The Senate

# Community Affairs Legislation Committee

## Therapeutic Goods Amendment (2016 Measures No. 1) Bill 2016 [Provisions]

March 2017

ISBN 978-1-76010-546-4

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This document was produced by the Senate Community Affairs Committee Secretariat and printed by the Senate Printing Unit, Parliament House, Canberra.

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## 45th Parliament

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| | |
|---|---|
| Senator Richard Di Natale | Victoria, AG |

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# ABBREVIATIONS

| | |
|---|---|
| ARTG | Australian Register of Therapeutic Goods |
| ADIA | Australian Dental Industry Association |
| CHF | Consumers Health Forum of Australia |
| MBS | Medicare Benefits Schedule |
| MMDR | Expert Panel Review of Medicines and Medical Devices Regulation |
| MTAA | Medical Technology Association of Australia |
| TGA | Therapeutic Goods Administration |

# LIST OF RECOMMENDATIONS

**Recommendation 1**

**2.55 The committee recommends that the Bill be passed.**

# Chapter 1

# Introduction

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

## Objectives of the Bill

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

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

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

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

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

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

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

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

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

## Conduct of the inquiry

1.7 In accordance with its usual practice, the committee advertised the inquiry on its website and wrote to relevant individuals and organisations inviting submissions to the inquiry by 3 March 2017.

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

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

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

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

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

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

## Note on references

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

## Summary of the Bill

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

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

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

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

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

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

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

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

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

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

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

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

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

## Legislative scrutiny

### *Senate Standing Committee for the Scrutiny of Bills*

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

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

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

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

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

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

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

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

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

***Parliamentary Joint Committee on Human Rights***

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

# Chapter 2

## Issues

2.1 The Bill was referred to this committee by the Selection of Bills committee following concerns that critical details about implementation of the Expert Panel Review of Medicines and Medical Devices Regulation (MMDR) recommendations would be included only in delegated legislation.

2.2 It is important to note, however, that the overwhelming majority of the 44 submissions to the inquiry have supported both the MMDR and the Bill. Support for the Bill has been expressed by organisations representing a wide range of stakeholders, including:

- consumer groups;[1]
- medicine and medical device sponsors and their industry bodies;[2]
- practitioners/prescribers of medicines, medical devices and other therapeutic goods and their representative groups;[3] and
- the Australian Nuclear Science and Technology Organisation (ANSTO) and the Prostheses List Advisory Committee.[4]

2.3 The issues that were raised by submitters could be categorised as:

- ensuring a balance between faster access to new medicines and technologies and safety;
- ensuring wide consultation on the detail of any regulations and transparency in their implementation; and

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1 Melanoma Patients Australia, *Submission 5*; ACON, *Submission 10*; Australian Federation of AIDS Organisations and the National Association of People with HIV Australia, *submission 15*; Haemophilia Foundation of Australia, *Submission 19*; Rare Cancers Australia, *Submission 25*; and Consumers Health Forum, *Submission 27*.

2 AusBiotech, *Submission 3*; Roche Products, *Submission 4*; IVD Australia, *Submission7*; Medical Technology Association of Australia, *Submission 8*; Novartis, *Submission 9*; Complementary Medicines Australia, *Submission 11*; Biotronik Australia Pty Ltd, *Submission 12*; Pfizer Australia, *Submission 14*; Merck Sharp and Dohme, *Submission 18*; Australian Medical Device Manufacturers and Distributers, *Submission 20*; Medicines Australia, *Submission 21*; Swisse Wellness, *Submission 23*; Stryker, *Submission 24*; Cancer Drugs Alliance, *Submission 26*; Medtronic Australasia Pty Ltd, *Submission 28*; Bristol-Myers Squibb Australia, *Submission 29*; Australian Self Medication Industry, *Submission 30*; Generic and Biosimilar Medicines Association Australia, *Submission 34*; Glaxo Smith Klein, *Submission 35*; Johnson and Johnson Pty Ltd, *Submission 37*; and Cochlear Ltd, *Submission 42*.

3 Australasian Society for HIV, Viral Hepatitis and Sexual Health Medicine, *Submission 1*; Australasian Tuberculosis Forum, *Submission 2*; Pharmaceutical Society of Australia, *Submission 6*; and Day Hospitals Australia, *Submission 13*.

4 ANSTO, *Submission 33*; and Prostheses List Advisory Committee, *Submission 16*.

- ensuring sufficient resources to implement the proposed changes, in particular in relation to post-market monitoring.

2.4 Concerns about the use of regulations to implement proposed changes to therapeutic goods administration will be considered first, followed by consideration of the issues raised by submitters.

## Use of regulations

2.5 The senators who sought referral of this Bill to the Community Affairs Committee recognised that regulation of therapeutic goods in Australia is a complex system and the Bill relegates considerable detail to subsidiary legislation which is yet to be drafted.[5]

2.6 The Department of Health has indicated that there will be two Bills (the Bill under consideration in this report, and a bill to be introduced later this year) and there will be two tranches of therapeutic goods regulations.[6]

2.7 In this first Bill, the key proposed regulations relate to:

- allowing variations of entries to the Australian Register of Therapeutic Goods (ARTG) to be made by notification (Schedule 1);
- enabling the Secretary to designate Australian companies to undertake conformity assessments of medical devices and determining whether those assessments may be used in deciding whether medical devices should be included in the ARTG (Schedule 2);
- providing for priority applicant determinations, so that certain medicines, medical devices and therapeutic goods can be provided to patients sooner than is currently available (Schedule 6);
- allowing certain therapeutic goods that are not included in the ARTG, but which have an established history of safe use in comparable overseas countries, to be supplied to certain classes of patients without first having to seek prior approval after notifying the TGA (Schedule 3); and
- specifying the record-keeping requirements for sponsors of listed or registered medicines and medical devices (Schedule 8).

2.8 Many submissions express support for the Bill while recognising that further detail on the proposed regulations is needed. For example, in their submission, Johnson and Johnson Pty Ltd stated that:

> we anticipate receiving greater detail and have requested more information in some areas to enable a more comprehensive analysis and feedback. We expect this will be addressed when draft Regulations are issued for

5 Senate Standing Committee for the Selection of Bills, *Report*, No. 1 of 2017, Appendix 5.

6 Adjunct Professor John Skerritt, Deputy Secretary, Department of Health, *Committee Hansard*, 17 March 2017, p. 24.

consultation. The availability and design of the draft Regulations will determine the successful implementation of the MMDR recommendations.[7]

2.9 The Department of Health has articulated the reasons for implementing the MMDR Recommendations in this manner. These are:

(a) consistency within the therapeutic goods regulatory scheme, where these goods are currently regulated by the *Therapeutic Goods Act 1989*, the *Therapeutic Goods (Charges) Act 1989*, the Therapeutic Goods Regulations 1990 (the Regulations), the Therapeutic Goods (Charges) Regulations 1990, and the Therapeutic Goods (Medical Devices) Regulations 2002.[8]

(b) consistency with other Commonwealth regulatory legislation, for example, the *Biosecurity Act 2015*, *Civil Aviation Act 1988* and the *Navigation Act 2012*, where details of schemes are placed in regulations rather than being included in the Act.[9]

(c) reducing complexity in the *Therapeutic Goods Act 1989*, in accordance with the Office of the Parliamentary Counsel's Guide to Reducing Complexity in Legislation.[10]

(d) enabling flexibility in the regulatory scheme, to allow for changes in the first years of operation of new schemes (for example, Schedule 2 conformity assessments of medical devices, and Schedule 6 priority assessments of therapeutic goods), and also to enable changes to for example, the list of unregistered goods that may be supplied by notification under Schedule 3.[11]

(e) facilitating public consultation, where placing some material in regulations has allowed thorough consultations with consumer and industry stakeholders to be undertaken by the TGA within the timeframe the Government committed to;[12] and

(f) the availability of disallowance provisions if the regulations are considered not to be appropriate, where the Parliament has the power to disallow regulations under section 42 of the Legislation Act 2003. [13]

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7 Johnson and Johnson Pty Ltd, *Submission 37*, p. 5. See also, for example, Ms Elizabeth de Somer, Director Policy and Research, Medicines Australia, *Committee Hansard*, 17 March 2017, p. 12.

8 Department of Health, *Submission 22*, p. 7.

9 Department of Health, *Submission 22*, p. 8.

10 Department of Health, *Submission 22*, p. 8.

11 Department of Health, *Submission 22*, p. 9.

12 Department of Health, *Submission 22*, p. 9.

13 Department of Health, *Submission 22*, p. 10.

## Delegating powers

2.10 The Scrutiny of Bills Committee also expressed concern about the proposed ability for the Secretary of the Department of Health to delegate some of his powers to 'a wide class of persons'.[14]

2.11 The Australian Dental Industry Association(ADIA), which has been a participant in the MMDR and in ongoing consultations with the Department of Health about implementation of the review's recommendations, considers that:

> an appropriate balance has been struck with respect to limiting the number of persons who exercise delegated powers and the need for the Act to afford the TGA the ability to ensure that the regulatory system for the approval of medical devices is responsive to new and innovative diagnostic treatment options.[15]

2.12 In its submission, ADIA provided data to the committee on the number of delegated decisions made by the TGA in relation to medical devices over a 12 month period, which provided the committee with a clear idea of the volume of decisions required to be made by the TGA in just one of its areas of responsibility. The ADIA further commented that:

> If such decision making was concentrated in a handful of nominated officers and members of the Senior Executive Service within the Department, the numbers of decisions to be made would represent an excessive and supererogatory burden on those charged with this responsibility.[16]

## Committee view

2.13 The committee notes that the majority of submissions and evidence from stakeholders support the proposed amendments in the Bill in principle. Little detail is known about the specific details that would be contained in the subsequent regulations.

2.14 As the Department of Health has noted, however, it has sought to maintain consistency with its own and other regulatory systems in planning and developing this Bill and the proposed regulations.

2.15 The committee also notes that the Department of Health is attempting to balance the need for certainty which many stakeholders seek and the need for flexibility in responding to changes in the environment in which medicines and medical devices are regulated.

2.16 The committee awaits with interest the Minister for Health's response to the Scrutiny of Bills Committee's questions in relation to the Bill.

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

15 Australian Dental Industry Association, *Submission 44*, p.18.

16 Australian Dental Industry Association, *Submission 44*, p.18.

2.17 However, the committee is of the view that the balance that the Department of Health has managed between certainty and flexibility through the use of regulations is acceptable to the great majority of stakeholders.

## Balancing public safety and improved access to therapeutic goods

### *New priority pathways for therapeutic goods*

2.18 The amendments in Schedule 6 establish the foundations for priority approval of therapeutic goods.

2.19 The majority of submissions support the changes to facilitate approval of medicines and medical devices. AusBiotech commented that:

> The new framework for allowing some breakthrough medicines and medical devices to be evaluated more quickly is intended to provide faster access to market (and care of patients) without lowering the standard of scrutiny. This is attractive to consumers, health professionals and industry and for example could reduce the evaluation time for some medicines from a maximum of 255 working days to 150 working days.[17]

2.20 Key consumer groups that may benefit from the proposed changes have strongly supported for the Bill. For example, the submission from the Haemophilia Foundation of Australia makes the observation that:

> Having a process to fast-track access to new treatments like these would be of great benefit to people with bleeding disorders in Australia, not only for improved quality of life but also for their clinical benefit in preventing bleeding episodes, each one of which may be life- or limb-threatening.[18]

2.21 However, the Royal Australasian College of Physicians (RACP) notes that:

> New priority approval pathways for the registration of medicines or medical devices must not be developed at the expense of patient safety. Faster access to medicines and medical devices comes with significant implications, and a considered and at times slower approach can have advantages as it allows for more rigorous evaluation of medicines and medical devices in a real-world setting, as opposed to the homogenous setting of the clinical trial.[19]

2.22 The RACP cited examples where medicines have been approved through a priority process in another jurisdiction and were subsequently found to be unsafe. However, the RACP also praised the TRG's current systems, and suggests that these current systems have worked to prevent such errors.[20]

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17 AusBiotech, *Submission 3*, [p. 2].

18 Haemophilia Foundation of Australia, *Submission 19*, p. 2.

19 Royal Australasian College of Physicians, *Submission 43*, p. 1.

20 Royal Australasian College of Physicians, *Submission 43.1*, p. 3.

2.23 The Consumers Health Forum of Australia (CHF) stressed the need to ensure that with new and faster pathways for approval of medicines and medical devices, that safety remains a priority:

> While we support streamlining processes to bring new innovative medicines and devices onto the market, we caution that it must not be at the expense of ensuring they are safe. Faster access to medicines and medical devices which turn out to be unsafe is not in anybody's interests and could have long-term cost implications for individuals and the health system. The old saying 'less haste, more speed' might be usefully applied here.[21]

2.24 While the CHF raised these concerns, it also acknowledged that the package of reforms, if implemented, would achieve the balance between access to medicines and medical devices and patient and community safety:

> We are pleased that the expert review that undertook the review of medicines and medical devices put an emphasis on patient safety and made recommendations to improve post-market monitoring and adverse-event reporting. We are also pleased that some of these measures have been picked up in the legislation before us today.[22]

2.25 The association representing medical device sponsors, the Medical Technology Association of Australia (MTAA) also stressed the importance of ensuring strong regulation for safety:

> I think the bill certainly moves towards greater scrutiny. It certainly moves towards greater safety and effectiveness. As much as I guess it would appear that we can get frustrated with too much regulation or overregulation sometimes, the reputations of all companies that provide medical devices stand or fall on outcomes for patients. So it is critical that those are overseen.[23]

2.26 Similarly, the association representing medicines sponsors, Medicines Australia, pointed to the strengthening of measures to protect patients and consumers:

> With regard to improvements in postapproval monitoring, the bill enables the TGA to introduce further enhancements to the existing postmarket monitoring surveillance scheme for medicines. For example, some of the enhancements to postmarket monitoring will identify very clearly to health professionals and consumers that a new medicine has been approved under an expedited pathway and therefore will be subject to specific monitoring by the TGA.[24]

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21 Ms Josephine Root, Policy Manager, Consumers Health Forum, *Committee Hansard*, 17 March 2017, p. 6.

22 Ms Josephine Root, Policy Manager, Consumers Health Forum, *Committee Hansard*, 17 March 2017, p. 6.

23 Mr George Faithfull, Medical Technology Association of Australia, *Committee Hansard*, 17 March 2017, p.16.

24 Ms Elizabeth de Somer, Director Policy and Research, Medicines Australia, *Committee Hansard*, 17 March 2017, p. 10.

2.27 However, the CHF expressed concerns that the proposed post-market monitoring reforms, which in principle provide a way to identify safety issues, do not address all of CHF's concerns:

> We do not think it is the complete picture, but it certainly, if you like, takes some important steps in terms of record keeping and the need to report things, which is the first step. So it is how well it is done. It is not just what we are going to do but what, in effect, happens, how they are going to report on what they do and the transparency of the outcomes. I think this bill as it currently stands does not deal with some of that detail.[25]

2.28 In response to concerns raised by stakeholders, the Department of Health stated that the proposed new priority pathways would still necessitate the same level of scrutiny, but would simply be expedited:

> We are still using precisely the same amount of oversight. How we accelerate things is: instead of saying to our internal doctors, 'Do these in the order you have received them,' we will say, 'I am sorry'—a bit like any boss does when something is urgent—'can you spend the next week doing this one rather than doing it in the order it arrived in.'
>
> The second thing is we have panels of external clinical members of our advisory committee for medical devices plus we also have over 100 expert advisers. This is an innovation, a formal panel of over 100 expert advisers. The difference with these fast-track models is we will be consulting those people out of session. So instead of waiting for a meeting that is held every eight or nine weeks for our medicines or devices to go to external experts, they will basically be called as soon as ready to look at the data and information. So we actually do not think the amount of scrutiny will be less. In fact, if anything, because there is a pre-designation step where we will be looking at the data to see if it warrants being included in an accelerated evaluation line, it will actually have an additional cycle of review.[26]

2.29 The Department also provided further detail on not only the proposed post market monitoring in the Bill, namely, new record keeping requirements and new powers to obtain information from sponsors and distributors, but also on other areas not covered by legislation or regulation:

> When I speak about the range of things that we are doing in post-market, I guess I should re-emphasise that there are three types of things. There are things that we are specifying in the bill, and it is important to specify things like search powers and so forth or the ability to make regulations for search powers in a bill. There are some other things that are basically administrative procedures. You quoted earlier the list of things such as the

25 Ms Josephine Root, Policy Manager, Consumers Health Forum, *Committee Hansard,* 17 March 2017, p. 8.

26 Adjunct Professor John Skerritt, Deputy Secretary, Department of Health, *Committee Hansard,* Friday 17 March 2017, p. 26.

> ability to interrogate big datasets and use PBS. We do not need a bill or a regulation to do that. We are starting to do it now.[27]

## Committee view

2.30 The committee notes the concerns raised by practitioner and consumer groups in relation to the need for balancing greater or faster access to therapeutic goods with consumer safety.

2.31 The committee also notes that while concerns have been raised in relation to consumer and public safety, most submitters support the approach being taken by the Department of Health.

2.32 It is the committee's view that the stakeholders who have raised concerns in relation to this balance should continue to participate in the ongoing consultations with the Department of Health to monitor this and alert the department to any concerns they may have.

## Conformity assessments

2.33 Another measure that raised concerns for some submitters is the proposed introduction of regulations allowing Australian companies to be registered and authorised to undertake conformity assessments of medical devices under Schedule 2 of the Bill.

2.34 A range of concerns in relation to conformity assessments have been raised. These include concerns raised by Day Hospitals Australia who:

> would like to emphasize that risk management strategies should be in place with respect to the selection of "notified Bodies".
>
> Criteria for qualification, as a one of the nominated new Notified Bodies, must guarantee transparency of the assessment process, ensuring no conflict of interest with respect to the medical device, the manufacturing process and the safety of the product.
>
> It would be concerning for example, if a body that is designated as a Body which is permitted to undertake conformity assessments was under the control/direction of one or more manufacturers.[28]

2.35 Some submissions raised concerns that the TGA would remain able to undertake conformity assessments while at the same time approving and overseeing third parties to undertake the same work.[29]

2.36 However, the Prostheses List Advisory Committee submission noted that the TGA will continue in its capacity to undertake conformity assessments:

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27 Adjunct Professor John Skerritt, Deputy Secretary, Department of Health, *Committee Hansard*, 17 March 2017, p. 33.

28 Day Hospitals Australia Ltd, *Submission 13*, p.1.

29 See for example, the Medical Technology Association of Australia, *Submission 8*, and IVD Australia, *Submission 7*.

> it is essential that there is confidence that any change to the conformity assessment processes by setting up Australian Notified Bodies to carry out the assessment of medical devices maintain high levels of safety and performance. The PLAC notes that the TGA will continue to maintain capacity to carry out conformity assessments for medical devices in addition to any work by an Australian Notified Body.[30]

2.37 In response to concerns raised by stakeholders over conformity assessment bodies, the Department of Health stated:

> Most conformity assessments—indeed, some 90 per cent of conformity assessments—of medical devices or of products that enter the Australian market are currently carried out by European companies, so-called notified bodies. Now, there is oversight of those bodies by reputable, similar agencies, such as the British medicines regulator and devices regulator, or the French and German equivalents, but Australia does not have direct legal oversight of these. So, if anything, the ability to have Australian agencies, companies or university organisations, whatever they are, here that have been designated by us and have the direct legal oversight by us that we do not have with these European organisations, actually could strengthen the regulatory system, rather than weaken it.[31]

## Consultation

2.38 Most submissions welcomed the level of consultation that had been undertaken as part of the review of medical devices and medicines and the development of the Bill. The Royal Australasian College of Physicians notes the critical importance of consultation on the detail of the proposed regulations:

> the Explanatory Memorandum to this Bill promises 'extensive consultation' on the details of the new pathways for approval of medicines and medical devices. This consultation will be of great interest to us, as it concerns the core component of the Bill that will have implications for patient safety and the quality use of medicines.[32]

2.39 The representative from the CHF responded to a question about the level of consultation in relation to the current reforms being undertaken by the TRG:

> Maybe in the past we have not been that thrilled, but certainly the level of consultation on most of the provisions of this round of reforms in medicines and medical devices has been quite high. We have been quite happy with the level of consultation.[33]

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30 Professor Terry Campbell, Chair, Prostheses List Advisory Committee, *Submission 16*, p. 2.

31 Adjunct Professor John Skerritt, Deputy Secretary, Department of Health, *Committee Hansard*, 17 March 2017, p. 21.

32 Royal Australasian College of Physicians, *Submission 43*, p. 1.

33 Ms Josephine Root, Policy Manager, Consumers Health Forum, *Committee Hansard*, 17 March 2017, p. 7.

2.40 In its opening statement at the inquiry's public hearing on Friday 17 March 2017, Department of Health representatives provided an outline of the consultation that has occurred to date on the MMDR and subsequent implementation of the MMDR recommendations:

> the stakeholder forums that the expert panel has consulted with had over 200 attendees. They had 60 separate meetings with small groups and had 100 submissions to the review team. Since the release of the reports there have been about 15 stakeholder forums on various aspects of the review. As has been alluded to in other presentations, there has been, or there will be in the course of things, over 20 public consultation papers in which we will seek public feedback on options for implementation, and that is public feedback right across the spectrum from patient groups to clinicians, pharmacists, dentists, scientists, individuals and through to industry—all sorts of stakeholders.[34]

2.41 In relation to the development of regulations and associated consultations, the Department of Health has stated:

> So, I do want to emphasise that while we expect two broad sets of regulations mirroring the provisions in the respective bills and hopefully acts, there is intensive consultation and in-depth detailed consultation going on. And all of these papers are publicly available on our website.[35]

## Committee view

2.42 The committee has been impressed with the level of consultation undertaken as part of the review of medicines and medical device regulation and the Department of Health's implementation of those aspects of the review adopted by the Government.

2.43 The committee agrees that the level of support for the Bill is, at least in part, due to the extensive stakeholder consultation that has taken place over a lengthy period.

2.44 The committee encourages all stakeholders to continue to be inclusive and participate actively in the ongoing reform planning and implementation.

## Resourcing

2.45 A number of submissions and witnesses refer to concerns about the resourcing of the proposed reforms. For example, the CHF stated that:

> I guess our concern is TGA's capacity to actually do this monitoring. With the cost recovery model, it is going to fall onto industry to fund it. We

34 Adjunct Professor John Skerritt, Deputy Secretary, Department of Health, *Committee Hansard*, 17 March 2017, p. 20.

35 Adjunct Professor John Skerritt, Deputy Secretary, Department of Health, *Committee Hansard*, 17 March 2017, p. 20.

> would probably like to see, alongside the legislation, some view that TGA should in fact be funded to do some more post-market monitoring.[36]

2.46 Similarly, the MTAA also mentioned the importance of resources as part of the broader package of reforms:

> But it is just as critical that the regulations are put in place in a timely and defined fashion and are adequately resourced to enable their effective implementation and execution.[37]

2.47 In Vitro Diagnostics Australia (IVD Australia) asked the committee to recommend to the Government that the:

> TGA needs to adequately resource the Priority Review pathway so that BAU applications comprising the majority of regulatory submissions (not less than 90%) are not delayed.[38]

2.48 The committee was provided with a number of recommendations from submitters wanting to ensure that the Department of Health adequately resource the priority pathway to ensure that the current standard pathway is not slowed:

> This does not require an amendment to the legislation but is a recommendation that we would like the Committee to make to Government. The TGA needs to adequately resource the Priority Review pathway so that routine applications which form the vast majority of regulatory submissions are not delayed.[39]

2.49 In its evidence on 17 March 2017, the department indicated that the MMDR recommendation in relation to the TGA receiving:

> government appropriation funding was not rejected but the cheque has not arrived yet. They basically said, 'Look, we are doing a larger portfolio funding review in 2017-18,' so some of them were deferred to that.[40]

## Committee view

2.50 The committee notes that, as with most reforms, resourcing is a central concern for both government and stakeholders.

2.51 The committee notes that the Department of Health has been allocated resources to implement the proposed changes and is doing so within the limits set for it.

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36 Ms Josephine Root, Policy Manager, Consumers Health Forum, *Committee Hansard*, 17 March 2017, p. 8.

37 Mr George Faithfull, Medical Technology Association of Australia, *Committee Hansard*, 17 March 2017, p.16.

38 IVD Australia, *Submission 7*, p. 5.

39 Medical Technology Association of Australia, *Submission* 8, p. 3.

40 Adjunct Professor John Skerritt, Deputy Secretary, Department of Health, *Committee Hansard*, 17 March 2017, p. 30.

## Concluding view

2.52 While acknowledging the concerns identified by some submitters and witnesses, the committee also acknowledges the broad support for the proposed changes and the level of consultation that has been, and continues to be, undertaken by the Department of Health.

2.53 The committee considers that these changes to the regulation of therapeutic goods in Australia reflect a need that has been identified through ongoing engagement and consultation with key stakeholders, including consumers, and are generally considered to achieve a balance between greater access to new medicines and technologies, and consumer safety.

2.54 The committee also notes that the proposed changes reflect a balance between creating certainty for stakeholders while retaining the flexibility to adjust reasonably rapidly to a changing environment and unanticipated developments. The committee considers that the requirement for regulations to be tabled in Parliament and subject to disallowance is an appropriate check as part of achieving this balance.

**Recommendation 1**

**2.55 The committee recommends that the Bill be passed.**

**Senator Jonathon Duniam**

**Chair**

# Labor Senators' Additional Comments

1.1 While not opposing the Committee's recommendation that the Bill be passed, Labor Senators remain concerned about some aspects of the Bill and wish to note the following comments.

## Legislative approach

1.2 Labor has offered in-principle support to the recommendations of the Expert Panel Review of Medicines and Medical Devices Regulation. However, as many submitters and witnesses noted, faster access to therapeutic goods comes with significant risks that need to be carefully managed during implementation.

1.3 In this context, the Government's decision to progress a bare-bones Bill, with implementation details left to regulations that have not been drafted, makes it difficult for Senators to assess the Bill. Time and time again during the hearing on this Bill, the Department of Health and other witnesses said that Labor Senators' questions could only be answered once the regulations were available.

1.4 In essence, the Government is asking the Parliament to pass the Bill and trust that the Government will sort implementation details later. The last time this approach was adopted in the Health portfolio was on the National Cancer Screening Register Bill. Labor Senators note that the Register and the improvements to the National Cervical Screening Program that it will support have now been delayed – potentially putting women's lives at risk.

1.5 In its submission, the Department of Health notes that one argument for this legislative approach is the availability of disallowance provisions. Labor Senators reserve their right to scrutinise the eventual regulations closely, and to disallow any regulations that do not strike an appropriate balance between access and safety.

## Third party conformity assessment of medical devices

1.6 Labor Senators are particularly concerned by the Bill's lack of detail around third party conformity assessment of medical devices (Schedule 2). As the Department of Health notes in its own submission, even basic details of this process are yet to be settled:

> Details of applications for designation as conformity assessment bodies (including the criteria for becoming such a body), application forms, information that must accompany the application, processes for assessing the competence of applicant companies, information about fees, conditions that may apply in respect of a body's designation, the lapsing of applications and provision for the Secretary to revoke or vary a designation as a conformity assessment body will be set out in regulations.[1]

1.7 The Department of Health notes that conformity assessments for many of the therapeutic goods available in Australia are currently conducted by European

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1 *Submission 22*, p. 6.

regulators or third parties. Nonetheless, the shift to conformity assessments by Australian corporations is a significant one that comes with risks as well as opportunities. In light of the dangerous and high-profile failures of some implantable medical devices in recent years, Labor Senators will scrutinise regulations made under Schedule 2 of the Bill with particular rigour.

1.8 Labor Senators note that at this stage the Government appears to have ignored the Consumers Health Forum of Australia's (CHF) recommendation that third party conformity assessment be limited to lower-risk medical devices and not applied to high-risk implantable devices.

## Post-market monitoring

1.9 Labor Senators note that the inquiry demonstrated widespread support—including from industry—for stronger post-market monitoring. Submitters and witnesses argued that this was an essential complement to quickening access to medicines and devices by streamlining regulatory arrangements. For example, the CHF noted that:

> Our support for a move to a limited third party conformity assessment regime is contingent on the improvements to the post marketing [sic] arrangements…[2]

1.10 The Government states that it is implementing Recommendation 27 of the Expert Panel Review via this Bill. However, Labor Senators note that Recommendation 27 is made up of five sub-recommendations on post-market monitoring, not all of which appear to be addressed by this Bill.

1.11 Labor Senators also note that the Department of Health was unable to clarify (but has taken on notice) how much of the 2016-17 Budget measure Improving the Regulation of Therapeutic Goods in Australia will be allocated to post-market monitoring.

1.12 Labor Senators join submitters and witnesses in calling on the Government to strengthen post-market monitoring in implementing this Bill.

**Senator the Hon Lisa Singh** **Senator Murray Watt**

2 *Submission 27*, p. 5.

# APPENDIX 1

## Submissions and additional information received by the Committee

**Submissions**

**1** Australasian Society for HIV, Viral Hepatitis and Sexual Health Medicine

**2** Australasian Tuberculosis Forum

**3** AusBiotech

**4** Roche Products Pty Ltd

**5** Melanoma Patients Australia

**6** Pharmaceutical Society of Australia

**7** IVD Australia

**8** Medical Technology Association of Australia

**9** Novartis

**10** ACON

**11** Complementary Medicines Australia

**12** BIOTRONIK Australia Pty Ltd

**13** Day Hospitals Australia

**14** Pfizer Australia

**15** Australian Federation of AIDS Organisations

**16** Prostheses List Advisory Committee

**17** Research Australia

**18** Merck Sharp & Dohme

**19** Haemophilia Foundation Australia

**20** Australian Medical Device Manufacturers and Distributers

**21** Medicines Australia

**22** Department of Health

**23** Swisse Wellness

**24** Stryker

**25** Rare Cancers Australia

**26** Cancer Drugs Alliance

**27** Consumers Health Forum of Australia

**28** Medtronic Australasia Pty Ltd

**29** Bristol-Myers Squibb Australia

**30** Australian Self Medication Industry

**31** Australian and New Zealand Society for Vascular Surgery

**32** Health Consumers' Council WA

**33** Australian Nuclear Science and Technology Organisation

**34** Generic and Biosimilar Medicines Association Australia

**35** Glaxo Smith Klein

**36** Australian Traditional Medicine Society

**37** Johnson & Johnson

**38** Australian Dental Association

**39** Confidential

**40** Medical Oncology Group of Australia

**41** Australian Taxpayers Alliance and MyChoice Australia (plus three attachments)

**42** Cochlear Ltd

**43** Royal Australasian College of Physicians (plus an attachment)

**44** Australian Dental Industry Association

## Answers to Questions on Notice

**1** Answers to Questions taken on Notice during 17 March public hearing, received from Department of Health, 27 March 2017

# APPENDIX 2

## Public hearings

***Friday, 17 March 2017***

***Parliament House, Canberra***

**Witnesses**

**Royal Australasian College of Physicians**
SHENFIELD, Professor Gillian, Member
MARTIN, Professor Jennifer Helen, Member

**Consumers Health Forum of Australia**
ROOT, Ms Josephine, Policy Manager

**Medicines Australia**
ALEXANDER, Ms Susan, Chair, Regulatory Affairs Working Group
de SOMER, Ms Elizabeth, Director, Policy and Research
KARPISH, Ms Larissa, Manager, Industry and Regulatory Policy

**Medical Technology Association of Australia**
FAITHFULL, Mr George, Chair, Regulatory Sub Committee
THEISZ, Ms Val, Director of Regulatory Affairs

**Department of Health**
SKERRITT, Dr John Howard, Deputy Secretary
KELLY, Dr Lawrence, First Assistant Secretary, Medicines Regulation
DAVIS, Ms Jackie, Principal Legal and Policy Adviser