The Senate

Community Affairs Legislation Committee

Therapeutic Goods Amendment (2013 Measures No. 1) Bill 2013 [Provisions]

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43rd Parliament

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2.47 The committee recommends that the Senate consider any findings or recommendations made by the Scrutiny of Bills committee in respect of proposed section 7AA.

Recommendation 2

2.89 The committee recommends that the Senate consider any findings or recommendations made by the Parliamentary Joint Committee on Human Rights in respect of amendment of section 60.

Recommendation 3

2.100 The committee recommends that the bill be amended to align the publication options between proposed section 9F and other existing provisions in the Act.

Recommendation 4

2.109 Subject to the preceding recommendations, the committee recommends that the bill be passed.

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:
>
> (i) for therapeutic use; or
>
> (ii) for use as an ingredient or component in the manufacture of therapeutic goods; or
>
> (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
>
> 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.
>
> 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:
>
> 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.

Chapter 2

Issues

2.1 Several issues were raised by submitters about the proposed bill, and the remainder of this report addresses several of these.

Presentation

The current situation

2.2 The Therapeutic Goods Act contains complex provisions that govern the listing and registering of goods. These provisions cover a range of conditions and procedures that need to be followed, and requirements that goods have to meet, relating to things like safety or product information.

2.3 One criterion that therapeutic goods must meet relates to presentation. The 'presentation' of therapeutic goods means

> the way in which the goods are presented for supply and includes matters relating to the name, labelling and packaging and any advertising or other informational material associated with the goods.[1]

2.4 The precise standard of presentation that a good must meet in order to be placed on the Register depends on the category into which it falls. For *registered* goods, the presentation must be 'acceptable'.[2] For the category of *listed* goods, for those listed under section 26 of the Act, the secretary cannot refuse listing unless the presentation is 'unacceptable'.[3] The process is slightly different for medicines being listed under section 26A of the Act, in which cases the presentation of the medicine must be 'not unacceptable'.[4]

2.5 Section 3(5) of the Act defines 'unacceptable' presentation:

> For the purposes of this Act, the presentation of therapeutic goods is unacceptable if it is capable of being misleading or confusing as to the content or proper use or identification of the goods and, without limiting the previous words in this subsection, the presentation of therapeutic goods is unacceptable:
>
> (a) if it states or suggests that the goods have ingredients, components or characteristics that they do not have; or

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1 Explanatory Memorandum, p. 36.

2 *Therapeutic Goods Act 1989*, Section 25(1)(e).

3 *Therapeutic Goods Act 1989*, Section 26(1)(e). See also Explanatory Memorandum, p. 36.

4 *Therapeutic Goods Act 1989*, Section 26A(2)(c).

> (b) if a name applied to the goods is the same as the name applied to other therapeutic goods that are supplied in Australia where those other goods contain additional or different therapeutically active ingredients; or
>
> (c) if the label of the goods does not declare the presence of a therapeutically active ingredient; or
>
> (ca) if the therapeutic goods are medicine included in a class of medicine prescribed by the regulations for the purposes of this paragraph—if the medicine's label does not contain the advisory statements specified under subsection (5A) in relation to the medicine; or
>
> (d) if a form of presentation of the goods may lead to unsafe use of the goods or suggests a purpose that is not in accordance with conditions applicable to the supply of the goods in Australia; or
>
> (e) in prescribed cases.[5]

2.6 While the Act defines 'unacceptable', it does not define 'not acceptable', which the committee understands has a different meaning. The Explanatory Memorandum comments on this in the context of the presentation of registered goods:

> whether the presentation of such goods is 'not acceptable' can encompass a range of factors that might go beyond the scope of the definition of 'unacceptable presentation' in subsection 3(5) of the Act. For example, the presentation of registered goods may cover matters such as the consumer medicine information for the goods.[6]

2.7 Just as sections 25 and 26 of the Act create procedures for the registering or listing of products,[7] Section 30 of the Act establishes the procedure by which therapeutic goods can be cancelled from the Register. Section 30 is complex, but the main provisions relevant to this discussion about cancellation are in subsection 30(2):

> (2) Subject to subsection (3), the Secretary may, by notice in writing given to a person in relation to whom therapeutic goods are included in the Register, cancel the registration or listing of the goods if:
>
> > (a) it appears to the Secretary that the quality, safety or efficacy of the goods is unacceptable; or
> >
> > (b) the goods have changed so that they have become separate and distinct from the goods as so included; or
> >
> > (ba) in the case of a medicine listed under section 26A, it appears to the Secretary that any of the certifications under paragraph 26A(2)(b), (c), (d), (f), (fa), (fb), (fc), (h), (i), (j) or (k) or subsection 26A(2A) are incorrect; or

5 *Therapeutic Goods Act 1989*, Section 3(5).

6 Explanatory Memorandum, p. 37.

7 As noted above, this does not include medicines, which are listed under 26A.

> (c) the sponsor has refused or failed to comply with a condition to which the inclusion of the goods is subject (other than the condition under paragraph 28(5)(d)); or
>
> (ca) the person has contravened subsection 29A(1) or 29AA(1) in relation to the goods; or
>
> (d) the goods become required to be included in the other part of the Register; or
>
> (e) the goods do not conform to a standard applicable to the goods or to a requirement relating to advertising applicable to the goods under Part 5‑1 or under the regulations; or
>
> (f) the annual registration or listing charge is not paid within 28 days after it becomes payable.[8]

2.8 Notably, this list does not contain a reference to the presentation of goods. Thus, while under section 30 of the Act the Secretary may cancel the registration or listing of therapeutic goods for a number of reasons, there is currently no provision for the registration or listing of therapeutic goods to be cancelled by the Secretary on the basis that the presentation has become deficient in some way.[9]

Proposed amendment

2.9 The proposed legislation seeks to amend subsection 30(2), to add to the grounds on which goods may be cancelled, so that the Secretary may 'cancel the registration or listing of the goods if':[10]

> it appears to the Secretary that the presentation of the goods:
>
> in the case of registered goods—is not acceptable; or
>
> In the case of listed goods—is unacceptable[11].

2.10 Under the proposed legislation this would mean that the Secretary could, after giving written notice of a proposal to cancel and considering any submissions made by a sponsor in relation to that proposal, cancel goods from the Register if the presentation of registered medicines or biologicals is not (i.e. no longer) acceptable, or if complementary and export-only medicines are unacceptable.[12]

2.11 In the departmental submission and government explanatory memorandum it was explained that the inclusion of this new power would:

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8 *Therapeutic Goods Act 1989*, Section 30(2).

9 Explanatory Memorandum, p. 36.

10 These are the existing words that lead into the set of circumstances set out in *Therapeutic Goods Act 1989*, Section 30(2).

11 Proposed section 30(2)(aa).

12 Department of Health and Ageing, Therapeutic Goods Administration, *Submission 5*, p. 7.

- 'ensure that there is a mechanism by which therapeutic goods continue to satisfy [the presentation requirements] for so long as they remain entered on the Register'[13] rather than having to satisfy them only at the point of application (and thereby filling a gap in the Act), and
- ensure 'that those using a medicine are not misled about its use or characteristics or confuse it with other medicines after it has been included in the register'.[14]

2.12 The existing Act has a mechanism by which biologicals can be cancelled if there are problems with presentation;[15] the amendment would create a parallel mechanism for other regulated goods.

Issue

2.13 Medicines Australia, while supportive of ensuring effective enforcement powers, was concerned about the interaction between the current reforms and possible outcomes from the packaging and labelling review that is still underway.[16] The packaging and labelling review:

> is primarily concerned with the presentation of the information on the medicine containers or on the boxes within which they are supplied. Of particular interest are the visual aspects that contribute to the usability of the information provided and facilitate the safe use of the medicine by health care professionals and consumers.[17]

2.14 Medicines Australia expressed concern at the potential impact of the review on the interpretation of 'acceptable presentation' and was 'cautious' with respect to the power of the Secretary to 'deregister products based on a potentially uncertain or changing requirement for presentation.'[18] The GMiA also expressed concerns stating:

> GMiA is concerned that an unintended consequence of the amendment in this Bill may be that the Secretary is able to suspend/cancel medicines from the ARTG that do not meet the, as yet undetermined, requirements mandated as a result of the TGA labelling and packaging review.[19]

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13 Explanatory Memorandum, p. 36.

14 Department of Health and Ageing, Therapeutic Goods Administration, *Submission 5*, p. 7.

15 *Therapeutic Goods Act 1989*, subsection 32GC(1).

16 Medicines Australia, *Submission 6*, p. 2.

17 Department of Health and Ageing, Therapeutic Goods Administration, TGA medicine labelling and packaging review: Consultation, http://www.tga.gov.au/newsroom/consult-labelling-packaging-review-120524-02-about.htm

18 Medicines Australia, *Submission 6*, p. 2.

19 Generic Medicines Australia, *Submission 9*, pp. 2–3.

2.15 Mr Kentwell had a different concern, querying the distinction for the two classes of goods:

> The bottom line is that if legislative guidance is afforded to goods that are subject to less regulatory scrutiny such as low risk listed medicines[,] by what justification should those higher risk registered goods not be afforded similar guidance. For registered goods the "range of factors that might go beyond the scope of the definition of 'unacceptable presentation'" in my view should not be open-ended but codified at least to the same extent as it has for listed goods.[20]

2.16 In its response the department indicated that Mr Kentwell's submission may have misunderstood the way the amendment is intended to operate:

> This reference was not intended to imply that the matters set out in subsection 3(5) of the TG Act would not be relevant in considering whether the presentation of registered goods may be 'not acceptable'. Rather, this reference sets out that such matters would (where applicable) be relevant in understanding the meaning of 'not acceptable', but that there could also be other factors or circumstances (in addition to those in subsection 3(5)) in which the presentation of registered goods may not be acceptable. Such additional circumstances may relate to matters particular to registered medicines, such as the presentation of product information or consumer medicine information.[21]

2.17 On the relationship between the amendments and the review currently underway, the department stated that the amendments relating to presentation, as per Schedule 7 of the Bill:

> …do not relate to, or pre-empt the outcomes of the TGA's Labelling and Packaging Review…the proposed new power would not be necessary for or related to, the enforcing of any new labelling and packaging requirements as these are expected to be implemented using a different mechanism…[22]

2.18 The department indicated that it anticipates that the pending labelling and packaging reforms will be 'implemented through the making or amending of a standard for relevant therapeutic goods under section 10' of the Act.[23] As such an application for registration or listing of a therapeutic good would, as is currently required, need to comply with the applicable standards in relation to labelling and

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20 Mr Doug Kentwell, *Submission 7*, p. 9.

21 Department of Health and Aging, Therapeutic Goods Administration, answer to written questions on notice (received 28 May 2013), p. 6.

22 Department of Health and Ageing, Therapeutic Goods Administration, answer to written questions on notice (received 28 May 2013), pp. 6, 7.

23 Department of Health and Ageing, Therapeutic Goods Administration, answer to written questions on notice (received 28 May 2013), p. 7. Section 10(2)(c) of the *Therapeutic Goods Act 1989* currently states that an order can be made to establish standards in relation to labelling and packaging.

packaging in addition to and separately from requirements relating to presentation. The power to suspend or cancel a good from the Register for breach of or non-compliance with a standard is and would continue to be separate from the power to suspend or cancel a good because of non-compliance with presentation requirements.[24] The department also indicated that any amendments to the standards as a result of the labelling and packaging review 'would be the subject of consultation.'[25]

Committee view

2.19 The committee is supportive of the policy objective reflected in the proposed amendment. The committee understands the concern of some submitters, and found the provisions of the existing legislation and the proposed amendment difficult to navigate. There are several overlapping reasons that make the operation of these sections difficult to interpret:

- The construction of section 25 in the positive, but section 26 in the negative;
- The fact that 'acceptable' and 'unacceptable' do not mean the exact opposite of each other; and
- The fact that 'unacceptable' and 'not acceptable' do not have the same meaning.

2.20 On balance, the committee is satisfied that the amendments will achieve an important policy objective. The committee suggests that, in the course of the broader review of the Act, the government consider simplification of the legislation, by changes such as framing sections 25 and 26 in the same form, or considering removal of the distinction between unacceptable and not acceptable.

New ministerial power: proposed section 7AA

2.21 The current definition of 'therapeutic goods' has the potential 'to extend to a wide range of goods that may not have been intended to be regulated under the Act'.[26] For example, the making of a claim that goods have a health benefit may potentially subject them to regulation under the Act, even if no public health risk is likely. There might also be goods (for instance food about which low level health claims are made) that fall within the scope of the Therapeutic Goods Act, but which are more appropriately regulated under other existing laws.

24 Department of Health and Ageing, Therapeutic Goods Administration, answer to written questions on notice (received 28 May 2013), pp. 6, 7.

25 Department of Health and Ageing, Therapeutic Goods Administration, answer to written questions on notice (received 28 May 2013), p. 7.

26 Explanatory Memorandum, p. 1.

2.22 Whilst it is currently possible to exempt goods from certain requirements under the Act, 'it is not possible to entirely exclude such products from the regulatory scheme for therapeutic goods'.[27]

2.23 Currently section 7 of the Act provides the Secretary with the administrative power to determine whether certain products are, or are not, therapeutic goods. The Secretary is required to base the decision on the definition of 'therapeutic goods' as found in subsection 3(1) of the Act. The section does not allow the Secretary to cancel goods from the Register, and decisions under the section are reviewable by the Minister and the Administrative Appeals Tribunal.[28]

2.24 The power of the Secretary under section 7 is constrained in two respects. First, the Secretary can only act to exclude a product if satisfied that it does not meet the definition of therapeutic goods in the Act. That definition is extremely broad. It may capture things that were never intended to be regulated as therapeutic goods, but the legislation does not allow the Secretary to consider the intention of the Act or the consequences of a product being regulated under the Act. Second, the Secretary must be 'satisfied' that a product is not therapeutic goods. In the absence of sufficient information for the Secretary to satisfy herself one way or the other, she cannot reach a conclusion and cannot proceed to make a determination.

2.25 The power under section 7 is therefore limited. Proposed section 7AA[29] of the Act would enable the Minister, by way of disallowable legislative instrument, to exercise a broader judgement than that available to the Secretary, and determine that goods should be excluded altogether from the scope of the regulatory scheme in the Act.[30]

2.26 In its submission to the committee the department stated that the new provision:

> …would ensure that the focus of regulation under the Act remains directed at goods that have some impact on public health, and that the resources of the Therapeutic Goods Administration are more appropriately directed at the regulation of therapeutic goods and not household items, jewellery and a range of other goods in relation to which therapeutic claims may be made. The proper focus of regulation under the Act should be directed at products which could potentially represent a health risk to the Australian public.[31]

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27 Department of Health and Ageing, Therapeutic Goods Administration, *Submission 5*, p. 4; Explanatory Memorandum, p. 1.

28 Department of Health and Ageing, Therapeutic Goods Administration, answer to written questions on notice (received 28 May 2013), pp. 9, 20.

29 See schedule 3 item 2 of the bill.

30 Department of Health and Ageing, Therapeutic Goods Administration, *Submission 5*, p. 4; Explanatory Memorandum, p. 1.

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

2.27 The committee asked the department to respond to issues raised by submitters regarding the purpose of the new provision. The department elaborated:

> The primary reason for inserting this provision is to address the increasingly common practice for therapeutic claims to be made for a range of goods (perhaps to make them more appealing to health conscious consumers), even if they have no or little bearing on actually preventing, or alleviating any illness or injury, or any other health-related impact, with the result that these goods become subject to regulation under the TG Act.[32]

Issues

2.28 Mr Kentwell queried the necessity of introducing proposed section 7AA.[33] He expressed concern that decisions under the new section would not be subject to merits review. He observed:

> This provides the regulator with the option of utilising this mechanism if fearful of defeat via merits review…it begs the question as to why, notwithstanding the manner in which the EM describes the justification, such an additional power is necessary other than to provide an alternative mechanism more insulated from scrutiny than sponsor initiated merits review.[34]

2.29 Concerns were expressed by CHC that there is no criteria for excluding goods by means of a determination under proposed section 7AA:

> The CHC's concern is that there is no boundary to what the Minister can exclude from the Register and the definition of what may be excluded is incongruous.[35]

2.30 It felt that the effective expansion of the Ministers powers could possibly mean that certain complementary medicines could be adversely affected:

> …if genuine therapeutic products were to be excluded following the expansion of the Ministers powers, this would be an unintended consequence causing very real concern for the complementary medicines industry.[36]

2.31 There was also concern that the proposed legislation contained no requirement for consultation with industry prior to a determination being made. Some felt that this meant that there would be no opportunity for the sponsor of products that may be excluded under this power to defend their position:

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32 Department of Health and Ageing, Therapeutic Goods Administration, answer to written questions on notice (received 28 May 2013), p. 9.

33 Mr Doug Kentwell, *Submission 7*, p. 5.

34 Mr Doug Kentwell, *Submission 7*, pp. 5, 7.

35 Complementary Healthcare Council of Australia, *Submission 8*, p. 6.

36 Complementary Healthcare Council of Australia, *Submission 8*, p. 6.

> …there appears to be no comparable requirement for an affected party to be consulted prior to the Minister declaring a good not to be a therapeutic good under a determination in 7AA(1) or (2). Although this determination would be made via legislative instrument, the disallowance period does not amount to meaningful industry consultation. In the interests of a consultative approach to regulation, Medicines Australia supports industry consultation prior to determinations that affect members' interests.[37]
>
> Under the new power there is no defence against the removal of a product from the definition of a therapeutic good – if the decision can be made regardless of whether the Minister believes that a product is a therapeutic good or not.[38]

2.32 In contrast ADIA felt that the disallowable nature of the determination was adequate:

> …ADIA is confident in the fact that such a determination would be required to be tabled before Parliament and would be disallowable, providing an appropriate safeguard in the case of an egregious decision by the Minister.[39]

2.33 The committee asked the department to respond to issues raised by submitters, including Mr Kentwell. The department's response to Mr Kentwell's queries about section 7 drew attention to the limitations of the Secretary's powers:

> To clarify, section 7 of the TG Act allows the Secretary to confirm by way of determination that goods are not therapeutic goods. It is predicated on the Secretary being satisfied that the goods are not in fact therapeutic goods. If there is insufficient material on which she could come to that view then no determination can be made. Section 7AA allows the Minister to declare that products are not therapeutic goods whether or not they come within the definition of therapeutic goods. The kinds of products in relation to which the Minister might make a determination would not be ones that in order to be supplied safely in Australia, require regulation of the kind found in the TG Act.[40]

2.34 The department in their response to CMC indicated that Minister will operate on a 'case-by-case basis' and 'take into account all relevant factors for the product in question'[41] when considering whether to exclude products from regulation under the Act, including:

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37 Medicines Australia, *Submission 6*, p. 2.

38 Complementary Healthcare Council of Australia, *Submission 8*, p. 6.

39 Australian Dental Industry Association, *Submission 4*, p. 5.

40 Department of Health and Ageing, Therapeutic Goods Administration, answer to written questions on notice (received 28 May 2013), p. 10.

41 Department of Health and Ageing, Therapeutic Goods Administration, *Submission 5*, p. 5; Department of Health and Ageing, Therapeutic Goods Administration, answer to written questions on notice (received 28 May 2013), p. 19.

- whether the product is of a kind that has the potential to harm a person's health;
- whether the application of the regulatory requirements under the Act that are designed to test the safety, quality, efficacy and performance of a product for it to be supplied in Australia would be appropriate to a product of that kind; and
- whether the kinds of risks to which the public might be exposed from the supply of the product (for instance, unsupported therapeutic claims) can be more effectively managed under other Commonwealth or state and territory laws.[42]

2.35 The department went on to indicate the kinds of goods that could be excluded under such a determination:

> Examples of goods that may well be inappropriate for regulation under the TG Act regulatory scheme include household items such as mattresses, and jewellery and clothing, for which therapeutic claims are made, and in relation to which none of the current exceptions to the definition of 'therapeutic goods' apply.[43]

2.36 The department also indicated that the new power cannot be used:

- to expand the range of goods coming within the definition of 'therapeutic goods'.[44]
- to take a therapeutic good that should be cancelled (for whatever reason) outside the regulatory regime;[45] or
- to exclude products such as prescription, over-the-counter and complementary medicines which are clearly appropriate for regulation under the Act[46]

and noted that determinations made by the Minister would be subject to parliamentary review through the disallowance process.[47]

2.37 On the issue of what consultations would be associated with proposed section 7AA, in their response the department indicated that:

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

43 Department of Health and Ageing, Therapeutic Goods Administration, answer to written questions on notice (received 28 May 2013), p. 19.

44 Department of Health and Ageing, Therapeutic Goods Administration, answer to written questions on notice (received 28 May 2013), p. 10.

45 Department of Health and Ageing, Therapeutic Goods Administration, answer to written questions on notice (received 28 May 2013), p. 10.

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

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

> Consultation is likely to be undertaken before any exercise of the new power in proposed section 7AA, for example with sponsors and suppliers or products that are proposed to be excluded, as well as with consumer representative bodies. *The Legislative lnstruments Act 2003* (the LI Act) sets out various requirements in relation to consultation requirements for legislative instruments. Unless a legislative instrument is, for instance, of a 'minor or machinery nature' that 'does not substantially alter existing arrangements' or is required as a 'matter of urgency' (section 18 of the LI Act refers), a rule-maker must not make a legislative instrument before being satisfied that any consultation that is considered by the rule-maker to be appropriate and reasonably practical to undertake has been undertaken (section 17 of the LIAct refers).
>
> In addition, depending on the nature of any products proposed to be excluded, a Regulation Impact Statement (RIS) may also be required to be completed prior to the making of instruments under the new power as part of the Department's compliance with best practice regulation requirements.[48]

Committee consideration

2.38 There was broad support for the proposed amendments to the definition of therapeutic goods to cover those products 'which do not meet a conventional and accepted term of definition of "therapeutic products"':[49]

> ADIA concurs …that such products are unlikely to fall within the definition of therapeutic product and thus the protections afforded to consumers within the *Competition and Consumer Act (Cth) 2010*, specifically the Australian Consumer Law (ACL), are more appropriate. ADIA also concurs with the Australian Government's view that it is important that there is as much clarity as possible about which goods are covered by the regulatory scheme, and for the Minister to consider whether particular goods which may come within the definition are appropriate for regulation under the Act.[50]

2.39 Mr Kentwell and the CMC have however identified an issue that requires further consideration. Given the scope of the proposed regulation-making power, the committee considered some of the options for defining it, or guiding its application.

2.40 One option would be to define 'therapeutic goods' more narrowly in the first place. As the minister pointed out in the second reading speech, the need for reform has arisen because health claims are now being made for a wide variety of goods, bringing them within the Act's current definition, even though it was never meant to regulate such claims. However the Act deliberately casts a wide net. Changing its

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48 Department of Health and Ageing, Therapeutic Goods Administration, answer to written questions on notice (received 28 May 2013), p. 5.

49 Australian Dental Industry Association, *Submission 4*, p. 5.

50 Australian Dental Industry Association, *Submission 4*, p. 5.

scope would be difficult, requiring extensive and careful consultation, and could risk undermining the core objective of providing for 'the establishment and maintenance of a national system of controls relating to the quality, safety, efficacy and timely availability of therapeutic goods'.[51]

2.41 Rather than limiting the definition of therapeutic goods in general, it might be possible to define specific categories of goods that are exempted from the Act. This is the approach taken in existing paragraph (e) of the definition of therapeutic goods, which exempts from the Act products that instead fall within the regulatory scope of the *Food Standards Australia New Zealand Act 1991*. While this approach is feasible in the case of well-defined subjects of alternative regulatory regimes, the goods at which proposed section 7AA is likely to be aimed are those that would more appropriately be regulated by consumer law. They are goods – such as mattresses or jewellery – where there is no relevant regulatory regime to which the Act could refer. It would also be impractical to try and predict what goods might in future have health claims made for their use. Finding a way to define these goods would be difficult, if not impossible.

2.42 A third option would be to use the existing, more limited power currently available to the minister under section 18 of the Act. That section allows the Minister to remove goods from the operation of Part 3.2 of the Act by regulation. The committee sought TGA advice on why this power was not sufficient for the purpose. The department responded, pointing out that a good that was exempted by regulation under section 18:

> will still be subject to other requirements in the Act that apply to therapeutic goods of that kind (ie those that would otherwise need to be listed or registered). This would include, for instance:
>
> The requirements in Part 3-3 of the TG Act for the goods if manufactured in Australia to be manufactured by a licenced manufacturer in compliance with Good Manufacturing Principles
>
> Compliance with any standards made under section 10 of the Act that would apply to the goods, and
>
> Compliance with the advertising provisions in Part 5-1 of the Act and the provisions in Part 5-2 and 5-3 of the Act about counterfeit therapeutic goods and product tampering.
>
> While it is possible to exempt therapeutic goods from the operation of Part 3-3 by regulation (see section 34 of the TG Act) and for a sponsor to seek an exemption from various standards that would otherwise apply under section 10 of the TG Act (and possibly all standards), it is **not** possible to exempt therapeutic goods from the advertising, counterfeit and product tampering standards.[52]

51 *Therapeutic Goods Act 1989*, subsection 4(1).

52 Correspondence from Department of Health and Ageing, received 12 June 2013.

2.43 There are at least two further possibilities, although the committee received no evidence from stakeholders about them. One would be to identify categories of goods to which regulations under section 7AA could not be applied. The Therapeutic Goods Act for example currently contains definitions of medicines (section 3(1)) and biologicals (section 32A). The scope of proposed 7AA could be limited by preventing the minister from determining that specific classes of goods, such as medicines or biological, are not therapeutic goods, if there is no intention that any such goods ever be exempted from the Act as a whole.

2.44 Another approach could be to provide guidance around the exercise of the regulation-making power. This is already done to some degree. The Act contains an objects clause that provides guidance to the minister as to the purpose of the Act's application. Section 17 of the Legislative Instruments Act requires appropriate consultation to take place. In addition, during the course of this inquiry, the department provided some guidance, quoted above, about situations in which the power may be called upon, and constraints that the government anticipates would apply to its exercise. In the event of a case coming before the courts regarding the scope of the minister's power under proposed 7AA, the department's submissions to this committee could provide guidance, though only if the court considered there to be ambiguity in the legislation itself.[53]

2.45 The committee thus notes there is a range of ways to further define the exercise of delegated legislative power, but also that there are reasons why several of these options may not be suitable in this case. The committee did not receive sufficient evidence to consider the matter in more detail, but notes that the Selection of Bills Committee has also drawn attention to the issue of the scope of proposed section 7AA.

2.46 The Community Affairs committee notes that, should the Scrutiny of Bills committee still have concerns after receiving a response from the minister, it will draw these to the Senate's attention. At the very least, if there are no appropriate options to more tightly define the powers of the minister, the government could more fully explain why some parameters cannot be set around this power.

Recommendation 1

2.47 The committee recommends that the Senate consider any findings or recommendations made by the Scrutiny of Bills committee in respect of proposed section 7AA.

53 *Acts Interpretation Act 1901*, section 15AB(2).

Section 9F

2.48 Non-therapeutic goods may appear in the Register for the following reasons:

- low risk products which are registered electronically can be included in the Register without TGA scrutiny if the applicant/sponsor certifies as to a range of matters. This can result in a product being placed on the Register which is later found to not satisfy the definition of a therapeutic good.[54]
- products that were therapeutic goods when included in the Register may cease to come within the definition because therapeutic claims are no longer made.[55]
- products that were therapeutic goods when included in the Register may cease to come within the definition because they may (in the future) come within a legislative instrument made by the Minister under proposed section 7AA.[56]

2.49 Currently goods determined to be non-therapeutic cannot be removed or cancelled from the Register. Section 7 of the Act as it now stands does not have any provision for such a power and 'current cancellation powers under the Act only apply to ‘therapeutic goods’ and so cannot be used to remove goods in the Register that are not, or have ceased to be, therapeutic goods.'[57]

2.50 Proposed section 9F of the Act[58] contains a new power which would allow the Secretary to remove goods from the Register that do not fall within the definition of 'therapeutic goods' under the Act (i.e. non-therapeutic goods).[59] The effect of removing such products from the Act would mean that these goods would not be subject to any 'regulatory burden' imposed under the Act.[60] In contrast if the product was cancelled it would still be subject to regulation under the Act and it would become unlawful to import, manufacture, supply or advertise the goods.

2.51 Under this proposed power the Secretary could only remove the goods from the Register after giving the affected person notice of a proposal to remove a good and give them the opportunity to make submissions in relation to the proposal. The Secretary must take account of the submissions in their decision and any decision to

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

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

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

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

58 See Therapeutic Goods Amendment (2013 Measures No.1) Bill 2013, Schedule 3, Item 5.

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

60 Department of Health and Ageing, Therapeutic Goods Administration, answer to written questions on notice (received 28 May 2013), p. 19.

remove a good would be subject to internal review and review by the Administrative Appeals Tribunal.[61]

2.52 Medicines Australia were supportive of the amendments generally, including of this provision, however they emphasised:

> that sponsors must be informed, and have an opportunity to respond, before a product is removed from the register under the proposed s 9F(3) of the Act.[62]

2.53 Other submitters also expressed their support for the Secretary's new power:

> This will be important in particular for medicines listed in the Register under section 26A of the Act on the basis of certifications made by the applicant, where the electronic listing process does not involve pre-market scrutiny by the TGA…The amendment will also allow the Secretary to remove a product that may have come within the definition when it was included but no longer does so, for instance where claims about its therapeutic use are no longer being made.
>
> This amendment is supported by ADIA.[63]
>
> …
>
> There is currently limited capacity to remove products from the Register…the provision of this additional capacity to the Secretary is a valuable addition in maintaining the quality of the Register. This can only strengthen the reassurance that the application of the Act can provide.[64]

2.54 Mr Kentwell, however, expressed some concerns in relation to the new power, largely in relation to its necessity:

> The procedures for removal generally mirror the existing procedures at subsection 30(3) and (4), "Cancellation of registration or listing".[65]

2.55 The department's response to Mr Kentwell's concern drew attention to the difference between the 'removal' of a good and the 'cancellation' of a good from the Register:

> The power to remove products from the Register is quite separate from the existing powers under the Act to cancel goods from the Register about which there are safety, quality or efficacy issues. Such goods do not stop being therapeutic goods and remain regulated under the Act as therapeutic goods.[66]

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

62 Medicines Australia, *Submission 6*, p. 2.

63 Australian Dental Industry Association, *Submission 4*, p. 6.

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

65 Mr Doug Kentwell, *Submission 7*, p. 6.

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

Advertising

2.56 As the Act now stands sections 25, 26 and 26A make reference to factors that the Secretary must take into account when evaluating an application to register therapeutic goods in the Register. Included is a requirement for the Secretary to make an assessment of whether a good is conforming to an applicable standard and whether it is compliant with any other requirements related to advertising as found under Part 5-1 of the Act or Regulations.[67] The level of compliance with these advertising standards and requirements are also factors which the Secretary must consider in determining whether to suspend or cancel a good or when requiring information or documents to be provided in relation to a good.

2.57 Although the Therapeutic Goods Advertising Code (the Code) is referred to in Part 5-1 of the Act, the requirement for advertising of a good to comply with the Code is not stated specifically in section 25. To ensure that there is no doubt about the relevance of the Code under the proposed legislation amendments would be made to Section 25(1) which would 'clarify that a reference to advertising requirements includes a reference to the Code.'[68]

2.58 Both Mr Kentwell and the CHC expressed concern that these amendments would effectively be a 'broadening'[69] of the power of the Secretary to cancel products. They were also concerned that the specification of the Code in this section would introduce 'doubt and uncertainty' due to the fact that 'elements of the code can be subject to very broad interpretation.'[70]

2.59 The department in response stated that

> The amendments in Schedule 1 in the Bill do not make any changes to the Therapeutic Goods Advertising Code (the Code) and are not 'substantive changes'.[71]
>
> …
>
> The effect of the amendments contained in Schedule I of the Bill is to make absolutely clear that the reference to "any requirements relating to advertising applicable under Part 5-1 (of the TG Act) or under the regulations" where it appears in the TG Act for these purposes includes a reference to the Code.
>
> The proposed changes in Schedule I of the Bill therefore do not add to the current powers relating to advertising, but serve to put beyond doubt the

67 Explanatory Memorandum, p. 7.

68 Explanatory Memorandum, p. 7.

69 Complementary Healthcare Council of Australia, *Submission 8*, p. 8.

70 Mr Doug Kentwell, *Submission 7*, pp. 4–5.

71 Department of Health and Ageing, Therapeutic Goods Administration, answer to written questions on notice (received 28 May 2013), p. 8.

existing requirements in relation to advertising requirements including the Code.[72]

2.60 It is noted that as part of the ongoing reform process as articulated in *TGA reforms: A blueprint for TGA's future* (the Blueprint) the TGA is undertaking consultation with stakeholders on the recommendations for advertising reform outlined in the *Advertising Regulatory Framework – Options for Reform* report and will provide advice to Government on the outcomes of this consultation process.[73]

Provision of information to the Secretary

2.61 The Secretary under the Act has a range of information-gathering powers used to assist in making relevant regulatory decisions such as:

- whether to include a product in the Register;
- whether to cancel or suspend a product from the Register; or
- whether to place conditions on a product in order to ensure compliance with regulatory requirements and standards. [74]

Failure to provide information

2.62 In the current legislation the Secretary has the power to cancel listed or registered goods from the Register where a sponsor has failed to provide information requested by the Secretary about these goods.[75] However as the Act now stands this power, under section 30, has been restricted to requests for information about complementary medicines (those medicines listed under section 26A).[76]

2.63 Under the proposed legislation, section 30(2) of the Act would be amended so that the Secretary would be able to apply this power to 'all instances where a section 31 request for information is made (in relation to, for example, other classes of medicines and therapeutic devices) and the sponsor fails to provide the required information within the timeframe set by the Secretary.'[77] This power would be 'in line with the Secretary's existing powers in relation to requests made to sponsors for

72 Department of Health and Ageing, Therapeutic Goods Administration, answer to written questions on notice (received 28 May 2013), pp. 8–9.

73 Department of Health and Ageing, Therapeutic Goods Administration, *Delivering reforms - Implementation plan for TGA Reforms: A blueprint for TGA's future*, http://www.tga.gov.au/about/tga-reforms-blueprint-implementation-04-attachmenta.htm

74 Department of Health and Ageing, Therapeutic Goods Administration, *Submission 5*, pp. 7–8.

75 It is also an offence to not comply with a request for information from the Secretary under subsection 31(4) of the Act.

76 Department of Health and Ageing, Therapeutic Goods Administration, *Submission 5*, p. 8.

77 Department of Health and Ageing, Therapeutic Goods Administration, *Submission 5*, p. 8.

information about biologicals and medical devices where the sponsor has not complied.'[78]

2.64 Mr Kentwell expressed concern that the existing and proposed time-frames in relation to the provision of requested information were not 'liberal' enough and would be difficult for multi-national drug companies to comply with.[79]

2.65 The department in their response articulated that the Secretary has discretion in nominating timeframes that relate to requests for information, as well as discretion in deciding whether or not to cancel a good from the Register. The department also made reference to the Secretary's obligations under the cancellation power and the fact that there are review processes available:

> …the exercise of the proposed power to cancel is predicated on the Secretary giving the sponsor notice of a proposal to cancel and the opportunity to make submissions in response (see subsection 30(3) of the TG Act) which the Secretary must take into account before making any final decision (see subsection 30(4) of the TG Act). Any cancellation decision is subject to internal review and review by the Administrative Appeals Tribunal (see section 60 of the TG Act).[80]

Providing information in relation to certifications associated with listed products

2.66 Under the current legislation

> 'listed medicines are included on the Register via a low-cost and streamlined electronic application and validation process (ELF). At the time of listing it is the sponsor's responsibility to certify that its product complies with the requirements of the TG Act. If the sponsor certifies this on ELF, and the application fee has been paid, the medicine will be included on the Register.' [81]

2.67 These certifications include:

- that the product is eligible for listing i. e. it only includes certain ingredients the quality and safety of which have been considered by the TGA;
- that only low level claims are made in relation to the medicine;
- that the presentation of the medicine is not unacceptable;

78 Department of Health and Ageing, Therapeutic Goods Administration, answer to written questions on notice (received 28 May 2013), p. 17.

79 Mr Doug Kentwell, *Submission 7*, p. 13.

80 Department of Health and Ageing, Therapeutic Goods Administration, answer to written questions on notice (received 28 May 2013), p. 18.

81 Department of Health and Ageing, Therapeutic Goods Administration, answer to written questions on notice (received 28 May 2013), p. 22.

- that the medicine complies with applicable standards and advertising requirements; and
- that the sponsor holds evidence to support the claims made in relation to the product.[82]

2.68 Currently the Secretary only has the power to request information and documents in relation to one of these certifications i.e. 'that the sponsor holds evidence to support the claims made in relation to the product'.[83]

2.69 Under the proposed legislation the Secretary would have this power broadened in order to be able:

> '…to request information and documents from the sponsors of listed medicines about any of the certifications made by the sponsor at the time of the listing of a medicine in the Register…'[84]

and come to a view about whether the product complies with the regulatory requirements.[85]

2.70 CHC were concerned that the proposed amendment was in fact a new power to delist a product from the register if certifications were incorrect.

2.71 In their response the department sought to alleviate these concerns stating that

> The Secretary already has a power under paragraph 30(2)(ba) of the TG Act to suspend/cancel goods from the Register if it appears to her that certifications made at the time the goods were included in the Register are incorrect.[86]

'Effective' applications

2.72 Under the current legislation section 23 sets out the procedures and requirements that must be complied with when applying for the registration or listing of therapeutic goods in the Register. In order for an application to be 'effective':

- all the required kinds of information must be provided;
- all the information must be provided in the appropriate form;

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82 Department of Health and Ageing, Therapeutic Goods Administration, answer to written questions on notice (received 28 May 2013), p. 22.

83 Department of Health and Ageing, Therapeutic Goods Administration, answer to written questions on notice (received 28 May 2013), pp. 22, 23.

84 Department of Health and Ageing, Therapeutic Goods Administration, answer to written questions on notice (received 28 May 2013), p. 23.

85 Department of Health and Ageing, Therapeutic Goods Administration, answer to written questions on notice (received 28 May 2013), p. 23.

86 Department of Health and Ageing, Therapeutic Goods Administration, answer to written questions on notice (received 28 May 2013), p. 23.

- the application fee must have been paid; and
- if applicable the product information and any samples must be provided.[87]

A 'non-effective' application would result if one or more of the above elements was not provided as part of the application.

2.73 Depending on the type of product, 'different kinds and amounts of information'[88] may be required as part of the application process, in order for the Secretary to assess the application and make an appropriate determination. If this information is not provided with the application, the application itself is taken not to be 'effective' and cannot be evaluated.[89]

2.74 Currently the requirements are that such information needs to be provided 'in a form approved, in writing, by the Secretary, as will allow the determination of the application'.[90] Similar requirements exist in section 9D in relation to apply for variations to entries in the Register.

2.75 The proposed amendments to sections 9D and 23 would specify that the kind of information required by the Secretary would be that 'of the kind specified in a legislative instrument made by the Secretary for the purposes of this paragraph.'[91] The requirement to have this information in an approved form would remain.

2.76 Mr Kentwell articulated his suspicions in relation to this proposed amendment, noting industry 'dissatisfaction' with the application process for registration of a prescription medicine and their perception that it:[92]

> …amounts to a mini evaluation with the object of rejecting up-front any applications that may ultimately be rejected after a full evaluation and thus attract appeal rights under section 60….It may well be that this proposed amendment has been prompted by TGA fear that a legal challenge may be forthcoming and that bolstering the legislation in this manner may afford the regulator additional protection.[93]

2.77 Mr Kentwell went on to recommend that:

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87 *Therapeutic Goods Act 1989*, Section 23

88 Explanatory Memorandum, p. 60.

89 Department of Health and Ageing, Therapeutic Goods Administration, answer to written questions on notice (received 28 May 2013), p. 18.

90 *Therapeutic Goods Act 1989* Section 23(2)(b).

91 See Therapeutic Goods Amendment (2013 Measures No.1) Bill 2013, Schedule 16, Items 1 and 2.

92 Mr Doug Kentwell, *Submission 7*, p. 14.

93 Mr Doug Kentwell, *Submission 7*, p. 14.

> Appropriate amendments be made to section 23 and 60 to ensure that a right of appeal under section 60 is available where an application under section 23 is deemed to be "not effective."'[94]

2.78 It is important to note however that section 23 relates to the 'effectiveness' of an application and does not relate to the 'evaluation' of goods which are the subject of an application. Sections 25, 26, and 26A would apply in this instance.

2.79 It is also of note that under section 23 of the Act the Secretary does not make the decision in relation to an application's effectiveness and as such there is no provision for review under section 60. Existing processes under the *Administrative Decisions (Judicial Review) Act 1977* would apply if a review process was sought in relation to a non-effective application.

2.80 The department further indicated in their response to Mr Kentwell's concerns that the proposed amendments do not apply to 'issues dealing with applications not being "effective"' [95] and are only intended to:

> 'clarify the circumstances in which (and how) the Secretary approves the kind of information that must be provided for an application to be effective under those sections of the TG Act.'[96]

Committee view

2.81 The committee is of the view that it is important that any regulatory decisions made by the Secretary are fully informed by accurate information and is satisfied that the amendments are an essential step in ensuring that therapeutic goods are dealt with in a way that best serves to protect public health and safety.

Right to merits review

2.82 Under the current legislation the Act provides for a right to merits review of decisions relating to the approval of Product Information (PI) – 'a document that must be provided with particular kinds of medicines – mainly prescription and "pharmacist only" medicines.'[97] PI documents are required to undergo assessment by the TGA as part of the approval process for the medicine and should contain information such as:[98]

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94 Mr Doug Kentwell, *Submission 7*, p. 15.

95 Department of Health and Ageing, Therapeutic Goods Administration, answer to written questions on notice (received 28 May 2013), p. 18.

96 Department of Health and Ageing, Therapeutic Goods Administration, answer to written questions on notice (received 28 May 2013), p. 18.

97 Department of Health and Ageing, Therapeutic Goods Administration, answer to written questions on notice (received 28 May 2013), p. 12.

98 Department of Health and Ageing, Therapeutic Goods Administration, answer to written questions on notice (received 28 May 2013), p. 12.

> …the indication/s (i. e. what the medicine is to be used for), dosage and administration, composition, the medicine's contraindications (i. e. when the medicine must not be used) and any particular information and precautions concerning its use including its interactions with other medicines and adverse effects. It also contains information about the pharmacology and pharmacological actions of the medicine, clinical trials related to the indications, symptoms, signs and recommended treatment of overdose or accidental poisoning, presentation (dosage form, quantity, proportion or strength of each therapeutically active ingredient, container type, pack size etc) and storage conditions, the name and address of the sponsor and the relevant schedule of the Poisons Standard of the substance in the medicine.[99]

2.83 Although the proposed legislation would clarify that the approval by the Secretary of PI for a medicine is a separate decision to the Secretary's decision approving a medicine's registration or variation, the PI is evaluated at the same time and as part of the evaluation of the application for registration or variation of the medicine.[100]

> The content of the product information is a critical element of the process by which the Secretary forms her view that the medicine can be registered on the basis that it satisfies the relevant statutory criteria or, as proposed to be varied, can continue to be registered.[101]

2.84 Under the proposed legislation section 60 of the Act would be amended[102] to remove the right to a specific merits review process for decisions made in relation to PI. The merits review process would still remain available for decisions made by the Secretary in relation to a medicine's registration or variation.

2.85 The department justified the proposed removal of the PI merits review process stating that was necessary in these instances:

> …because a decision to approve, or to approve a variation to, PI is an integral part of the decision by the Secretary to register the medicine to which the PI relates or to approve a variation to that medicine's entry in the Register.[103]
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> …

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99 Department of Health and Ageing, Therapeutic Goods Administration, answer to written questions on notice (received 28 May 2013), p. 12.

100 Department of Health and Ageing, Therapeutic Goods Administration, answer to written questions on notice (received 28 May 2013), p. 14; See Explanatory Memorandum, p.30 regarding Schedule 5, Item 10.

101 Department of Health and Ageing, Therapeutic Goods Administration, answer to written questions on notice (received 28 May 2013), p. 14.

102 See Therapeutic Goods Amendment (2013 Measures No.1) Bill 2013, Schedule 5, Item 10.

103 Explanatory Memorandum, Statement of Compatibility For a Bill That Raises Human Rights Issues, p. 4.

> As the product information approved by the Secretary will reflect the decision of the registration or variation decision of the Secretary (which is amenable to review) any concerns with the PI can effectively be addressed through a review of the registration or variation decision.[104]

2.86 They also stated:

> There is also a concern that if the approval of product information were to be the subject of a separate right to merits review, a situation could arise whereby product information is altered through the merits review process and, as a result, contains information that is inconsistent with the basis upon which the goods were considered by the delegate of the Secretary to be suitable for registration including, in particular, in relation to its safety, quality and efficacy and/or does not accurately describe the basis on which the delegate came to the view that it could be safely prescribed or used for the purposes approved by the delegate.
>
> In such circumstances, there would not appear to be a mechanism to amend or revisit the decision as to the registration of the medicine. Such an outcome could be confusing for prescribers, and could potentially pose a threat to the health of patients.[105]

2.87 The removal of the PI merits review process and the department's justification, as articulated in the explanatory memorandum,[106] was of concern to Mr Kentwell:

> I do not accept the rationale advanced to justify the exclusion of merits review of a decision under 25AA approving the Product Information (PI).[107]…This would appear to be a retrograde step in the context of open and transparent decision making.[108]

Committee View

2.88 The committee understands the argument put by the department. It is important that anyone wishing to have a decision in this area reviewed has clearly explained to them that they have access to merits review that extends to the substance of matters included in PI, even if the PI decision itself is not reviewable.

2.89 The Parliamentary Joint Committee on Human Rights has also raised similar concerns in relation to the proposed amendments to section 60 (see Chapter 1). They will be seeking clarification of this issue from the Parliamentary Secretary for Health

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104 See Explanatory Memorandum, p. 30, regarding Schedule 5, Item 10.

105 Department of Health and Ageing, Therapeutic Goods Administration, answer to written questions on notice (received 28 May 2013), p. 13.

106 Explanatory Memorandum, p. 30, regarding Schedule 5, Item 10; Explanatory Memorandum, Statement of Compatibility For a Bill That Raises Human Rights Issues, pp.4–6.

107 Mr Doug Kentwell, *Submission 7*, p. 1.

108 Mr Doug Kentwell, *Submission 7*, p. 4.

and Ageing and reporting on the response in due course. This committee notes that, should the Parliamentary Joint Committee on Human Rights still have concerns, it will draw these to the Senate's attention.

Recommendation 2

2.90 The committee recommends that the Senate consider any findings or recommendations made by the Parliamentary Joint Committee on Human Rights in respect of amendment of section 60.

Publication of regulatory decisions

2.91 Under the current legislation the Secretary must publish certain regulatory decisions made under the Act in the Australian Government Gazette.

2.92 Under the proposed legislation the Secretary will have the option to publish these regulatory decisions in either the Australian Government Gazette or the TGA website, or in both, if that is considered appropriate.[109]

2.93 ADIA was not supportive of the amendment particularly as they understood from the explanatory memorandum that the website was to be considered preferable to the Gazette.[110]

> Although ADIA is supportive of the TGA publishing its decisions on its website, ADIA believes that in the interest of transparency and good regulatory process, such decisions should also be featured in the Australian Government Gazette.[111]

2.94 In response the department stated:

> Publication on the TGA's website (noting that the TGA is a division of the Department of Health and Ageing) ensures maximum accessibility for consumers, industry health care professionals and the public to the information. There is also a cost to the TGA for publishing decisions in the Gazette (paid for by industry as the TGA operates on a 100% cost recovery basis). Publication on the TGA's website is designed to provide the public with an easier, and more familiar, way of accessing information about regulatory decisions than through the Gazette. There is nothing to prevent the decisions being published in both, if that is considered appropriate.[112]

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109 There are currently only four collective areas where publication in the Gazette only will continue – these involve subsections 18A(10); 32CF(1); 41GW(1); 30F(4); 32CJ(4); 16(2), (3) and (3A) of the Act. Department of Health and Ageing, Therapeutic Goods Administration, answer to written questions on notice (received 28 May 2013), pp. 4–5; Explanatory Memorandum, pp. 51–52.

110 Australian Dental Industry Association, *Submission 4*, p. 8; Explanatory Memorandum, p. 52.

111 Australian Dental Industry Association, *Submission 4*, p. 8.

112 Department of Health and Ageing, Therapeutic Goods Administration, answer to written questions on notice (received 28 May 2013), pp. 4–5.

2.95 Although the proposed amendments would provide the Secretary with the publication options for 'almost all provisions in the Act that currently require, or authorise the Secretary to publish information or the particulars of regulatory decisions'[113] it was noted that the option did not extend to the Secretary's new powers under proposed Section 9F with respect to a 'notice of removal'. The proposed legislation would require that the publication of such a notice would be on the TGA website only.[114]

2.96 Mr Kentwell whilst supporting the publication of the 'notice of removal' sought to:

> …include the requirement that where the Secretary's decision is overturned on appeal that an appropriate notice setting out the particulars of the outcome of the appeal and reinstatement of the good of the Register is also published on the Department's website.[115]

He also felt that there should be a similar requirement in circumstances where the Secretary's decision to cancel a therapeutic good was overturned.

2.97 In response to Mr Kentwell's proposal the department acknowledged:

> …that there is no obligation on the Secretary to ensure that particulars of the overturning of a decision to remove the product from the Register (for instance on internal review or by the Administrative Appeals Tribunal) is also published, the Department notes that there is no current obligation on the Secretary under the TG Act to publish in the Gazette outcomes of such reviews where the Secretary is obliged to publish particulars of the original decision in the Gazette.[116]

2.98 The department also indicated that this was also the case for particulars of the overturning of a decision in relation to the cancellation of a good from the Register. However they indicate that:

> …as part of the Blueprint reforms currently being implemented, the TGA is considering the wider publication of information about its regulatory decisions which would include providing information about the outcome of reviews of such decisions.[117]

Committee view

2.99 The committee notes two issues, one specific, and one of broader importance.

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113 Explanatory Memorandum, pp. 51–52.

114 Therapeutic Goods Amendment (2013 Measures No.1) Bill 2013, Schedule 3, Item 5

115 Mr Doug Kentwell, *Submission 7*, p. 6.

116 Department of Health and Ageing, Therapeutic Goods Administration, answer to written questions on notice (received 28 May 2013), pp. 11, 16.

117 Department of Health and Ageing, Therapeutic Goods Administration, answer to written questions on notice (received 28 May 2013), pp. 11, 16.

2.100 The committee is unsure why the proposed 'notice of removal' power would be the only one for which gazettal is not an option (in contrast to others where there is a choice between Gazette and website).

Recommendation 3

2.101 The committee recommends that the bill be amended to align the publication options between proposed section 9F and other existing provisions in the Act.

2.102 The committee seeks clarification of a broader issue about the permanence of records, relevant to these provisions in the Act and in other government legislation. The committee supports web-based publication of information as a means that has the advantage of timeliness and widespread, easy accessibility.

2.103 However, websites do not create a permanent record in the way that the Gazette does. It is not clear how superseded orders or regulatory actions, for example, might be found if they are removed from the website. In contrast, previous government gazettes can always be examined.

2.104 The committee seeks an undertaking from the government that there will be an equally permanent (and public) record of decisions published on the TGA's website as there is for those published in the Gazette.

Consultation on the Bill

2.105 There was concern expressed in relation to the lack of consultation with industry and consumer stakeholders prior to the release of the Bill. ADIA was particularly concerned that 'the first opportunity that industry had to discuss the proposed legislative amendments was on 26 March 2013… some six days after the Bills were presented to parliament' and indicated that the Bill:

> …constitutes a response to several major reviews of therapeutic goods regulation that were undertaken in 2010 and 2011 and addresses matters from product regulatory standards, advertising, promotion and transparency. It would have been possible, and indeed desirable, to deal with the proposals before the parliament as part of, rather than separate from, that series of reforms. ADIA is confident that if this had been the case, proper industry consultation could have been undertaken.[118]

2.106 Medicines Australia also suggested that more consultation would have been welcome and urges that this be a future consideration:

> Industry has consistently supported a transparent and consultative approach to regulatory reform. Industry welcomes advance notification or

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

> consultation prior to introduction of future legislation into the Parliament.[119]

2.107 In their response the department noted that:

> Consultation was not undertaken in relation to the Bill, as the amendments in it are principally designed to clarify the operation of a number of existing provisions in the TG Act, or ensure that various requirements in the TG Act are more consistent, and better aligned across the different types of therapeutic goods, rather than introducing new policy measures or implementing any of the reforms the Government is currently considering in relation to therapeutic goods.
>
> There is extensive stakeholder and public consultation being undertaken in relation to the current reform proposals on medical devices and complementary medicines. There will also be consultation undertaken in relation to proposals relating to advertising reforms.[120]

Conclusion

2.108 The committee is supportive of the bill and the improvements it is designed to achieve. The complexity of some of the provisions, and the confusion they have elicited amongst (often experienced) stakeholders, indicate the importance of appropriate consultation on bills prior to the introduction to parliament, where at all possible, particularly in those cases where legislative timelines are comparatively tight.

2.109 The committee has noted its concerns in respect of proposed section 7AA and amendments to section 60, and refers the Senate to any findings or recommendations of the Scrutiny of Bills and Human Rights committees.

Recommendation 4

2.110 Subject to the preceding recommendations, the committee recommends that the bill be passed.

Senator Claire Moore

Chair

119 Medicines Australia, *Submission 6*, p. 3.

120 Department of Health and Ageing, Therapeutic Goods Administration, answer to written questions on notice (received 28 May 2013), p. 4.

APPENDIX 1

Submissions and Additional Information received by the Committee

Submissions

1 Australian Orthopaedic Association

2 NSW Government

3 Australian Medical Association

4 Australian Dental Industry Association

5 Department of Health and Ageing

6 Medicines Australia

7 Mr Doug Kentwell

8 Complementary Healthcare Council of Australia

9 Generic Medicines Industry Association

10 Australian Commission on Safety and Quality in Health Care

11 Northern Territory Government

Answers to Questions on Notice

1 Answers to Questions on Notice received from Department of Health and Ageing, 28 May 2013

2 Answers to Questions on Notice received from Department of Health and Ageing, 12 June 2013