Chapter 1
Introduction

The referral

1.1 On 21 March 2013, on the recommendation of the Selection of Bills Committee, the Senate referred the provisions of the Therapeutic Goods Amendment (2013 Measures No. 1) Bill 2013 to the Community Affairs Legislation Committee for inquiry and report by 17 June 2013.[1]

Conduct of the inquiry

1.2 The committee advertised the inquiry in the national press and on its website. A number of known stakeholders were also invited to make submissions. The committee received 11 submissions relating to the bill (listed at Appendix 1), which are available for viewing on the committee's website.

1.3 The committee thanks all those submitters for their contribution and participation in the inquiry process. The committee is particularly grateful to legal advisers in the Therapeutic Goods Administration for assisting the committee in understanding the operation of provisions of the bill.

Background

1.4 The Therapeutic Goods Administration's (TGAs) purpose is to protect public health and safety by regulating the supply, manufacturing and advertising of therapeutic goods that are supplied either imported or manufactured, or exported from Australia.[2]

1.5 Therapeutic goods are those goods:

> (a) that are represented in any way to be, or that are, whether because of the way in which the goods are presented or for any other reason, likely to be taken to be:
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> (i) for therapeutic use; or
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> (ii) for use as an ingredient or component in the manufacture of therapeutic goods; or
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> (iii) for use as a container or part of a container for goods of the kind referred to in subparagraph (i) or (ii); or

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1 *Journals of the Senate*, 21 March 2013, p. 3866.

2 Department of Health and Ageing, Therapeutic Goods Administration, *Who we are & what we do*, http://www.tga.gov.au/about/tga-who-we-are.htm; Department of Health and Ageing, Therapeutic Goods Administration, *What the TGA regulates*, http://www.tga.gov.au/about/tga-regulates-what.htm

(b) included in a class of goods the sole or principal use of which is, or ordinarily is, a therapeutic use or a use of a kind referred to in subparagraph (a)(ii) or (iii);

and includes biologicals, medical devices and goods declared to be therapeutic goods under an order in force under section 7, but does not include:

(c) goods declared not to be therapeutic goods under an order in force under section 7; or

(d) goods in respect of which such an order is in force, being an order that declares the goods not to be therapeutic goods when used, advertised, or presented for supply in the way specified in the order where the goods are used, advertised, or presented for supply in that way; or

(e) goods (other than goods declared to be therapeutic goods under an order in force under section 7) for which there is a standard (within the meaning of subsection 4(1) of the Food Standards Australia New Zealand Act 1991); or

(f) goods (other than goods declared to be therapeutic goods under an order in force under section 7) which, in Australia or New Zealand, have a tradition of use as foods for humans in the form in which they are presented.[3]

1.6 Common therapeutic goods can include:

medicines prescribed by a doctor or dentist;

medicines available from behind the pharmacy counter;

medicines available in the general pharmacy;

medicines available from supermarkets;

complementary medicines such as vitamins, herbal, or traditional medicines;

medical devices, from simple devices like bandages to complex technologies like heart pacemakers;

products used to test for various diseases or conditions (in vitro diagnostic devices), such as blood tests; and

vaccines, blood products, and other biologics.[4]

How therapeutic goods are classified

1.7 The TGA broadly divides therapeutic goods into two classes: medicines and medical devices. These goods must be entered on the Register before they can be

3 *Therapeutic Goods Act 1989* Section 3(1).

4 Department of Health and Ageing, Therapeutic Goods Administration, *What the TGA regulates*, http://www.tga.gov.au/about/tga-regulates-what.htm

lawfully supplied in, or exported from, Australia. Goods can be entered as registered goods, listed goods, biologicals or medical devices.[5]

1.8 Medicines (including complementary medicines) may be defined as being either registered or listed.

1.9 Registered Medicines are higher risk medicines and if suitable must be registered on the Australian Register of Therapeutic Goods (the Register) once the quality, safety and effectiveness of the product is evaluated. Such medicines include all prescription medicines, over the counter medicines and some complementary medicines.[6] This group of medicines can be further defined into high risk registered (e.g. prescription medication and sterile injectables) and low risk registered (non-prescription medicines e.g. mild analgesics, cough/cold preparations, anti-fungal creams).[7]

1.10 Listed Medicines are lower risk medicines which contain pre-approved, low-risk ingredients and that make limited claims. They are assessed by the TGA for quality and safety but not efficacy and can be listed on the Register. They include some over the counter medicines and most complementary medicines.[8]

1.11 Biologicals include:

- human stem cells;
- tissue-based products (skin, bone, ocular, cardiovascular);
- cell-based products (genetically modified, in vitro cell expansion or depletion); and
- combined cell and tissue products (collagen matrices for localised cell delivery).[9]

1.12 Medical devices include that objects that:

- are used on humans
- have therapeutic benefits
- generally have a physical or mechanical effect on the body or are used to measure or monitor functions of the body.[10]

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5 Therapeutic Goods Administration website, *Australian Register of Therapeutic Goods (ARTG)* https://www.ebs.tga.gov.au/; *Therapeutic Goods Act 1989*

6 Department of Health and Ageing, Therapeutic Goods Administration, *Medicines and TGA classifications*, http://www.tga.gov.au/industry/regulation-basics-medicines-classifications.htm

7 Department of Health and Ageing, Therapeutic Goods Administration, *Registered medicines*, http://www.tga.gov.au/industry/regulation-basics-medicines-registered.htm

8 Department of Health and Ageing, Therapeutic Goods Administration, Me*dicines and TGA classifications*, http://www.tga.gov.au/industry/regulation-basics-medicines-classifications.htm

9 Department of Health and Ageing, Therapeutic Goods Administration, *Products regulated as biologicals*, http://www.tga.gov.au/industry/biologicals-products-regulated.htm

10 Department of Health and Ageing, Therapeutic Goods Administration, *What is a medical device?*, http://www.tga.gov.au/industry/devices-basics-whatis.htm

Regulation of therapeutic goods

1.13 The *Therapeutic Goods Act 1989* (the Act) sets out the legal requirements for the import, export, manufacture and supply of therapeutic goods in Australia. It details the requirements for listing, registering or including medicines, medical devices and biological products on the Register, as well as many other aspects of the law including advertising, labelling, and product appearance. The Act is supported by the Regulations, and various Orders and Determinations which provide further details of matters covered in the Act.[11]

1.14 Only products that are 'therapeutic goods' are required to be regulated under the Act[12] and this is usually done through:

> pre-market assessment;
>
> post-market monitoring and enforcement of standards; and
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> licensing of Australian manufacturers and verifying overseas manufacturers' compliance with the same standards as their Australian counterparts.[13]

1.15 'The level of TGA regulatory control increases with the level of risk the medicine or device can pose',[14] however all therapeutic goods are required to be included on the Register, which is essentially 'a record of the contents and classification details' of therapeutic goods that can be supplied in Australia.[15] In order to be able to be put on the Register, a therapeutic good must meet and be evaluated against criteria set out in the Therapeutic Goods Act, Regulations and Orders.

1.16 Depending on the product, the Secretary may evaluate the goods based on criteria such as advertising, labelling, packaging, product appearance, product information, applicable standards, presentation and manufacturing process.[16] Some provisions, such as the scheduling of substances and the safe storage of therapeutic goods, are covered by the relevant State or Territory legislation.[17]

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11 Therapeutic Goods Administration website, *About the Australian therapeutic goods legislation* http://www.tga.gov.au/industry/legislation-about.htm

12 Department of Health and Ageing, Therapeutic Goods Administration, *Submission 5*, p. 6.

13 Department of Health and Ageing, Therapeutic Goods Administration, *How the TGA regulates*, http://www.tga.gov.au/about/tga-regulates-how.htm

14 Department of Health and Ageing, Therapeutic Goods Administration, *How the TGA regulates*, http://www.tga.gov.au/about/tga-regulates-how.htm

15 Department of Health and Ageing, *Therapeutic Goods Administration, Searching the Australian Register of Therapeutic Goods (ARTG),* http://www.tga.gov.au/industry/artg-searching.htm

16 This list is not exhaustive. Please see *Therapeutic Goods Act 1989*, Chapter 3, Part 3.2, Division 1 and 2 for a more complete list with respect to Medicines and other therapeutic goods that are not medical devices. *Therapeutic Goods Act 1989*, Chapter 3, Part 3.2A relates to biological whilst *Therapeutic Goods Act 1989*, Chapter 4 relates to medical devices.

17 Department of Health and Ageing, Therapeutic Goods Administration, *Legislation & legislative instruments*, http://www.tga.gov.au/industry/legislation.htm

1.17 Any therapeutic good included in the Register may be also subjected to conditions of registration or listing as set out by the Minister in a legislative instrument. These conditions can relate to:

(a) the manufacture of the goods; or

(b) the custody, use, supply, disposal or destruction of the goods; or

(c) the keeping of records relating to the goods; or

(d) matters dealt with in, or matters additional to matters dealt with in, standards applicable to the goods; or

(e) such other matters relating to the goods as the Minister thinks appropriate.[18]

Suspension or Cancellation from the Register

1.18 Any therapeutic good included in the Register may be suspended or cancelled by the Secretary for any number of reasons including:[19]

- imminent risk of death, serious illness or serious injury,
- written request from product sponsor;
- the product becomes exempt;
- the product needs to listed elsewhere;
- the product is no longer eligible for registration or listing;
- the product contains prohibited imports;
- non-compliance with advertising requirements;
- breach of conditions of registration or listing;
- non-payment of fees;
- non-compliance with applicable standards;
- incorrect certifications;
- failure to notify of adverse or harmful effects of goods;
- failure to provide information or documents;
- the quality, safety or efficacy of the goods becomes unacceptable;
- the goods have changed so that they no longer resemble the original goods as listed.

1.19 Upon cancellation the therapeutic good in question is still subject to regulation under the Act and it becomes unlawful to import, manufacture, supply and advertise the good. Thus, the rules and procedures involved in getting a product onto

18 *Therapeutic Goods Act 1989*, Section 28(2).

19 This list is not exhaustive and not all reasons for cancellation apply to all classes of therapeutic goods.

the Register, and which might lead to it being removed, are important to medical industries and health consumers.

Overview of the Bill

1.20 The Therapeutic Goods Amendment (2013 Measures No. 1) Bill 2013 would make a number of amendments to the Act.

1.21 Currently the 'definition of therapeutic goods in the Act is very broad and can capture products wherever claims are made suggesting that they can modify any physiological process in persons.'[20] Consequently this definition has the potential to be applied to a wide range of goods that may not have been intended to be regulated under the Act.[21]

1.22 Products such as these, for which 'public health is not, or is not likely to be an issue' may be more appropriately regulated under the provisions of consumer protection legislation rather 'than the more prescriptive therapeutic goods framework contained in the Act'.[22]

1.23 The amendments proposed by the Bill will allow the Minister to specify products that are taken not to be therapeutic goods for the purpose of the Act.[23]

1.24 If enacted, the amendments proposed by the Bill will:

- provide the Minister with the power to make legislative instruments excluding certain goods from the definition of 'therapeutic goods';[24]
- introduce an offence and a civil penalty provision for providing false or misleading information when seeking to vary an existing entry in the Register;[25]
- provide that the Secretary may cancel the registration or listing of therapeutic goods where the presentation of registered goods is not acceptable or, in the case of listed goods, is unacceptable;[26]

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20 C King, Second Reading Speech: Therapeutic Goods Amendment (2013 Measures No.1) Bill 2013, *House of Representatives Hansard,* 20 March 2013, p. 2739.

21 For example: 'power band' bracelets, clothing and household items such as mattresses designed to reduce the effects of dust mites by using bacteria spores. Explanatory Memorandum, p. 1; C King MP, Second Reading Speech: Therapeutic Goods Amendment (2013 Measures No.1) Bill 2013, *House of Representatives Hansard,* 20 March 2013, pp. 2738–2741.

22 C King, Second Reading Speech: Therapeutic Goods Amendment (2013 Measures No.1) Bill 2013, *House of Representatives Hansard,* 20 March 2013, p. 2739.

23 Explanatory Memorandum, p. 1.

24 Explanatory Memorandum, p. 4.

25 Explanatory Memorandum, p. 4.

26 Explanatory Memorandum, p. 4.

- provide that the Secretary may cancel the registration or listing of therapeutic goods where a request from the Secretary to provide specified information or documents about those good is not responded to;[27] and
- clarify the arrangements relating to the approval of product information (PI) for medicines accepted for registration in the Register.[28]

1.25 The Bill will also make a number of technical amendments to the Act in order to further 'streamline and improve the operation of the regulatory scheme for therapeutic goods'.[29]

Views of Parliamentary legislative scrutiny committees

1.26 The Bill has been the subject of comment by two parliamentary committees tasked with examining proposed legislation to ensure compliance with established Commonwealth legislative principles and requirements.

Parliamentary Joint Committee on Human Rights

1.27 The Parliamentary Joint Committee on Human Rights is tasked with examining proposed legislation to ensure compatibility with human rights standards.[30] The committee examined the Bill, noting in its sixth report of 2013 its concern with one aspect of the proposed legislation.[31]

1.28 The committee drew attention to the provision in the Bill which will remove a right to merits review of decisions relating to product information registration approvals. The committee advised that:

> While noting the explanation in the statement of compatibility, it is not clear to the committee why the existing possibility of review on the merits of product information decisions needs to be dispensed with. If, as the statement of compatibility maintains, such a decision will always be dealt with as part of a reviewable decision relating to registration, then retaining merits review has no impact. However, if it should turn out that there are circumstances in which a decision relating to PI is made separately from a decision to register or vary registration, a failure to provide for merits review (with only judicial review available) may limit article 14(1) of the ICCPR.[32]

1.29 The Parliamentary Secretary for Health and Ageing's advice was sought in order to clarify 'as to why it is necessary to remove the merits review of certain decisions relating to product information and whether, as a result of these

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27 Explanatory Memorandum, p. 4.

28 Explanatory Memorandum, p. 4.

29 C King, Second Reading Speech: Therapeutic Goods Amendment (2013 Measures No.1) Bill 2013, *House of Representatives Hansard*, 20 March 2013, p. 2738.

30 *Human Rights (Parliamentary Scrutiny) Act 2011*, s. 7.

31 Parliamentary Joint Committee on Human Rights, Sixth report of 2013, May 2013, p. 86.

32 Parliamentary Joint Committee on Human Rights, Sixth report of 2013, May 2013, p. 88.

amendments, there would be any circumstances in which merits review of a product information decision would not be available at all.'[33]

1.30 As of the time of tabling this report, no response from the Parliamentary Secretary for Health and Ageing had been published.

Senate Standing Committee for the Scrutiny of Bills

1.31 The Senate scrutiny of bills committee identified a number of issues for clarification with the Minister in its fifth alert digest of 2013.[34]

1.32 In relation to the Bill, the committee asked questions regarding the power given to the Minister in respect of allowing the Minister to exclude from the definition of 'therapeutic goods' those goods which have been determined by the Minister in a legislative instrument not to be therapeutic goods or not to be therapeutic goods when used, advertised or presented for supply in a specified way:

> The consequence of excluding a particular good from the definition of 'therapeutic goods' is that it would no longer be regulated in accordance with the requirements of the Act. The explanatory memorandum notes that the definition of therapeutic goods is very broad and offers a detailed case for the importance of allowing 'the Minister to respond flexibly, on a case by case basis, to ensure that the Therapeutic Goods Administration is not involved in the regulation of products for which there is no public health focus or for which there may be sound public policy reasons for their not being regulated under the therapeutic goods legislation' (at 22). Although the need for flexibility may be accepted, it is not clear what sort of public policy reasons will be considered appropriate for excluding the requirements of the Act.
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> The committee therefore seeks the Minister's advice as to whether consideration has been given as to specifying the purposes for which this power may be exercised or to other ways to confine this power (which amounts to a broad discretion to exclude the operation of the Act in relation to particular goods).[35]

1.33 The committee also asked questions regarding the introduction of a strict liability offence for providing false and misleading information in relation to a request to vary an entry for therapeutic goods on the Register:

> As noted in the statement of compatibility, variations to goods listed on the Register can relate to a variety of matters, including quite serious safety issues, such as adding a warning or a precaution to the product information of a prescription medicine in connection with the use of the medicine' (at 5). What is lacking, however, is an explanation as to why strict liability will significantly enhance effective regulatory enforcement and why it is

33 Parliamentary Joint Committee on Human Rights, Sixth report of 2013, May 2013, p. 88.

34 Senate Standing Committee for the Scrutiny of Bills , Alert Digest No.5 of 2013, p. 99.

35 Senate Standing Committee for the Scrutiny of Bills , Alert Digest No.5 of 2013, p. 100.

> legitimate to penalise persons who lack fault. The committee therefore seeks the Minister's further explanation of this matter.[36]

1.34 As of the time of tabling this report, no response from the Minister had been published.

General views on the Bill

1.35 The Bill received broad support, with a number of submitters believing that the proposed amendments would 'clarify terminology and the operation of the Act':[37]

> These amendments are supported as they will clarify a number of matters in the *Therapeutic Goods Act 1989 (CW)*, and improve protection measures for consumers and patients.[38]
>
> On balance, ADIA supports the amendments as they make more clear and transparent a number of regulatory processes and requirements applying to the regulation of all classes of therapeutic goods by the Therapeutic Goods Administration (TGA).[39]

1.36 Many submitters[40] acknowledged that many of the proposed amendments were of a technical nature with the ADIA particularly supportive of the intention of these technical amendments:

> … to ensure, where appropriate, consistent regulatory treatment of the different types of therapeutic goods including prescription, over-the-counter and complementary medicines, therapeutic devices, biologicals and medical devices.[41]

1.37 The GMiA was particularly supportive of 'a number of amendments that seek to improve the safety and quality if the use of therapeutic goods in this country.'[42] Others qualified their support, registering concern on issues such as presentation, consultation and any potential unintended consequences that may arise out of enacting the Bill:

> In general terms, Medicines Australia supports the various policy objectives of the amendments. Nevertheless, Medicines Australia seeks:
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> to ensure no unintended consequences flow from the Bill;

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36 Senate Standing Committee for the Scrutiny of Bills, Alert Digest No.5 of 2013, p. 101.

37 Australian Commission on Safety and Quality in Health Care, *Submission 10*, p. 1.

38 Department of Health, Northern Territory Government, *Submission 11*, p. 1.

39 Australian Dental Industry Association, *Submission 4*, p. 3.

40 Australian Dental Industry Association, *Submission 4*; Generic Medicines Industry Association, *Submission 9;* Australian Commission on Safety and Quality in Health Care, *Submission 10;* Medicines Australia, *Submission 6*

41 Australian Dental Industry Association, *Submission 4*, p. 4.

42 Generic Medicines Industry Association, *Submission 9*, p. 2.

> certainty regarding the new power to cancel registration of a medicine due to presentation in the context of the current labelling and packaging review; and further engagement on future reform.[43]

And:

> …members of GMiA are concerned about the implications of this Bill on the cancellation of medicines from the Australian Register of Therapeutic Goods (ARTG) based on "presentation" and the follow on consequences that may follow as a result of the current Therapeutic Goods Administration (TGA) review of labelling and packaging.[44]

43 Medicines Australia, *Submission 6*, p. 1.

44 Generic Medicines Industry Association, *Submission 9*, p. 2.