent performance standards. However, Roche's preference would be:

> …to eventually have a single committee that would specialise in multicentre trials, which everyone could then just outsource to. They might still conduct the ethics review of what their own institution is doing just within their institution, but if it's a multicentre trial—you could certainly aim to have that best practice.[53]

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49 Roche Products Pty Ltd, *Submission 1*, p. 1; Medical Technology Association of Australia, *Submission 3*, p. 3; Medicines Australia, *Submission 9*, pp. 1–2.

50 Helen Aunedi, Country Head, Country Clinical Operations, Roche Products Pty Ltd, *Committee Hansard*, 9 February 2018, p. 3. Also see: p. 5.

51 For example: David Pullar, Head of Government Affairs and Public Policy, Roche Products Pty Ltd, *Committee Hansard*, 9 February 2018, p. 1; Medical Technology Association of Australia, *Submission 3*, p. 3; Medicines Australia, *Submission 9*, p. 2

52 Medicines Australia, *Submission 9*, p. 2.

53 David Pullar, Head of Government Affairs and Public Policy, Roche Products Pty Ltd, *Committee Hansard*, 9 February 2018, p. 3. Also see: p. 6.

2.57 Elizabeth De Somer, Director, Policy and Research, advised that Medicines Australia favoured national coordination at the COAG level:

> There are opportunities to create national coordination that may not require the institutionalisation of an office. It's not unprecedented to have national coordination across activities with the states and territories. Indeed, that's why the COAG exists. The best way to do that might be discussion with the COAG on what their appetite for change is. Clearly, each of the states and territories have an interest in improving clinical trial activities.[54]

2.58 The committee notes that the Senate Select Committee into Funding for Research into Cancers with Low Survival Rates recently examined the issue of ethics approvals. After considering a large volume of submissions and evidence, that committee supported the expeditious streamlining of ethics and governance approval processes for clinical trials, and recommended:

> …that the National Health and Medical Research Council develops a standard template and associated guidelines, including timeframes, for ethics and other governance approvals for consideration and possible adoption by each state and territory.[55]

Committee view

2.59 The committee is concerned that, again, submitters and witnesses have highlighted an area that is ripe for reform, yet reform is slow to arrive. The committee considers that governments could reduce the red tape associated with clinical trials, by standardising and harmonising the ethics approval process. The suggestion for the development of a standard template and associated guidelines is practical and sensible, with clear benefits for industry and consumers.

Recommendation 6

2.60 The committee recommends that the Australian Government, through the Council of Australian Governments, develop a standard template and associated guidelines, including reasonable timeframes, to streamline ethics and governance approval processes for clinical trials across Australia.

Diagnostic imaging equipment

2.61 Some submitters and witnesses drew attention to state/territory licensing requirements that affect businesses which supply, own and operate diagnostic imaging equipment. ADIA, for example, submitted that regulatory variation creates a compliance burden for suppliers and healthcare professionals:

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54 Elizabeth De Somer, Director, Policy and Research, Medicines Australia, *Committee Hansard*, 9 February 2018, p. 20.

55 Senate Select Committee into Funding for Research into Cancers with Low Survival Rates, Report, 28 November 2017, Recommendation 7, p. 89, https://www.aph.gov.au/Parliamentary_Business/Committees/Senate/Funding_for_Research_into_Cancers/FundingResearchCancers/Report (accessed 22 March 2018).

> Inconsistencies make it difficult for the dental industry to furnish oral healthcare professionals across the country, and the compliance burden associated with it imposes costs on business. These costs are passed on to patients and governments in the form of increased diagnostic imaging costs.[56]

2.62 ADA submitted that there is inefficient and unnecessary duplication:

> Currently, across most jurisdictions in Australia, dentists are required to purchase two sets of licences with respect to radiation machines such as intra-oral, rotational tomography X-rays and Cone Beam Volumetric Tomography (CBVT). One licence is to own or possess the machine, and the other is to use it. The same duplication with two licences applies for Class 4 laser equipment, one to possess and one to use...Ultimately there should be a greater move towards harmonisation and mutual recognition of licensing requirements and licences provided and obtained for the operation and use of radiation machines.[57]

2.63 In evidence, Dr Bonanno questioned why it is so difficult to achieve national consistency in this area. He referred to the National Registration and Accreditation Scheme, where over 600 pieces of legislation were consolidated into 80 pieces of legislation to achieve the national registration of dentists:

> That made sense. Why couldn't we do it with everything else? Why have we gone from state based registration as health practitioners, singling that out, but left everything else state based?…A lot of work was done there, but the thing is that we have a system now which is working better as it evolves, so there's no reason why that can't happen with these other areas of duplication.[58]

2.64 Mr Troy Williams, Chief Executive Officer of ADIA, suggested one answer: 'the current system isn't broken to the extent that it's not working, so there's just no impetus for reform'.[59]

Committee view

2.65 The committee is aware that the Senate Community Affairs References Committee has recently inquired into the 'Availability and accessibility of diagnostic imaging equipment around Australia'.[60]

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56 Australian Dental Industry Association, *Submission 7*, p. 13.

57 Australian Dental Association, *Submission 6*, p. 3.

58 Dr Carmelo Bonanno, Vice President, Australian Dental Association, *Committee Hansard*, 9 February 2018, pp. 14–15.

59 Troy Williams, Chief Executive Officer, Australian Dental Industry Association, *Committee Hansard*, 9 February 2018, p. 9. Also see: Australian Dental Industry Association, *Submission 7*, p. 13.

60 Parliament of Australia, 'Availability and accessibility of diagnostic imaging equipment around Australia', https://www.aph.gov.au/Parliamentary_Business/Committees/Senate/Community_Affairs/Diagnosticimaging (accessed 22 March 2018).

2.66 The committee acknowledges there are many harmonisation issues requiring attention from COAG, with some matters more pressing than others. However, the committee heard that regulatory variation with respect to diagnostic imaging equipment is a significant and ongoing concern for dental practitioners. The committee agrees that there is clear scope to reduce red tape in the licensing of this equipment.

Recommendation 7

2.67 The committee recommends that the Australian Government place licensing requirements for the supply, ownership and operation of diagnostic imaging equipment on the agenda for consideration by the Council of Australian Governments.

Review of Medicines and Medical Devices Regulation

2.68 The 2015 *Review of Medicines and Medical Devices Regulation* identified ways to improve access to therapeutic goods for consumers and to reduce unnecessary red tape for industry, while maintaining consumer safety. The Australian Government accepted nearly all of the 58 recommendations, which are being implemented in a staged approach through to 2019.[61] The Department submitted:

> As a result, medicines and medical devices will be able to be brought to the Australian market more quickly. The reforms will benefit consumers, the therapeutic goods industry and health professionals and are expected to deliver red tape reductions of $74.9 million annually.[62]

2.69 Several submitters acknowledged the Australian Government's positive efforts to reduce red tape in response to the Review.[63] However, ADIA cautioned against the literal interpretation of one recommendation, which called for the regulation of medical devices to be aligned with that of the European Union (EU) (Recommendation 20). ADIA argued that such alignment should occur 'only when there is a reason to do so…[and] conditional on such reform aligning with an Australian Government approach to regulation making'.[64] It argued that the EU approach should be seen as an upper limit, with a lower level of regulation sometimes being more appropriate.

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61 Department of Health, 'Australian Government Response to the Review of Medicines and Medical Devices Regulation', http://www.health.gov.au/internet/main/publishing.nsf/Content/MMD-govresp (accessed 22 March 2018).

62 Department of Health, *Submission 11*, p. 2.

63 For example, see: Medicines Technology Association of Australia, *Submission 3*, pp. 1–2; Medical Oncology Group of Australia, *Submission 5*, p. 2; Australian Dental Industry Association, *Submission 7*, p. 3; Medicines Australia, *Submission 9*, p. 1.

64 Australian Dental Industry Association, *Submission 7*, p. 7. Also see: Williams, p. 2, where ADIA questioned whether the regulatory cost to Australian businesses had been properly assessed by the TGA. The submission suggested that the Therapeutic Goods Administration is starting to exhibit a non-risk based approach to regulation: p. 8.

2.70 Mr Pullar from Roche assured the committee that the TGA does not automatically adopt overseas decisions, at least in relation to medicines:

> Generally the review came to the conclusion that we would still like some oversight in Australia. I think that's a community expectation. What they can do is: they can take evaluation reports, they can take some of the critique that has been done overseas, and use that to speed up their own assessment. So we'd still be making a distinct Australian judgement about whether to approve a medicine.[65]

Concluding comment

2.71 The Australian Government's 2013 Deregulation Agenda aims to reduce excessive, unnecessary and complex regulation to lift productivity and boost growth. The committee supports this objective but has found that there are areas in which red tape continues to affect health services.

Senator David Leyonhjelm

Chair

65 David Pullar, Head of Government Affairs and Public Policy, Roche Products Pty Ltd, *Committee Hansard*, 9 February 2018, p. 3.

Additional Comments by Labor Senators

1.1 Labor Senators make the following additional comments on the Red Tape (Health Services) Report.

1.2 Comment on Recommendation 2—Labor Senators are committed to improving preventive health and primary health care, to help keep Australians healthy and out of hospital wherever possible. However, Labor Senators note concerns that allowing insurers to cover out-of-hospital care could undermine the universality of Medicare and create a two-tiered primary health care system. Labor Senators also note concerns that introducing a second major payer into primary health care could have an inflationary effect, driving up costs for patients and taxpayers.

1.3 Comment on Recommendations 3 and 4—Labor has proposed a Productivity Commission inquiry into the private health system, which would be the most significant review of private health in 20 years (since the then Industry Commission's last review). Pending its terms of reference, which Labor will develop in consultation with experts and the sector, the inquiry could consider cost drivers for private health insurance, the regulation of the prostheses market, and other reform proposals. Labor Senators urge the Government to adopt Labor's proposal for a Productivity Commission inquiry.

Senator Murray Watt

Deputy Chair

Additional Comments by Coalition Senators

1.1 Coalition Senators make the following additional comments on the interim report.

1.2 The Senate Select Committee on Red Tape's motivation in addressing the considerable regulatory burden of red tape on health services has identified issues that may affect the efficiency of the sector, as well as access to services, the variety of services provided, access to medicines, and the ability of practitioners to provide their services in the most efficient manner.

1.3 The committee identified numerous issues of over regulation, duplication of regulatory processes, regulatory efficiency, regulatory complexity and regulatory volume.

1.4 Noting that this is an interim report, Coalition Senators will provide additional comments on these issues once the final report has been tabled.

Senator James Paterson

Senator for Victoria

Senator Slade Brockman

Senator for Western Australia

Appendix 1

Submissions and additional documents

Submissions

1. Roche Products Pty Ltd
2. Day Hospitals Australia
3. Medical Technology Association of Australia
4. Pharmaceutical Society of Australia
5. Medical Oncology Group of Australia
6. Australian Dental Association
7. Australian Dental Industry Association
8. Private Healthcare Australia
9. Medicines Australia
10. Royal Australian College of General Practitioners
11. Department of Health

Answers to questions on notice

1. Answers to questions on notice from a public hearing held in Canberra on 9 February 2018, received from the Department of Health on 20 March 2018

Appendix 2
Public hearing

9 February 2018, Canberra ACT

Members in attendance: Senators Burston, Leyonhjelm and Paterson

Witnesses

APPLEYARD, Ms Sharon, First Assistant Secretary, Office of Health Protection, Department of Health

AUNEDI, Ms Helen, Country Head, Country Clinical Operations, Roche Products Pty Ltd

BONANNO, Dr Carmelo, Vice President, Australian Dental Association

BOWSKILL, Mr Andrew, Manager, Research and Data, Medicines Australia

CORMACK, Mr Mark, Deputy Secretary, Health Financing Group, Department of Health

DAVID, Dr Rachel, Chief Executive Officer, Private Healthcare Australia

DE SOMER, Ms Elizabeth, Director, Policy and Research, Medicines Australia

KARPISH, Ms Larissa, Manager, Industry and Regulatory Policy, Medicines Australia

KELLY, Dr Larry, First Assistant Secretary, Medicines Regulation, Department of Health

MASKELL-KNIGHT, Mr Charles, Principal Adviser, Portfolio Strategies Division, Department of Health

NGUYEN, Mr Bryan, Senior Policy Officer, Australian Dental Association

PINSKIER, Dr Nathan, Chair, RACGP Expert Committee, eHealth and Practice Systems, Royal Australian College of General Practitioners

PULLAR, Mr David, Head of Government Affairs and Public Policy, Roche Products Pty Ltd

SHAW, Mrs Gillian, Assistant Secretary, Office of Health Protection, Department of Health

WILLIAMS, Mr Troy, Chief Executive Officer, Australian Dental Industry Association