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.
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> 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