Chapter 1

Introduction

1.1 On 9 February 2017, the Senate referred the provisions of the Therapeutic Goods Amendment (2016 Measures No. 1) Bill (the Bill) to the Senate Community Affairs Legislation Committee for inquiry and report by 27 March 2017.

Objectives of the Bill

1.2 The Bill was introduced in the House of Representatives on 1 December 2016.[1] The Bill amends the *Therapeutic Goods Act 1989* to:

- enable designated Australian companies to undertake conformity assessments of medical devices;
- alter the requirements for the minister to consult with committees;
- provide review and appeal rights for persons applying to have new ingredients permitted for use in listed complementary medicines;
- enable priority approval of therapeutic goods, biologicals and medical devices;
- specify timeframes within which the secretary must complete actions or make decisions in relation to listed complementary medicines;
- amend record-keeping arrangements to assist with post-marketing monitoring of medicines and medical devices;
- provides further grounds on which applications to vary an entry in the register will be considered ineffective;
- update terminology and provide for certain public notifications in relation to the recall of therapeutic goods;
- enable the secretary to obtain certain information from sponsors of listed medicines; and
- make miscellaneous amendments in relation to powers to approve unapproved goods in the event of a shortage, alignment of cancellation powers, revoking the cancellation of goods cancelled for non-payment of annual charges, information-gathering powers in relation to holders of manufacturing licences, and conditions of inclusion in the register of medical devices.

1.3 The Bill also amends the *A New Tax System (Goods and Services Tax) Act 1999* and the *Therapeutic Goods Act 1989* to enable health practitioners to supply certain therapeutic goods not on the Australian Register of Therapeutic Goods (ARTG) to patients under a notification scheme.

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1 *House of Representatives Votes and Proceedings*, No. 27, 1 December 2016, p. 433.

1.4 In introducing the Bill, the then Minister for Health and Aged Care, the Hon. Sussan Ley MP, stated that the Bill supports the recommendations made by the Expert Panel Review of Medicines and Medical Devices Regulation (MMDR) about improving key aspects of the regulatory scheme for therapeutic goods. These include decreasing the regulatory burden on industry and on medical practitioners through:

- providing industry with more flexible and timely pathways to market;
- enabling patients to access new medicines and medical devices faster;
- increasing collaboration with overseas counterparts to minimise regulatory burden; and
- enhancing post-market monitoring of the safety of products.[2]

1.5 The MMDR was undertaken in 2014 and 2015 by Emeritus Professor Lloyd Sansom AO, as chair of the panel, Mr Will Delaat AM and Professor John Horvath AO. The review was commissioned to make recommendations that:

> would assist the Government in enhancing the regulatory framework for therapeutic goods so that:
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> - Australia continues to be well positioned to respond effectively to global trends in the development, manufacture, marketing and regulation of therapeutic goods
> - areas of unnecessary, duplicative or ineffective regulation are removed or streamlined without undermining the safety or quality of therapeutic goods available in Australia.[3]

1.6 The Department of Health submission to this inquiry notes that the government response to the MMDR supported 56 of the 58 recommendations4

Conduct of the inquiry

1.7 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 3 March 2017.

1.8 The committee received 44 submissions up to and after that date, and conducted a public hearing on Friday 17 March 2017. Submitters and witnesses are listed at Appendices 1 and 2.[5]

1.9 The committee thanks those individuals and organisations who contributed to the inquiry.

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2 The Hon. Sussan Ley MP, Minister for Health, *House of Representatives Hansard*, 1 December 2016, p. 5113.

3 Department of Health, *Submission 22*, p. 4.

4 Department of Health, *Submission 22*, p. 5.

5 Submissions and public hearing transcripts are available on the committee's website: http://www.aph.gov.au/senate/Community_Affairs/TGA2016MeasuresNo1.

Note on references

1.10 References to Committee Hansard are to proof transcripts. Page numbers may vary between the proof and official transcripts.

Summary of the Bill

1.11 The Bill is divided into 12 schedules, each deals with a different aspect of the proposed reforms.

1.12 **Schedule 1** will enable variations of entries to the Australian Register of Therapeutic Goods (ARTG) to be made by way of notification, rather than waiting for approval by the Therapeutic Goods Administration (TGA). The kinds of variations which can be made in this way will be specified in regulations.

1.13 **Schedule 2** will enable the Secretary to designate Australian companies to undertake conformity assessments of medical devices and will provide that those assessments may be used in deciding whether medical devices should be included in the ARTG. 'Conformity assessment' is the systematic examination of evidence and procedures to determine the safety of a medical device and whether it is acceptable and performs as intended.

1.14 **Schedule 3** will enable a legislative instrument to be made allowing certain therapeutic goods that are not included in the ARTG to be provided to specific patients without first having to seek approval from the TGA, if the good has an established history of safe use in comparable overseas countries and the TGA is notified.

1.15 **Schedule 4** will remove the requirement for the Minister, when making standards for therapeutic goods, to consult the Therapeutic Goods Committee. This schedule also removes the reference to the Minister's discretion to obtain advice from a statutory committee before determining manufacturing principles.

1.16 **Schedule 5** will provide new review and appeal rights for persons who apply to have new ingredients permitted for use in listed complementary medicines.

1.17 **Schedule 6** introduces new pathways for the approval of medicines, medical devices and biologicals and will enable persons to apply for priority applicant determinations, so that patients can get faster access to new products.

1.18 **Schedule 7** provides a regulation making power to set out timeframes within which regulatory decisions or statutory powers must be made or exercised under the Act.

1.19 **Schedule 8** includes requirements that sponsors of therapeutic goods comply with record-keeping requirements prescribed in regulations as part of the conditions of registration or listing of those therapeutic goods.

1.20 **Schedule 9** will provide further grounds on which the Secretary may determine an application to vary an entry in the ARTG to be defective, and will enable the Secretary to determine what information must be supplied with an application to vary an entry in the ARTG.

1.21 **Schedule 10** updates the terminology relating to product notification and recalls and enables the Secretary to require therapeutic goods sponsors to inform the Secretary about the persons to whom goods have been supplied, and to inform the public or users of goods about any matters that may give rise to recall action by the Secretary under the Act.

1.22 **Schedule 11** will enable the Secretary to obtain information from a sponsor about any matters a sponsor has certified as confirmation that their goods meet the criteria for listing in the ARTG, so that the Secretary may establish whether or not the sponsor's goods qualify for listing, and whether the goods continue to meet the regulatory requirements that apply to listed goods.

1.23 **Schedule 12** provides new powers for the Secretary to approve unapproved therapeutic goods in the event of a shortage of registered/listed goods and require a person granted approval to import or supply goods to provide information about matters relating to the importation or supply, and establishes offences in relation to provision of false or misleading information.

Legislative scrutiny

Senate Standing Committee for the Scrutiny of Bills

1.24 The Standing Committee for the Scrutiny of Bills has sought advice from the Minister for Health in relation to the:

- broad regulation-making powers the Bill would establish; [6]
- delegation of the Secretary's administrative powers to a wide range of people;[7]
- proposed strict liability offence in relation to persons with certain notification obligations who omit to follow the requirements under the proposed new provisions;[8]
- removal of the requirement to consult with a committee prior to the making of standards for the approval of medicines and therapeutic goods and removal of the Minister's discretion to obtain advice from a statutory committee before determining principles to be followed in therapeutic goods' manufacture;[9]
- whether the Minister considered providing greater legislative guidance on how fees are to be determined, and why there is both an application and an evaluation fee;[10]

6 Senate Standing Committee for the Scrutiny of Bills, *Scrutiny Digest 1 of 2017*, pp. 32-34.

7 Senate Standing Committee for the Scrutiny of Bills, *Scrutiny Digest 1 of 2017*, pp. 34-35.

8 Senate Standing Committee for the Scrutiny of Bills, *Scrutiny Digest 1 of 2017*, p. 35.

9 Senate Standing Committee for the Scrutiny of Bills, *Scrutiny Digest 1 of 2017*, pp. 35-36.

10 Senate Standing Committee for the Scrutiny of Bills, *Scrutiny Digest 1 of 2017*, pp. 37-38.

- why it is proposed to use offence-specific defences (which reverse the evidential burden of proof) for offences relating to the provision of false or misleading information or documents; and
- why abrogation of the privilege against self-incrimination is proposed.[11]

1.25 The Scrutiny of Bills Committee requested that key information in the response provided by the Minister be added into the explanatory memorandum for each of the concerns raised[12] and provided some further comment for the consideration of Senators.[13]

Parliamentary Joint Committee on Human Rights

1.26 The Parliamentary Joint Committee on Human Rights has raised concerns in relation to the proposed maximum penalty for individuals who are found to contravene proposed section 41AF:

> the civil penalty provisions imposing a maximum of 5000 penalty units appear to impose a particularly severe penalty and may be considered to be 'criminal' for the purposes of international human rights law.[14]

1.27 The report notes that this proposed maximum penalty is 'substantially more than the financial penalty available under the related criminal offence provisions, which are restricted to 1000 penalty units (or $180 000) (and/or) 12 months' imprisonment)'.[15]

1.28 The Parliamentary Joint Committee on Human Rights has sought further information from the Minister for Health in relation to this provision and whether 'the measure accords with the right to a fair trial.'[16]

1.29 At the time of tabling of this report, the Standing Committee for the Scrutiny of Bills had not published the Minister's response to the matters raised above.

Community Affairs References Committee inquiry into the availability of new, innovative and specialist cancer drugs in Australia

1.30 In 2015, the Senate Standing Committee on Community Affairs reported on its inquiry into the availability of cancer drugs in Australia.[17] The report

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11 Senate Standing Committee for the Scrutiny of Bills, *Scrutiny Digest 1 of 2017*, pp. 38-39.

12 Senate Standing Committee for the Scrutiny of Bills, *Scrutiny Digest 3 of 2017*, pp. 105, 110, 112, 114, 117 and 123.

13 Senate Standing Committee for the Scrutiny of Bills, *Scrutiny Digest 3 of 2017*, pp. 110, 113, 117 and 121.

14 Parliamentary Joint Committee on Human Rights, *Human Rights Scrutiny Report*, Report 2 of 2017, 21 March 2017, pp. 27-28.

15 Parliamentary Joint Committee on Human Rights, *Human Rights Scrutiny Report*, Report 2 of 2017, 21 March 2017, p. 27.

16 Parliamentary Joint Committee on Human Rights, *Human Rights Scrutiny Report*, Report 2 of 2017, 21 March 2017, p. 28.

recommended that the Government undertake a comprehensive review of the system of registration and subsidisation of medicines, including (but not limited to):

- all available pathways for the registration and listing of new medicines, or new indications for medicines already registered on the ARTG and listed on the Pharmaceutical Benefits Scheme, including making provision for utilisation of assessments conducted by comparable overseas regulators; provision for clinicians and/or patient groups to apply for an extension of existing registrations to additional indications, managed access programs and risk-sharing, and the adoption of more flexible evidential requirements;
- options for improving the operation of assessment processes; and
- options for expanding the post-market review of medicines.[18]

17 Senate Standing Committees on Community Affairs, *Availability of new, innovative and specialist cancer drugs in Australia*, 17 September 2015, http://www.aph.gov.au/Parliamentary_Business/Committees/Senate/Community_Affairs/Cancer_Drugs/Report (accessed 22 March 2017).

18 Senate Standing Committees on Community Affairs, *Availability of new, innovative and specialist cancer drugs in Australia*, 17 September 2015, p. xi.