Chapter 1

Introduction

1.1 On 30 November 2017, the Senate referred the provisions of the Therapeutic Goods Amendment (2017 Measures No.1) Bill 2017 (TGA Bill) and the Therapeutic Goods (Charges) Amendment Bill 2017 (TGCA Bill) to the Senate Community Affairs Legislation Committee, for inquiry and report by 2 February 2018.[1]

1.2 The committee decided to consider the two bills together in a single report, because they both concern the regulatory framework underpinning the Therapeutic Goods Administration, the regulator for therapeutic goods, and because they both are a response to recommendations arising from the Expert Panel Review of Medicines and Medical Devices Regulation (MMDR Review).

1.3 This committee previously produced a report on the Therapeutic Goods Amendment (2016 Measures No. 1) Bill, on 27 March 2017. This bill also proposed amendments to the *Therapeutic Goods Act 1989* in response to recommendations from the MMDR Review.[2] The bill passed both houses of Parliament on 14 June 2017, and became the *Therapeutic Goods (2016 Measures No. 1) Act 2017*.[3] The current bills address further key recommendations from the MMDR Review.

Purpose and key provisions of the bills

1.4 The bills that are the subject of this report propose amendments to the *Therapeutic Goods Act 1989* and the *Therapeutic Goods (Charges) Act 1989* to support the implementation of recommendations from stages one and two of the MMDR Review.[4] Stage one of the MMDR Review concerned 'the regulation of prescription medicines, over-the-counter medicines, medical devices and access to unapproved therapeutic goods'. Stage two concentrated on 'the regulatory framework for both complementary medicines and the advertising of therapeutic goods'.[5]

Summary of the Therapeutic Goods Amendment (2017 Measures No. 1) Bill

1.5 The TGA Bill is divided into nine schedules, each of which deals with a different aspect of the proposed reforms.

1.6 **Schedule 1** would establish a scheme for the registration of medicine via a provisional approval pathway, through which promising but not yet approved

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1 *Journals of the Senate*, *No. 75*, 30 November 2017, p. 2402.

2 Senate Community Affairs Legislation Committee, *Therapeutic Goods Amendment (2016 Measures No. 1) Bill 2016 [Provisions]*, March 2017.

3 *Journals of the Senate*, *No. 43*, 14 June 2017, pp. 1422–1423.

4 TGA Bill Explanatory Memorandum, p. 1; TGCA Bill Explanatory Memorandum, p. 1.

5 Lloyd Sansom, Will Delaat and John Horvath, *Review of Medicines and Medical Devices Regulation – Stage Two: Report on the Regulatory Frameworks for Complementary Medicines and Advertising of Therapeutic Goods*, July 2015, p. 1.

medicines could be made available earlier for patients with serious medical conditions than might otherwise be the case.[6]

1.7 **Schedule 2** would enable the Minister for Health (the Minister) to determine a list of 'permitted indications' that could be made for medicines listed in the Register under section 26A of the *Therapeutic Goods Act 1989*, as well as a list of non-permitted indications that should not be used in medicines listed under the same section. Applicants would be required to only use indications that are permitted for use in these medicines.[7]

1.8 **Schedule 3** would introduce a new assessment pathway for medicines to be included in the Register, should the sponsor provide self-assessment and certification of the safety and quality of the product, in tandem with an assessment by the Secretary of the Department of Health (the Secretary) of the medicine's claims and indications. Sponsors of complementary medicines would be able to indicate in their promotional material if a product had passed the assessment.[8]

1.9 **Schedule 4** would clarify and reflect current administrative practices used when assessing applications, including the requirement that applications meet preliminary preconditions, such as using an approved form for the relevant class or type of therapeutic goods, before the application can be processed further.[9]

1.10 **Schedule 5** would further define the operation and role of Australian conformity assessment bodies. Australian conformity assessment bodies are private corporations introduced under the *Therapeutic Goods (2016 Measures No. 1) Act 2017* with the task of assessing whether the manufacturing process for medical devices is appropriate, and examining whether these devices meet the minimum safety and performance standards outlined in the *Therapeutic Goods Act 1989*. The proposed amendments would ensure that the Secretary has significant oversight of these bodies, and allow the Secretary when assessing applications for inclusion in the Register to make increased use of assessments of medical devices made by comparable overseas regulators.[10]

1.11 **Schedule 6** concerns the advertising of therapeutic goods. The proposed amendments, according to the Explanatory Memorandum, are designed to improve consistency in the regulation of different types of therapeutic goods, implement a more efficient and transparent complaints management process for therapeutic goods advertising, and broaden penalties and sanctions for inappropriate and misleading advertising. The amendments would also repeal the requirement that certain advertisements be pre-approved.[11]

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6 TGA Bill Explanatory Memorandum, p. 19.

7 TGA Bill Explanatory Memorandum, p. 26.

8 TGA Bill Explanatory Memorandum, p. 38.

9 TGA Bill Explanatory Memorandum, p. 46.

10 TGA Bill Explanatory Memorandum, p. 57.

11 TGA Bill Explanatory Memorandum, pp. 71, 98.

1.12 **Schedule 7** proposes to amend provisions on compliance and enforcement by ensuring that regulatory action corresponds to the severity of a compliance breach.[12]

1.13 **Schedule 8** concerns the record-keeping and reporting requirements of biologicals listed in the Register and proposes amendments so that these are consistent with other medicines, such as prescription medications.[13]

1.14 **Schedule 9** contains minor amendments aimed to improve consistency in the regulation of different kinds of therapeutic goods, decrease public health risks and reduce regulation, as well as other minor changes.[14]

Summary of the Therapeutic Goods (Charges) Amendment Bill 2017

1.15 The TGCA Bill contains one schedule, designed to amend the *Therapeutic Goods (Charges) Act 1989* so that the Department of Health, through the Therapeutic Goods Administration, 'is able to…recover the costs of its post-market monitoring activities carried out as part of administering' the *Therapeutic Goods Act 1989.*[15]

1.16 The TGCA Bill also proposes a small number of other minor amendments, including the requirement that if the Secretary of the Department of Health suspends a conformity assessment body determination, an annual charge would continue to apply during the suspension period.[16]

Financial impact

1.17 The Explanatory Memorandum for the TGA Bill states that the Australian Government has committed $20.4 million over four years from 2016–17 'to improve the regulation of therapeutic goods in Australia'. These funds will be used 'to improve access to therapeutic goods for consumers and introduce more flexible and timely regulatory processes for the therapeutic goods industry'. The Therapeutic Goods Administration will use cost recovery arrangements to meet the ongoing costs of this measure from 2017–18.[17]

1.18 The Explanatory Memorandum for the TGCA Bill notes that regulation of Australian conformity assessment bodies will lead to administration costs. The charges proposed would allow the Commonwealth to recover direct costs involved in the administration of the framework that relates to Australian conformity assessment bodies.[18]

12 TGA Bill Explanatory Memorandum, p. 100.

13 TGA Bill Explanatory Memorandum, p. 135.

14 TGA Bill Explanatory Memorandum, p. 137.

15 TGCA Bill Explanatory Memorandum, p. 1.

16 TGCA Bill Explanatory Memorandum, p. 7 (Item 6).

17 TGA Bill Explanatory Memorandum, p. 6.

18 TGCA Bill Explanatory Memorandum, p. 2.

Consideration by other committees

1.19 The committee recognises the work undertaken by other Parliamentary committees responsible for considering draft legislation.

The Senate Standing Committee for the Scrutiny of Bills

1.20 In relation to the TGA Bill, the Senate Standing Committee for the Scrutiny of Bills requested that the Minister provide detailed justification for proposed amendments outlined in Items 14 to 17 of Schedule One. These amendments would permit only 'the person in relation to whom the medicine is registered' or 'the person who made the application for registration' to request a review of decisions about provisional determinations and provisional registration. The effect of these changes would mean that other interested parties, such as consumers, would be prevented from requesting a review.[19]

1.21 The Minister for Health, the Hon. Greg Hunt MP, explained in his reply to the committee why the right to merits review had been limited. Reasons included:

- To expedite processes for these applications;
- To promote administrative accountability, including increased transparency of decision-making;
- Because consumers may not have access to the technically complex information that the Therapeutic Goods Administration holds;
- Because a negative decision does not preclude an individual patient from accessing the medicine through other methods; and
- Because of the lack of appeals by consumers or consumer groups against decisions in the last ten years.[20]

1.22 The Minister added an addendum to the Explanatory Memorandum outlining these reasons.

1.23 In relation to the TGCA Bill, the Scrutiny of Bills Committee noted that the bill provides no guidance as to how an annual charge for conformity assessment would be calculated, and specifies no maximum charge. The Scrutiny of Bills Committee asked the Minister for further information as to why there would be no limits to the charge, and to consider whether guidance on the method of calculation and/or a maximum charge could be included in the bill.[21]

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19 Senate Standing Committee for the Scrutiny of Bills, Scrutiny Digest 12 of 2017, pp. 50–51. Biotronik Australia Pty Ltd also raised concerns about this proposal: *Submission 36,* p.1.

20 Senate Standing Committee for the Scrutiny of Bills, Scrutiny Digest 13 of 2017, pp. 130–132. The Department of Health submitted that 'appeals have been limited to the applicant only to prevent competitors delaying provisional registration of a product for commercial reasons as this is not in the interest of public health'. *Submission 46,* p. 10.

21 Senate Standing Committee for the Scrutiny of Bills, Scrutiny Digest 12 of 2017, pp. 54–55.

1.24 In his response, the Minister advised that the Department of Health through the Therapeutic Goods Administration 'will undertake detailed consultation with stakeholders' before prescribing the amount of annual charges. He wrote that this approach would be consistent with the existing approach taken in regards to annual charges for the registration, listing and inclusion of goods in the Australian Register of Therapeutic Goods, and licenses for manufacturers of therapeutic goods in the *Therapeutic Goods (Charges) Act 1989*.[22] The Minister further explained that the TGCA Bill does not include a maximum amount of charge 'because any such limit prescribed would be arbitrary and…would result in confusion for, and criticism by, stakeholders'. He stated that the charge would be set in accordance with the Australian Government Cost Recovery Guidelines.[23] An addendum was added to the Explanatory Memorandum for the TGCA Bill in response to the Scrutiny of Bills Committee's concerns.

1.25 In its response to the Minister's comments, the Scrutiny of Bills Committee highlighted its view that the Parliament, rather than makers of delegated legislation, should levy taxation, and continued to express its concerns about 'the appropriateness of allowing regulations to determine the amount of a charge payable without any guidance being provided'.[24]

The Parliamentary Joint Committee on Human Rights

1.26 The Parliamentary Joint Committee on Human Rights raised no concerns in relation to the TGA Bill or the TGCA Bill.[25]

1.27 The Explanatory Memoranda state that both bills are compatible with Australia's human rights obligations.[26] The Explanatory Memorandum for the TGA Bill further notes that while the provisions of the TGA Bill engage, or have to potential to engage, with a number of human rights through regulatory intervention, these limitations are reasonable, necessary and proportionate, and overall the bill promotes the right to health.[27]

Conduct of the inquiry

1.28 In accordance with its usual practice, the committee advertised the inquiry on its website and wrote to relevant individuals and organisations inviting submissions to the inquiry by 12 January 2018.

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22 Senate Standing Committee for the Scrutiny of Bills, Scrutiny Digest 13 of 2017, pp. 125–126.

23 Senate Standing Committee for the Scrutiny of Bills, Scrutiny Digest 13 of 2017, p. 126.

24 Senate Standing Committee for the Scrutiny of Bills, Scrutiny Digest 13 of 2017, p. 127.

25 Parliamentary Joint Committee on Human Rights, *Human Rights Scrutiny Report*, Report 11 of 2017, 17 October 2017, p. 60.

26 TGA Bill Explanatory Memorandum, p. 7; TGCA Bill Explanatory Memorandum, p. 4.

27 TGA Bill Explanatory Memorandum, p. 17.

1.29 The committee received fifty-three public submissions, which are listed at appendix 1 of this report. These submissions are available in full on the committee's website.

1.30 The committee would like to thank the individuals and organisations that made submissions to the inquiry.

Structure of this report

1.31 This report consists of two chapters:

- This chapter provides a brief background and overview of the bills, as well as the administrative details of the inquiry.
- Chapter 2 sets out the issues raised by submitters in relation to particular provisions of the TGA Bill. It also outlines the committee's view and recommendations.