Chapter 2

Regulatory issues

Introduction

2.1 This chapter examines the role of the Therapeutic Goods Administration (TGA) in the regulation of medical devices, including how issues of global harmonisation and collaboration affect those regulatory processes. The chapter considers whether the current mechanisms for pre-market assessment and post-market surveillance of medical devices are appropriate for ensuring patient safety. The chapter scrutinises a variety of current processes, as well as proposed reforms, related to provision of clinical evidence; third party conformity assessment; the classification and level of assessment of high risk medical devices; adverse event reporting, clinical registries; remanufacturing of medical devices; and the regulation of custom-made devices

2.2 This inquiry is being conducted in a dynamic policy and legal environment. It is occurring at the same time as on-going implementation of the recommendations of the Government's Review of Health Technology Assessment (HTA) conducted in 2009.[1] The Review made a number of recommendations which 'impact on the...TGA, its interaction with other HTA agencies, and improvement of post-market programs to better inform premarket regulatory decision making'. The recommendations of the HTA review are contained in appendix 3.[2]

2.3 In response to the HTA and other reviews, the TGA issued a discussion paper, *Reforms in the Medical Devices Regulatory Framework*, in October 2010.[3] In addition, the final report of the TGA Transparency Review was released on 20 July 2011. The report raised key issues regarding the failure of the TGA to communicate adequately with stakeholders.[4] The 13 member review panel, chaired by Emeritus Professor Dennis Pearce AO, made 21 recommendations. The recommendations sought to increase stakeholder involvement in the TGA; improve information provision on the market authorisation process; and facilitate reporting to the TGA, and provision of information by the TGA, in relation to adverse events. The

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1 Department of Health and Ageing, *Review of Health Technology Assessment in Australia*, December 2009.

2 Department of Health and Ageing, Therapeutic Goods Administration, *Reforms in the Medical Devices Regulatory Framework: Discussion Paper*, 25 October 2010, p. 4.

3 Department of Health and Ageing, Therapeutic Goods Administration, *Reforms in the Medical Devices Regulatory Framework: Discussion Paper*, 25 October 2010.

4 Panel to Review the transparency of the Therapeutic Goods Association, *Review to improve the transparency of the Therapeutic Goods Administration, Final Report*, June 2011, available at http://www.tga.gov.au/pdf/consult/review-tga-transparency-1101-final-report.pdf, accessed 20 September 2011.

recommendations of the Transparency Review are contained in appendix 4. The Government is yet to respond to the recommendations of the panel.

2.4 Echoing the recommendations of the TGA Transparency Review, a consistent theme of submissions to this inquiry is the need for the TGA to improve the way that it communicates with stakeholders, and facilitates stakeholder opportunity to communicate with the TGA. This issue is raised throughout this chapter and is also addressed in chapter 4 in relation to identifying and acting upon high revision rate medical devices.

2.5 It is also of note that this inquiry is being conducted at the same time as representative class actions in the Federal Court of Australia in relation to the DePuy ASR Hip and the DePuy LCS Duofix Femoral Component.[5] Related litigation is underway in other jurisdictions.

The role of the TGA in regulating quality of devices

2.6 The TGA is a division of the Department of Health and Ageing (DoHA). The TGA stated its overall purpose is to 'protect public health and safety by regulating therapeutic goods that are supplied in, or exported from, Australia' as well as aiming 'to ensure that the Australian community has access, within a reasonable timeframe, to new therapeutic goods'.[6]

2.7 Therapeutic goods include medicines, medical devices and biological products. Any product for which therapeutic claims are made (unless exempt) must be entered in the Australian Register of Therapeutic Goods (ARTG) before it can be supplied in Australia. The TGA carries out both pre-market assessment and post-market surveillance.[7]

2.8 In order to regulate medical devices, the TGA administers the following legislation:

- Therapeutic Goods Act 1989 (the Act);
- Therapeutic Goods Regulations 1990;
- Therapeutic Goods (Medical Devices) Regulations 2002 (the Regulations); and
- Therapeutic Goods (Charges) Act 1990.[8]

5 Tammy Maree Stanford v DePuy International Limited and Johnson & Johnson Medical Pty Limited, Federal Court of Australia Proceedings No. NSD213/2011; Pamela Joan Casey v DePuy International Ltd and Anor, Federal Court of Australia Proceedings No. ACD10/2010.

6 Therapeutic Goods Administration, *Submission 18*, p. 3.

7 Therapeutic Goods Administration, *Submission 18*, p. 3.

8 Therapeutic Goods Administration, *Submission 18*, p. 3.

2.9 Chapter 4 of the *Therapeutic Goods Act 1989* provides for the regulation of medical devices. The Act provides for various powers in relation to the regulation of medical devices including the power to issue conformity assessment certificates to manufacturers of a medical device; suspend or revoke conformity assessment certificates in particular circumstances; include a medical device in the ARTG; suspend or cancel entries of devices from the ARTG; obtain information about medical devices; and require the recovery (recall) of medical devices, or to inform the public about medical devices, where the devices do not comply with the requirements of the legislation.[9]

2.10 The regulation of medical devices in Australia includes the following elements:

> (a) A classification system for medical devices based on different levels of potential risk to the patient.
>
> (b) Manufacturers are required to demonstrate compliance with a set of internationally agreed 'Essential Principles' for the quality, safety and performance of the medical devices.
>
> (c) A requirement that manufacturers implement and maintain a suitable quality management system (QMS) for the design, production, release and post market monitoring of medical devices.
>
> (d) A requirement that medical devices be included in the ARTG unless they are exempt.
>
> (e) Medical devices available on the market are subject to monitoring by the TGA. This monitoring includes a comprehensive incident reporting scheme.[10]

2.11 The TGA explained that as the regulator, it needed to achieve a balance between safety and innovation. The TGA submitted that:

> Consumers and health professionals expect medical devices to be regulated to ensure an adequate level of safety and performance and that the latest therapeutic technologies will be available in a timely manner.[11]

2.12 Achieving this balance is becoming more involved due to advances in technology. The TGA explained that 'Medical devices are becoming increasingly complex, and can incorporate other therapeutic goods such as medicines and biological materials'.[12]

2.13 The TGA went on to describe how this regulatory balance is achieved:

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9 Therapeutic Goods Administration, *Submission 18*, p. 23.

10 Therapeutic Goods Administration, *Submission 18*, p. 4.

11 Therapeutic Goods Administration, *Submission 18*, p. 6.

12 Therapeutic Goods Administration, *Submission 18*, p. 6.

> The TGA seeks to apply a risk-based regulatory system that imposes sufficient regulatory controls, without imposing expensive and unnecessary requirements on manufacturers, that might limit patients' access to effective therapeutic products.[13]

2.14 Dr Rohan Hammett, National Manager, TGA, explained that it is not possible to completely remove risk from this regulatory process:

> It is a constant matter of balancing the challenges of regulating the large number of products we regulate. One of the important foundations of how we approach this is that we have an understanding that it does not matter what amount of resources we have; it is not possible to create a completely safe medical device, medicine or medical procedure. That just does not exist. So in fact, despite the FDA's [United States Food and Drug Administration] 17,000 staff, the ASR hip was approved and inserted in the US. We would, I think, expect that, regardless of how many resources we had, there would be some products that at some point in their life would result in adverse events to consumers. That is the nature of health care, unfortunately: it is a risky business. What we have to do is try to manage those risks.[14]

2.15 The Australian Medical Association (AMA) observed that 'the arrangements for assessing and regulating medical devices in Australia have served Australians well'. However, the AMA noted that 'there will always be a tension between introducing new products to the Australian market and being certain that those products are safe and improve patient outcomes. This tension is mitigated by rigorous pre and post-market assessment'.[15]

2.16 Medibank Private noted that the TGA 'considers the technical performance of a sponsor to consistently deliver the device as assessed through its documentation processes' such as Australian code of good manufacturing practice for medicinal products (GMP) and Independent Ethics Committee (IEC) compliance. However, Medibank Private commented that the TGA does not assess quality on the basis of clinical outcomes, 'rather, its primary role is as gatekeeper to ensure no unsafe or non-efficacious devices are allowed to enter the Australian market'.[16]

2.17 The Medical Technology Association of Australia (MTAA) emphasised the importance of the HTA Review in considering the regulation of medical devices. It explained that:

> The HTA Review provided a long-awaited opportunity for a whole of system consideration of the assessment of non-pharmaceutical medical

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13 Therapeutic Goods Administration, *Submission 18*, p. 6.

14 Dr Rohan Hammett, National Manager, Therapeutic Goods Administration, *Committee Hansard*, 27 September 2011, p. 51.

15 Australian Medical Association, *Submission 3*, p. 1.

16 Medibank Private, *Submission 1*, p. 3.

technologies. The need for a review had been identified over several years by the Productivity Commission. It was also supported by both political parties during their time in government.[17]

Global harmonisation and collaboration

2.18 The committee received evidence about the role the TGA plays in efforts to align the regulation of medical devices through global harmonisation processes. Evidence was also provided about how TGA regulation of medical devices is affected by developments in harmonisation.

2.19 The committee also received evidence that the HTA Review considered how harmonisation developments affected a number of pre-market assessment processes including third party conformity assessment and the regulatory assessment of higher risk medical devices.[18] These issues are discussed below.

2.20 The TGA has bilateral agreements in place with a number of countries 'ranging from the recognition and acceptance of regulatory decisions on specific products to sharing information about regulatory processes, such as what pre-market assessments occur before a product is able to be supplied'.[19]

2.21 By way of example, the Australia-European Union (EU) Mutual Recognition Agreement (MRA) is a trade agreement between the Government of Australia and the European Community (EC) which covers a range of industries including medical devices. The MRA allows the TGA to issue European conformity assessment certificates to Australian manufacturers to supply in Europe, and allows specified European Notified Bodies to issue Australian conformity assessment certificates to European manufacturers for supply in Australia.[20]

2.22 The MRA excludes radioactive materials that are medical devices; devices incorporating tissues of animal origin (with some exceptions); active implantable devices; intra-uterine contraceptive devices; heart valves; intra-ocular lenses; intra-ocular visco elastic fluids; powered drug infusion pumps; implantable breast prostheses (except water/saline filled); barrier contraceptives (excluding condoms); and instrument grade disinfectants.[21]

2.23 The TGA is a founding member of the Global Harmonisation Task Force (GHTF) for medical devices. The TGA explained the current role and function of the GHTF:

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17 Medical Technology Association of Australia, *Submission 12*, p. 8.

18 Department of Health and Ageing, *Review of Health Technology Assessment in Australia*, December 2009, Recommendation 8b and 8c.

19 Therapeutic Goods Administration, *Submission 18*, p. 4.

20 Therapeutic Goods Administration, *Submission 18*, p. 30.

21 Therapeutic Goods Administration, *Submission 18*, pp 30–31.

> The GHTF is comprised of representatives from five founding members: the EU, the USA, Canada, Australia and Japan. The GHTF has for 18 years worked on the development of a regulatory model and supporting documents to underpin globally harmonised regulation of medical device technologies.
>
> The purpose of the GHTF has been to encourage convergence in regulatory practices related to ensuring the safety, effectiveness / performance and quality of medical devices, promoting technological innovation and facilitating international trade. This was primarily achieved through the publication and dissemination of harmonised documents on basic regulatory practices. These documents provide a model for the regulation of medical devices that can then be adopted by national regulatory authorities.[22]

2.24 Australian medical device legislation is based on the regulatory system recommended by the GHTF and is aligned with the EU medical device framework.[23] Dr Hammett, TGA, noted that the GHTF system has become the basis of regulation of medical devices in most of the world. He explained that 'It has now been picked up by a mirror body called the Asian Harmonisation Working Party, which has adopted similar legislation throughout the Asia-Pacific region'.[24]

2.25 However, Medtronics Australasia noted that the role of the GHTF does not bind the member states of the organisation, who maintain independent control of their regulatory systems. Medtronics explained:

> The fact that Australia is a member of the GHTF and uses some harmonised principles in the operation of the regulatory system does not, in most cases, mean that there is automatic acceptance of products approved in other jurisdictions. Depending on the risk class of the product TGA does undertake its own assessments of the documents and clinical evidence presented for registration in other jurisdictions. The exception to this is for some products manufactured in the European Union and which fall under a specific mutual recognition arrangement. In most cases TGA can, and regularly does, question these assessments and from time to time rejects listings where it is not satisfied with the evidence presented, even for products approved in other geographies.[25]

2.26 The TGA has explained that the current GHTF will be disbanded and a new regulatory forum established in order 'to better reflect the changing global requirements of regulators of medical devices in 2011 and beyond'.[26]

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22 Therapeutic Goods Administration, *Submission 18*, p. 4.

23 Therapeutic Goods Administration, *Submission 18*, p. 3.

24 Dr Rohan Hammett, National Manager, Therapeutic Goods Administration, *Committee Hansard*, 27 September 2011, p. 55.

25 Medtronics Australasia, *Supplementary Submission 14*, p. 5.

26 Therapeutic Goods Administration, *Submission 18*, p. 3.

2.27 The Australian Dental Industry Association (ADIA), while describing TGA commitment to international harmonisation of the regulatory framework for medical devices as 'exemplary', has raised concerns that proposed restructuring of the GHTF will disenfranchise industry input.[27]

2.28 The ADIA submitted that the previous model that included industry input was being replaced by a 'regulator driven model', something the ADIA described as 'objectionable'. The ADIA argued that the TGA lacks the expertise to properly assess the impacts of its proposals for regulatory reform. The ADIA further submitted that:

> ...this approach is based on the flawed premise that regulators have a detailed understanding of the needs of industry and the effects of their decisions on the costs of supplying medical devices.[28]

Pre-market assessment

2.29 The TGA regulates medical devices differently, according to their classification, based upon the device's intended purpose and level of risk. Dr Rohan Hammett, TGA, explained to the committee how the TGA approaches risk management:

> We do that with a stratified framework of assessment, so we apply more assessment resources pre-market to high-risk devices than we do to low-risk devices. Then we balance that with post-market monitoring.[29]

2.30 There are five classes of medical devices, other than in vitro diagnostic devices which have their own system of categorisation, as described in Figure 1.

27 Australian Dental Industry Association, *Submission 30*, p. 2.

28 Australian Dental Industry Association, *Submission 30*, p. 9.

29 Dr Rohan Hammett, National Manager, Therapeutic Goods Administration, *Committee Hansard*, 27 September 2011, p. 51.

Figure 1: Medical Device Classes

Class	Risk	Examples
Class I	Low Risk	Surgical retractors, tongue depressors
Class IIa	Low-medium risk	Hypodermic needles, suction unit
Class IIb	Medium-high risk	Lung ventilator, bone fixation plate
Class III	High Risk	Heart Valves
AIMD (Active Implantable Medical Devices)		Implantable defibrillator

Source: TGA, *Submission 18*, pp 19 – 20.

2.31 The level of pre-marketing assessment carried out by the TGA is determined by these classes. There is no assessment by the TGA of most Class I medical devices, although applicants must certify as to a range of matters. Prior to making an application to include a Class IIa or IIb medical device the TGA must have accepted the Manufacturer's Evidence,[30] which is compared with the device to ensure appropriate conformity assessment certification. An administrative review of the application is conducted but no further assessment is carried out unless it is an application required to be audited under the regulations or the application is selected for a non-mandatory application audit.[31]

2.32 Applications for Class III and AIMD devices are also subject to acceptance of Manufacturer's Evidence. They will also generally undergo a Level 2 application audit assessment. This includes the requirements for a Level 1 audit assessment[32] as well as

30 The TGA defines Manufacturer's Evidence as the conformity assessment evidence that demonstrates that a manufacturer has appropriate manufacturing processes to make the devices. Once the Manufacturer's Evidence is accepted by the TGA the sponsor can make an application to include their device on the ARTG. Acceptable Manufacturer's Evidence for most medical devices includes equivalent conformity assessment certification issued under the provisions of the European Medical Devices Directives, commonly referred to as CE certificates. See Therapeutic Goods Administration, *Submission 18*, p. 19.

31 Therapeutic Goods Administration, *Submission 18*, pp 19–20.

32 A Level 1 audit assessment includes the original or correctly notarised copy of the manufacturer's Australian Declaration of Conformity; copy of the latest and current conformity assessment evidence for the medical device; and information about the device, including copies of the label; instructions for use; advertising material such as brochures, web pages and advertisements. Therapeutic Goods Administration, *Submission 18*, p. 17.

a risk management report; clinical evaluation report; and efficacy and performance data for medical devices that disinfect, including those that sterilise other medical devices.[33]

2.33 The AMA noted the importance that the medical profession places on the TGA pre-market assessment processes for listing on the ARTG. In addition the AMA observed that:

> The medical profession's involvement in the TGA assessment processes ensures they are guided by medical opinion. Consequently, medical practitioners are able to confidently choose from a wide range of medical devices on the ARTG to make decisions about the optimal treatment for the patient, based on the patient's particular clinical circumstances.[34]

2.34 However, the Australian Orthopaedic Association (AOA) was critical of the regulatory regime governing the introduction of prostheses and medical devices into the Australian market. In particular, the AOA was concerned about the number of 'gate-keepers' involved in the review process, a process they described as 'cumbersome, repetitive, time consuming and expensive'.[35] The AOA explained further:

> Prior to the HTA Review, there was in effect, three 'gatekeepers'. Despite the HTA Review recommendations these three gatekeepers remain. The gatekeepers are TGA, the Prostheses Listing Advisory Committee (PLAC - formerly the Prostheses and Devices Committee (PDC)) and MSAC [Medical Services Advisory Committee].[36]

2.35 The AOA went on to argue that despite apparent overlaps in the process none of these regulatory bodies 'undertakes a total assessment of new prostheses' with the result that 'serious and clinically unacceptable gaps remain in the assessment process'. The AOA provided an example:

> For instance, TGA will assess the biomechanical safety (for issuing the Australian Register of Therapeutic Goods-ARTG number), but will not look at efficacy, PLAC can comment on clinical safety, but only advise TGA and MSAC. The HTA review agreed the CAGs [Clinical Advisory Groups] could raise concerns related to safety but those concerns had to be referred to the TGA who was the sole decision maker on safety. There is however considerable overlap between safety and efficacy and while both should be assessed separately the process would be streamlined if it was done all at once because in many circumstances...the same information is used to assess both.[37]

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33 Therapeutic Goods Administration, *Submission 18*, pp 17 and 24.

34 Australian Medical Association, *Submission 3*, p. 1.

35 Australian Orthopaedic Association, *Submission 5*, [pp 1–2].

36 Australian Orthopaedic Association, *Submission 5*, [p. 1].

37 Australian Orthopaedic Association, *Submission 5*, [pp 1–2].

2.36 The AOA submitted that the development of a publicly available list of approved devices on the ARTG is vital. They explained that currently it is difficult for anyone to work out what has been approved as the TGA only publishes limited information about what is available on the ARTG.[38]

Clinical evidence

2.37 The following section considers evidence received by the committee that describes the TGA's approach to clinical evidence, examines concerns about the adequacy of clinical testing, discusses the difficulties of conducting clinical trails with implantable devices, looks at whether the current approach provides any clinical advantage, discusses the question of whose evidence should be relied upon and briefly looks at other approaches.

The TGA approach

2.38 The TGA has noted that clinical evidence plays an important role in pre-market assessment, with all medical devices 'required to have clinical evidence to support the safety and performance of the device at the time the device is placed on the market in Australia'.[39]

2.39 The TGA commented that there are limitations on the coverage of the Act, and the requirement to be included on the ARTG. These exceptions include clinical trial exemptions; the Authorised Prescriber Scheme; the Special Access Scheme (SAS); and personal importation.[40]

2.40 The TGA explained that the clinical evidence for medical devices must include:

> ...an appraisal (evaluation) of the available clinical data (including clinical trial data, post market surveillance and clinical experience data) for that device (or similar/equivalent devices) with respect to both performance of the device as intended by the manufacturer and the safety of the device.[41]

2.41 The TGA went on to explain that usually the manufacturer is only required to have signed a declaration that the device conforms to the Essential Principles (noted previously at paragraph 2.10) and that the supporting evidence of compliance, including clinical evidence, can be provided to the TGA if requested. The TGA will usually only see the clinical evidence in certain circumstances prescribed in the regulations. This includes:

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38 Australian Orthopaedic Association, *Submission 5,* [p. 5].

39 Therapeutic Goods Administration, *Submission 18,* p. 27.

40 Therapeutic Goods Administration, *Submission 18,* p. 27.

41 Therapeutic Goods Administration, *Submission 18,* p. 27.

> (a) for medium to higher risk devices in relation to which the TGA must undertake an application audit, to confirm that the declaration of conformity is valid (these will be subject to a Level 2 audit); and
>
> (b) for higher risk devices in relation to which the TGA is required to issue a conformity assessment certificate following full review of technical (including clinical) documentation for the device to confirm the device performs as intended, does not pose any undue safety concerns and that the benefits of using the device outweigh the risks; and
>
> (c) irrespective of the risk level, under the circumstances of a post-market review.[42]

Concerns about adequacy of clinical evidence

2.42 A number of submitters argued for improved clinical evidence prior to a device being listed on the market. Dr Armitage, AHIA, made the salient point that although there was a place for both pre-market assessment and post-market surveillance, he believed that:

> In the very first instance...if a more rigorous analysis of independently determined clinical evidence were the criterion upon which the TGA made its original decision many of the other problems would not occur.[43]

2.43 The AOA also told the committee that current clinical evidence requirements prior to devices being put on the market are not adequate.[44] It made a number of recommendations about improving clinical evidence including that:

> ...the clinical requirements pre-release be defined; two years pre-release clinical testing for joint replacement devices; and that RSA [Radio Stereometric Analysis][45] studies be undertaken in conjunction with post-market surveillance. The AOA also emphasised the importance of international collaboration on this issue.[46]

2.44 Brandwood Biomedical compared the regulatory system for clinical trials in Europe and Australia, and told the committee that:

> [the] TGA undertakes no meaningful audit or supervision of clinical trials – which is devolved entirely to local ethics committees, whereas Clinical Trial Supervision is a key responsibility of Competent Authorities and is

42 Therapeutic Goods Administration, *Submission 18*, p. 27.

43 The Hon Dr Michael Armitage, Australian Health Insurance Association, *Committee Hansard*, 27 September 2011, p. 2.

44 Australian Orthopaedic Association, *Submission 5*, [p. 5].

45 Radiostereometric analysis is an accurate method of determining the migration and wear of orthopaedic implants such as total hip arthroplasties. Email correspondence, Kathy Hill, AOA, 23 September 2011.

46 Australian Orthopaedic Association, *Submission 5*, [p. 5].

> extensively resourced in the larger agencies particularly of the UK, Germany and France.[47]

2.45 The Consumers Health Forum of Australia (CHF) raised concerns that 'many of the devices that gain automatic entry on to the ARTG have a significant risk of causing harm'. The CHF went on to observe that 'until recently, joint replacements had been judged to be low risk despite the fact that many fail, requiring re-operation and creating an increased risk of mortality for some people'.[48]

2.46 Ms Karen Carey, Board Director, CHF, questioned why untested medical devices are being registered, and brought on to the market, when alternative devices with a track record are already available. Ms Carey stated to the committee that:

> The only circumstance in which there is justification to go early to market—to give an early approval—is where there is no comparator device in that category, and therefore the patient is making a decision between a device that does not have a lot of evidence and no device at all. I think you can justify that. In terms of bringing things to market early, where there is already four, five, 10 or 20 similar devices, I just cannot see how you can justify the risk.[49]

Whose evidence should be relied upon?

2.47 Dr Armitage, AHIA, raised concerns about the reliance of the TGA on the clinical evidence provided by the manufacturer of a device:

> In Australia a device can be inserted into what in this instance would be an unsuspecting Australian patient and the only clinical evidence of that device's success which the TGA takes into account is information provided by the manufacturer of that device. They clearly have a financial conflict of interest and that ought to be stopped.[50]

2.48 Dr Armitage went on to argue that there are avoidable risks associated with accepting clinical evidence from overseas:

> If in fact one of the bodies with which the TGA is globally harmonised—in other words, similar bodies overseas—have authorised the use of a particular device the TGA is comfortable with accepting that recommendation and/or clinical evidence from the people who wish to sell the device. Unless there can be rigorous evidence that the overseas

47 Brandwood Biomedical, *Submission 7,* p. 6.

48 Consumers Health Forum of Australia, *Submission 2,* p. 3.

49 Ms Karen Carey, Board Director, Consumers Health Forum of Australia, *Committee Hansard*, 27 September 2011, p. 32.

50 The Hon Dr Michael Armitage, Australian Health Insurance Association, *Committee Hansard*, 27 September 2011, p. 2.

> processes have had appropriate clinical testing there will always be an element of risk. I think it can be avoided.[51]

2.49 Dr Armitage, submitted that Australia should become far more engaged with clinical testing. He told the committee that:

> I believe that there would be university departments that would be thrilled to set themselves up as centres of excellence in doing clinical trials. You would not have to have many of them around Australia, but it would be quite an easy way. There would be a financial commitment. I accept that. But I think that is better than subjecting people to the failure of the device. But you would have to set up a system whereby if somebody wanted to bring a device into Australia they would actually have to...submit it to appropriate clinical testing.[52]

Difficulties of conducting trials of implantable devices

2.50 Other submitters noted the difficulties of conducting clinical trials with implantable devices. Medtronics Australasia noted that:

> The risk management models adopted globally for assessment of medical devices acknowledge the differences between pharmaceuticals and devices, and the impractical nature of pharmaceutical type trials in the devices environment.[53]

2.51 Similarly, Ms Anne Trimmer, Chief Executive Officer, MTAA, argued that the standards of clinical evidence that are applied for pharmaceuticals cannot realistically be applied in the same way to medical devices. She explained that:

> The regulation of safety and efficacy of medicines is based on pharmacology and chemistry where the properties and action of active ingredients can be determined in preclinical and clinical studies. The clinical evidence was obtained mostly pre-market from large, double-blind, randomised controlled trials. In contrast, randomised, double-blind placebo controlled trial designs are very difficult and often unethical to implement as part of the evaluation of a device or a surgical procedure. That is for the obvious reason that it would not be ethical to put into a patient a device that is a placebo. Therefore, so much more of the assessment of a medical device happens after the device has been in use with the patient and the patient experience becomes a very critical part of assessment in an ongoing way.[54]

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51 The Hon Dr Michael Armitage, Australian Health Insurance Association, *Committee Hansard*, 27 September 2011, p. 2.

52 The Hon Dr Michael Armitage, Australian Health Insurance Association, *Committee Hansard*, 27 September 2011, p. 2.

53 Medtronics Australasia, *Submission 14*, p. 4.

54 Ms Anne Trimmer, Chief Executive Officer, Medical Technology Association of Australia, *Committee Hansard*, 27 September 2011, p. 7.

2.52 Ms Trimmer went on to argue that there are further differences in assessing drugs and devices that need to be understood, namely that the development cycle is very different. Ms Trimmer explained that:

> Medical devices are developed in a framework of continuous innovation and iterative improvements which can be based on advances in science, technology and materials. If you look at, for example, very early pacemakers, they were large, boxlike devices that were attached in some way to the outside of the patient. These days they are very small and implantable. In comparison, pharmaceuticals are developed following extensive research and development of a specific molecule or compound with the result that it can take many years for a new drug to enter the pipeline.[55]

Does the current approach provide clinical advantage?

2.53 Professor Stephen Graves, Director, National Joint Replacement Registry (NJRR), also addressed the issue of whether registering and placing untested new devices on the market provides any clinical advantage. He provided evidence to the committee that it may produce exactly the opposite effect. Professor Graves argued that many new devices were performing no better than, or in some cases worse than, existing devices. He explained to the committee:

> We have just had an article accepted for publication in the Journal of Bone and Joint Surgery in America, which is the premier orthopaedic journal, looking at new devices that came onto the market in the five-year period between 2003 and 2007. There were over 260 new devices, hips and knees, that came onto the market in that time, the vast majority of which were used only in a very small number of procedures, 75 per cent, less than 100 procedures, so it was very difficult to know whether or not they were going to work. Of the 25 per cent that were used in a large number of procedures the registry found that none performed better than the established prosthesis we already had on the market and that 30 per cent performed significantly worse. It is that 30 per cent that performed significantly worse that we do have concerns with.[56]

2.54 The difficulty in assessing a large number of devices that are each only used in a small number of procedures was also mentioned as a matter of concern by other submitters. Dr Armitage, AHIA, noted that there are thousands of devices available in Australia, something he believed has come about 'because the opportunity to have

55 Ms Anne Trimmer, Chief Executive Officer, Medical Technology Association of Australia, *Committee Hansard*, 27 September 2011, p. 7.

56 Professor Stephen Graves, Director, National Joint Replacement Registry, *Committee Hansard*, 27 September 2011, p. 23.

devices listed is too loose—it is being tightened, but we would say that is well overdue'.[57]

2.55 Mr Robert Lugton expressed great disquiet at the current proliferation of hip device combinations that are being used by surgeons. Mr Lugton drew attention to the NJRR annual report for 2011, noting that:

> This year the report identified 330 new femoral cup and acetabular cup combinations than last year. An over 20% increase in one year. This makes assertions that we operate a 'choice' based system laughable.[58]

2.56 The committee heard from Mr Richard Bartlett, First Assistant Secretary, Medical Benefits Division, Department of Health and Ageing, who confirmed that there is no requirement to prove that a device performs better than those already available, before it is listed. He stated that in Australia the criterion is 'essentially about maximising choice for both doctors and consumers'. Mr Bartlett went on to argue that:

> A device that may not perform in a superior way across the board may well perform in a superior way with an individual patient. We have a system that in effect allows doctors to make those choices with patients.[59]

Committee comment

2.57 The committee is of the view that the current perception that there is an increasing number of medical devices that perform no better than, and often worse than, those already available is concerning. The committee is unconvinced by Mr Bartlett's assertion that new devices may perform better in an individual, although not across the board. There appears to be no process to collect evidence to support this assertion.

2.58 The committee believes that Recommendation 8c of the HTA Review should be implemented in order to increase the rigour of regulatory assessment of higher-risk medical devices. An appropriate level of evidential review should be undertaken over an adequate period of time. The committee is also of the view that the requirements of the clinical evidence should be defined. The committee notes the AOA's recommendation for a minimum of two year's clinical evidence.

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57 The Hon Dr Michael Armitage, Chief Executive Officer, Australian Health Insurance Association, *Committee Hansard* , 27 September 2011, p. 4.

58 Mr Robert Lugton, *Supplementary Submission 29*, [p. 2].

59 Mr Richard Bartlett, First Assistant Secretary, Medical Benefits Division, Department of Health and Ageing, *Committee Hansard*, 27 September 2011, p. 46.

Other approaches

2.59 The committee received evidence from submitters about the way that France regulates its medical devices. Dr Armitage informed the committee that in France there is a predetermined number of devices. Dr Armitage went on to clarify that:

> If someone wishes to have a new device listed for reimbursement they must prove that their device performs better than the one that is already allowed for reimbursement.[60]

2.60 Dr Armitage supported this approach and commented:

> That seems, to me, completely reasonable. Why would anybody want to authorise the use of a device which potentially has dramatic consequences if it goes wrong unless it can be proven to give a better clinical outcome than the device that is already being used safely?[61]

2.61 However, Medtronics Australasia submitted that, in many respects, there is not much difference between the system for reimbursement of medical devices in Australia and France. Medtronics Australasia was of the view that:

> ...the French system, whilst it has some different nuances reflecting the different structure of their healthcare systems, in many respects parallels the Australian system, and has quite similar tests for the reimbursement of medical technology.
>
> Regulatory entry is governed by the French Competent Authority AFSSAPS which ensures that products entering the market in France have been assessed as meeting the Essential Principles required to gain a CE mark.[62] In most respects these Essential Principles are the same as those required under Australian Law and regulation and applied by the TGA.[63]

2.62 The CHF suggested a number of ways that consumers could be engaged in the approval of medical devices. They submitted that the committee might consider:

> ...the development of mechanisms to take into account consumer experience in the approval of devices. This may include: consumer representatives on committees, the use of consumer impact statements, public reporting of

60 The Hon Dr Michael Armitage, Australian Health Insurance Association, *Committee Hansard*, 27 September 2011, p. 3.

61 The Hon Dr Michael Armitage, Australian Health Insurance Association, *Committee Hansard*, 27 September 2011, p. 3.

62 Conformité Européenne (CE) marking indicates that a product may be legally sold in all Member States of the European Economic Area. http://www.innovation.gov.au/INDUSTRY/TRADEPOLICIES/MRA/Pages/EuropeanCommunity-AustraliaMutualRecognitionAgreementFAQ.aspx, accessed 26 September 2011.

63 Medtronics Australasia, *Supplementary Submission 14*, p.7.

> consumer experiences with devices and technologies [and] other models that have been effective internationally.[64]

TGA Medical Device Regulation Reform proposals

2.63 The TGA has released a number of discussion papers that address the regulation of medical devices. In December 2008 the TGA released *Use of Third Party Conformity Assessment Bodies for Medical Devices Supplied in Australia.* The issue of third party conformity assessment is discussed below at paragraph 2.67. In October 2009 the TGA released *A Proposal for the Reclassification of Joint Replacement Implants*. The reclassification of joint replacements is discussed below at paragraph 2.87.

2.64 Additionally, in October 2010 the TGA released *Reforms in the Medical Devices Regulatory Framework: Discussion Paper.* This contained nine proposals, including a package of reforms that responded to Recommendations 8b and 8c of the HTA Review:

- Proposal 2A proposed amending regulations so that Australian medical device manufacturers would no longer be required to hold TGA conformity assessment certification but could, in the alternative, use 'equivalent certification issued by third party assessment bodies to support medical device entries in the ARTG, as is currently available to overseas manufacturers'. This is discussed below at paragraph 2.67.

- Proposal 2B proposed increasing pre-market scrutiny for implantable devices and is discussed below at paragraph 2.96.

- Proposal 2C goes to recognition of third party assessment bodies through undertaking formal confidence building of those European Notified Bodies designated under the MRA between Australia and the European Commission, and setting up a system to enable assessment bodies based in Australia to operate as a third party for the purpose of issuing certification under the Australian legislation.[65] This is also discussed below at paragraph 2.67.

2.65 However, on 23 September 2011 the TGA announced, in relation to Proposal 2, that these proposals remain under consideration and further consultation will occur on amended versions of these proposals.[66]

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64 Consumers Health Forum of Australia, *Submission 2*, p. 4.

65 Department of Health and Ageing, Therapeutic Goods Administration, *Reforms in the Medical Devices Regulatory Framework: Discussion Paper*, 25 October 2010, p.13.

66 Department of Health and Ageing, Therapeutic Goods Administration, *Reforms to the medical devices regulatory framework: Proposals*, 23 September 2011, http://www.tga.gov.au/newsroom/consult-devices-reforms-110923.htm, accessed 29 September 2011.

Third party conformity assessment

2.66 As noted above, in December 2008, the TGA released a discussion paper *Use of Third Party Conformity Assessment Bodies for Medical Devices Supplied in Australia*, seeking the views of stakeholders on a number of proposals. The discussion paper canvassed issues regarding the appropriate role of the TGA, and the appropriate role and requirements of third party assessment bodies, in issuing conformity assessment certificates.[67]

2.67 The HTA Review, noting the above consultation, made the following recommendations:

> Recommendation 8: That the Therapeutic Goods Administration (TGA), in the context of international harmonisation:
>
> (a) continue its role as the independent national regulator solely responsible for assessing the safety, quality and efficacy of therapeutic goods for entry on The Australian Register of Therapeutic Goods (ARTG) and marketing in Australia;
>
> (b) respond to the issues raised in consultations regarding third party conformity assessment by July 2010, with a view to implementing changes agreed by government by 2011;
>
> (c) increase the rigour of regulatory assessment of higher risk medical devices by 2011, to ensure an appropriate level of evidential review is undertaken to ensure safety, quality and efficacy of these devices prior to entry on the ARTG and to provide a sound evidence basis for Australian Government HTA processes.
>
> and
>
> (d) develop protocols by July 2010 for sharing information with other HTA agencies through the SEP (subject to commercial-in-confidence constraints) on the outcomes of its safety assessments.[68]

2.68 In addition to evidence provided to the committee regarding the appropriate level of clinical evidence for higher risk medical devices, many submitters also addressed issues around third party conformity assessment. These issues have previously been, and continue to be, the subject of a number of government consultations and reviews as detailed below.

2.69 Inclusion of a medical device in the ARTG allows it to be supplied in, or exported from, Australia. For a medical device to be included in the ARTG, the TGA

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67 Therapeutic Goods Administration, *Use of Third Party Conformity Assessment Bodies for Medical Devices Supplied in Australia: Consultation Paper, December 2008,* available at http://www.tga.gov.au/pdf/archive/consult-devices-cab-thirdparty-081222.pdf, accessed 6 October 2011.

68 Department of Health and Ageing, *Review of Health Technology Assessment in Australia*, December 2009.

requires evidence that the conformity assessment procedures applied by the manufacturer of the device conform with the Essential Principles, including that the manufacturer's quality system is accredited to an acceptable standard. This evidence is provided as a conformity assessment certificate, and the body issuing the certificate is referred to as a Conformity Assessment Body (CAB).

2.70 If a medical device is made in Australia, only the TGA may issue a conformity assessment certificate. If a medical device is not made in Australia, and does not contain a designated material, then bodies other than the TGA may issue conformity assessment certificates.[69]

2.71 There are three main interrelated issues related to third party conformity assessment. The first issue goes to concerns, discussed previously, that unsafe medical devices approved in other jurisdictions, may be included on the ARTG. The second issue is that the requirements on Australian medical device manufacturers are currently more onerous than the requirements placed upon overseas medical device manufacturers. The third issue is whether, in Australia, bodies other than the TGA should be able to carry out third party conformity assessments.

2.72 In the previous section on clinical evidence the case for and against accepting the assessment of non-Australian evidence to fulfil the requirements of registration on the ARTG was discussed. Submitters, including Dr Armitage from the AHIA, expressed concern that devices assessed overseas may be introducing an unacceptable and avoidable risk into Australia's regulatory framework. Dr Armitage stated that there was a risk of 'a race to the bottom'.[70]

2.73 Other submitters argued that Europe's regulatory system is sufficiently strong and well aligned to Australia's regulatory system that if a product has been assessed by a notified body in Europe it should be accepted for approval.[71]

2.74 A number of submitters supported the TGA proposal to allow the use of accredited third party conformity assessment bodies, as an alternative to the TGA, for issuing conformity assessment certificates for Australian manufacturers. It is clear that Australian medical device manufacturers consider that they are disadvantaged in

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69 Therapeutic Goods Administration, *Use of Third Party Conformity Assessment Bodies for Medical Devices Supplied in Australia: Consultation Paper, December 2008,* available at http://www.tga.gov.au/pdf/archive/consult-devices-cab-thirdparty-081222.pdf, accessed 6 October 2011.

70 The Hon Dr Michael Armitage, Australian Health Insurance Association, *Committee Hansard*, 27 September 2011, p. 2.

71 Ms Robyn Chu, Director, Health Outcomes, Johnson & Johnson Medical, *Committee Hansard*, 27 September 2011, p. 42.

relation to their international counterparts.[72] Max Boccardo Associates explained how the TGA applies more stringent requirements on Australian manufacturers:

> The Therapeutic Goods (Medical Devices) Regulations 2002 follow closely, but not totally, the European Union Medical Device Directive 93/42/EEC (MDD). Under this Directive, Medical Device manufacturers need to obtain Conformity Assessment Certification from certain accredited third party inspection bodies, known as "Notified Bodies" in the European Union.
>
> TGA accepts readily such EU Certificates for the approval of Medical Devices in Australia from all manufacturers except those from Australia, which instead can only obtain their Certificates directly from TGA.[73]

2.75 The Department of Innovation, Industry, Science and Research (DIISR) submitted that:

> Use of third party assessment has the potential to save considerable time and money for Australian medical devices manufacturers and their customers and could provide a choice of conformity assessment pathways as is the case in larger markets such as the European Union (EU).[74]

2.76 A number of submitters were critical of the time and cost involved in current TGA conformity assessment.[75] DIISR went on to explain that:

> ...assessment in larger markets, such as for a European CE mark, is often quicker (around 90 days for the European market versus around nine months for the Australian market - 255 days plus clock stops in Australia); and cheaper (around AUD 5000 for the European market versus around AUD 100,000 for the Australian market) for identical products.[76]

2.77 The Medical Technology Association of Australia also supported the use of third party conformity assessment, noting that proposals for compulsory conformity assessment by the TGA of higher risk devices:

> ...removes the inequity between Australian and overseas manufacturers but subjects all to a much more expensive assessment process which in almost all cases will duplicate very rigorous assessments already undertaken by a European Notified Body.[77]

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72 Department of Innovation, Industry, Science and Research, *Submission 21,* pp 2–3; Max Boccardo Associates, *Submission 10,* [p. 1]; AusBiotech, *Submission 16,* pp 2 and 5.

73 Max Boccardo Associates, *Submission 10,* [p. 2].

74 Department of Innovation, Industry, Science and Research, *Submission 21,* p. 2.

75 Department of Innovation, Industry, Science and Research, *Submission 21,* p. 2; see also AusBiotech, *Submission 16,* pp 5–6.

76 Department of Innovation, Industry, Science and Research, *Submission 21,* p. 2.

77 Medical Technology Association of Australia (MTAA), *Submission 12,* p. 13.

2.78 The committee also heard that efficiencies could be achieved by lifting international regulatory standards to allow greater use of third party conformity assessment for the purposes of listing on the ARTG. Boston Scientific Australia New Zealand argued that as Australia has a small population and represents only 2.6 per cent of global medical device sales, use of third party conformity assessment would facilitate 'a balancing act between ensuring safety and quality requirements and ensuring access'.[78]

2.79 Similarly, Ms Robyn Chu, Director, Health Outcomes, Johnson & Johnson Medical (JJM), told the committee that:

> ...one of the issues we have is that the notified bodies in Europe are quite well resourced. If the product has already been assessed through these notified bodies and been given EC certification, we see that, in order for Australians to get access to innovative technologies, our regulatory system should adopt EC certification as approval.[79]

2.80 Brandwood Biomedical noted the already close alignment of Australian and European technical requirements and standards. It explained that although the technical standards and assessment processes in Australia and Europe are essentially identical, the European system divides the administration of regulation into two parts:

> 1. Notified Bodies conduct premarket assessments of manufacturers and issue CE certifications resulting in the so-called “CE marking” of medical devices. These are almost always private sector organisations.
>
> 2. Competent Authorities accredit and supervise the Notified Bodies. These are almost always national government departments or agencies. Competent Authorities are also responsible for the approval and audit of clinical trials.[80]

2.81 Brandwood Biomedical went on to submit that the TGA could relinquish direct assessment of medical devices and instead adopt the role of Competent Authority 'as has been done by larger medical device regulatory agencies in the UK, Germany and France'. Addressing concerns about 'more recently established smaller Notified Bodies', Brandwood Biomedical suggested that 'the TGA would be in a position to restrict accreditation to only those larger Notified Bodies which are adequately resourced and competent for the role'.[81]

2.82 Similarly, JJM submitted that the TGA should 'adopt the role of a designating authority for Conformity Assessment Bodies which can demonstrate competence to evaluate all devices', as well as:

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78 Boston Scientific Australia New Zealand, *Submission 13*, p. 8.

79 Ms Robyn Chu, Director, Health Outcomes, Johnson & Johnson Medical, *Committee Hansard*, 27 September 2011, p. 42.

80 Brandwood Biomedical, *Submission 7*, p. 3.

81 Brandwood Biomedical, *Submission 7*, p. 7.

> ...retain its role as a Competent Authority in determining which applications for inclusion in the Australian Register of Therapeutic Goods are accepted based on the conformity assessment evidence issued by third party Conformity Assessment bodies.[82]

2.83 JJM went on to argue that in order to enable third party conformity assessment to be implemented, the TGA should not only seek 'complete alignment of classification rules between the Australian regulations and the European Medical Device Directive assessment to be implemented', but that the TGA should also 'broaden existing and establish new mutual recognition agreements with other highly regulated countries such as Canada and Japan as well as Europe'.[83]

2.84 JJM submitted that this would allow the TGA:

> ...to approve products based on the third party conformity assessments such as provided by European Notified Bodies (EU NB), for all classes of medical devices supplied in Australia where there are no unique risks or differences in clinical practice can be identified.[84]

Committee comment

2.85 The committee is of the view that there is some merit in a country like Australia, with a small market share and finite resources, using some third party conformity assessment conducted overseas. However, the committee considers that a dilemma remains regarding the most effective way to monitor the quality of work performed by conformity assessment bodies in other jurisdictions, in order to remain assured of the quality and safety of medical devices in Australia.

Proposal to reclassify joint replacement implants from Class IIb to Class III

2.86 As noted above, in October 2009, the TGA released a Consultation Paper proposing reforms to the classification of implantable hip, knee and shoulder joints through 'upclassifying' joint replacement implants from Class IIb to Class III.[85] The paper noted that:

82 Johnson & Johnson Medical, *Submission 28,* p. 10.

83 Johnson & Johnson Medical, *Submission 28,* p. 19.

84 Johnson & Johnson Medical, *Submission 28,* p. 19.

85 Department of Health and Ageing, Therapeutic Goods Administration, *A Proposal for the Reclassification of Joint Replacement Implants,* October 2009, http://www.tga.gov.au/pdf/consult/consult-devices-joint-replacements-091023.pdf, accessed 30 September 2011.

> Recent data has shown that there appears to be a higher than average revision (failure) rate for some orthopaedic joint replacement implants than others which is a cause for concern.[86]

2.87 As discussed above, in February 2010 the HTA Review also recommended (Recommendation 8c) increasing the rigour of regulatory assessment of higher risk medical devices by 2011.[87]

2.88 The TGA's *Reforms in the Medical Devices Regulatory Framework: Discussion Paper*, discussed above, also contained a proposal that addressed the reclassification of joint replacements. Proposal 1 formed part of the response to Recommendation 8c of the HTA Review, proposing a reclassification of all hip, knee and shoulder joint replacement implants from Class IIb to Class III medical devices. The proposal was substantially similar to that introduced into European legislation by Commission Directive 2005/50/EC. However, the European legislation appears to only address total joint replacements whereas the TGA proposal covers both partial and total joint replacements.[88]

2.89 On 23 September 2011, following receipt of submissions and consultations the TGA released a statement outlining their proposed course of action in relation to the nine proposals contained in the discussion paper. In relation to Proposal 1 the TGA announced its intention to implement the proposal to reclassify joint replacement devices included in the ARTG from Class IIb to Class III 'through an amendment to the Therapeutic Goods (Medical Devices) Regulations 2002 with a two year transition period commencing from 1 July 2012'. [89]

2.90 Dr Hammett, TGA, told the committee that the TGA was not only trying to effect reforms to the way medical devices are regulated in Australia but also at an international level. Dr Hammett explained:

> ...we are trying to work with our international regulatory partners to effect that change globally. We are mindful that we are only two per cent of the world's market and, if we want to see improvements in the safety of products on the market, as we all do, we need to impact on the global

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86 Department of Health and Ageing, Therapeutic Goods Administration, *A Proposal for the Reclassification of Joint Replacement Implants*, October 2009, http://www.tga.gov.au/pdf/consult/consult-devices-joint-replacements-091023.pdf, accessed 30 September 2011.

87 Department of Health and Ageing, *Review of Health Technology Assessment in Australia*, December 2009.

88 Department of Health and Ageing, Therapeutic Goods Administration, *Reforms in the Medical Devices Regulatory Framework: Discussion Paper*, 25 October 2010, pp 14–15.

89 Department of Health and Ageing, Therapeutic Goods Administration, *Reforms to the medical devices regulatory framework: Proposals*, 23 September 2011, http://www.tga.gov.au/newsroom/consult-devices-reforms-110923.htm, accessed 29 September 2011, p. 3.

> regulatory system for medical devices. That is what Australia is actively engaged in doing currently.[90]

2.91 A number of submitters supported the TGA's proposed change of classification of joint replacement implants from Class IIb to Class III.[91] The AMA noted that 'this will ensure that these devices, which are constantly utilising new materials and construction techniques, undergo a more rigorous assessment before they are listed on the ARTG'.[92]

2.92 The AOA supported the change of classification but cautioned that this 'does not necessarily mean that there will be increased or defined clinical requirements in that assessment process'. The AOA submitted that 'what is required is movement to class III and standardised clinical assessment using internationally agreed criteria'.[93]

2.93 JJM also supported the reclassification from Class IIb to Class III, noting they understood 'the TGA's position to align Australia's regulatory system with equivalent international regulations such as the European Union (EU) Medical Device Directive 93/42/EEC (MDD)'. However, it submitted that the extra regulatory burden imposed by the reclassification means that a two year transition period is insufficient.[94]

2.94 JJM also raised specific concerns about additional requirements associated with ARTG inclusion and Unique Product Identifiers (UPI). JJM noted that although Australia and the EU have similar regulatory frameworks, the TGA has requirements additional to the EU regulatory system. It explained that in Australia there is a requirement for medical devices to be listed on the ARTG before supply and the devices must be listed at the level of UPI. JJM submitted that:

> While JJM supports the TGA's intent to increase visibility and traceability of high risk Class III devices, we have concerns regarding the TGA's interpretation and ruling on acceptable UPIs which we would submit has, at times, been inconsistently applied. JJM recommends that the TGA work with industry to clarify the UPI requirements for orthopaedic implants before introduction of the amended Regulations.[95]

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90 Dr Rohan Hammett, National Manager, Therapeutic Goods Administration, *Committee Hansard*, 27 September 2011, p. 55.

91 Australian Medical Association, *Submission 3*, p. 1; St Jude Medical, *Submission 8*, [p. 11]; Australian Orthopaedic Association, *Submission 5*, [p. 2]; Johnson & Johnson, *Submission 28*, p. 12.

92 Australian Medical Association, *Submission 3*, p. 1.

93 Australian Orthopaedic Association, *Submission 5*, [p. 2].

94 Johnson & Johnson Medical, *Submission 28*, pp 5–6.

95 Johnson & Johnson Medical, *Submission 28*, p. 6; see also Medical Technology Association of Australia, *Submission 12*, p. 4.

Proposal to increase the level of assessment of Class III devices

2.95 The October 2010 *Reforms in the Medical Devices Regulatory Framework: Discussion Paper* also responded to HTA Recommendation 8c. Proposal 2B addressed increasing pre-market scrutiny for implantable medical devices. This proposal had two parts: the first required a TGA conformity assessment to be issued for the highest risk (Class III/AIMD) implantable medical devices; and the second required medical device applications to be selected for auditing for the lower risk (Class IIb) implantable devices.[96] However, on 23 September 2011 the TGA announced that this proposal remained under consideration and that further consultation would occur on an amended proposal.[97]

2.96 As part of the evidence provided to the committee a number of submitters addressed the issue of the appropriate level of pre-market scrutiny for higher risk medical devices.

2.97 In a general sense many consumers supported the proposal to increase the level of assessment of high risk devices, as discussed in the section on clinical evidence. However, a number of medical device companies questioned whether this was necessary or possible given the resource constraints of the TGA.

2.98 St Jude Medical Australia submitted that the full conformity assessment proposed by the TGA for all Class III and AIMD products 'represents a costly and inefficient duplication of quality system and product evaluations that have previously been completed by a competent overseas Notified Body'. St Jude Medical went on to submit that:

> ...the TGA has failed to provide evidence to demonstrate how the current process of reliance on overseas evaluations for Class III and AIMD medical devices does not provide an appropriate level of protection for the Australian public or how duplicating this process in Australia will provide any additional level of assurance.[98]

2.99 Brandwood Biomedical and Medtronic Australasia raised concerns that the TGA does not have sufficient resources or technical personnel to undertake this increased level of regulatory review. They go on to argue that a combination of high assessment costs and time delays could lead to industry reducing the range of products supplied in Australia and a reluctance to introduce new devices.[99]

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96 Department of Health and Ageing, Therapeutic Goods Administration, *Reforms in the Medical Devices Regulatory Framework: Discussion Paper*, 25 October 2010, pp 16–19.

97 Department of Health and Ageing, Therapeutic Goods Administration, *Reforms to the medical devices regulatory framework: Proposals*, 23 September 2011, http://www.tga.gov.au/newsroom/consult-devices-reforms-110923.htm, accessed 29 September 2011.

98 St Jude Medical Australia, *Submission 8*, [pp 11–12].

99 Brandwood Biomedical, *Submission 7*, pp 5–6; Medtronic Australasia, *Submission 14*, pp 7–8.

2.100 Dr Hammett, TGA, told the committee, albeit in relation to the proposal to up-classify joint replacement implants from Class IIb to Class III, that they believed the TGA had adequate resources to carry out its role. Dr Hammett stated 'we think we can manage this process adequately and have developed an implementation plan to do that'.[100]

Committee comment

2.101 The committee is of the view that reclassifying joint replacement devices from Class IIb to Class III, as proposed by the TGA, is a sound approach. However, the committee is of the view that this should be supplemented by a higher level of assessment of Class III medical devices.

Post-market surveillance

2.102 The TGA's regulatory framework for medical devices includes provision for post-market monitoring. The TGA explained that this includes:

> ...checking evidence of conformity; conducting periodic inspections of manufacturer's quality management systems and technical documentation, including documentation held by a sponsor; and imposing specific requirements for manufacturers and sponsors to report, within specified timeframes, adverse incidents involving their medical devices.[101]

2.103 The TGA went on to comment on the HTA Review's findings regarding pre-market assessment:

> Feedback from stakeholders as part of the HTA Review identified that there was room for further improvement in post-market surveillance and in the ongoing monitoring of devices. This includes ensuring there is a continuing process of performance assessment over the 'life-cycle' of a device.[102]

2.104 Recommendations 13, 14 and 15 of the HTA Transparency Review address the issue of post-market surveillance. These recommendations addressed the need to improve adverse event reporting; increase the collection and use of post-market surveillance data; and establish, and expand participation in, clinical registers for high-risk implantable devices:

> **Recommendation 13**: That, in order to improve the contribution of post-market surveillance to patient safety, the TGA take steps to increase the rate of reporting of adverse events, including by health service providers and consumers.

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100 Dr Rohan Hammett, National Manager, Therapeutic Goods Administration, *Committee Hansard*, 27 September 2011, p. 55.

101 Therapeutic Goods Administration, *Submission 18*, p. 31.

102 Therapeutic Goods Administration, *Submission 18*, p. 3.

> **Recommendation 14**: That, in order to improve the contribution of post-market surveillance to the sustainability of the health system and the longer-term regulatory efficiency of HTA processes, DoHA explore options for consideration by government in 2011 to facilitate the expansion and use of post-market surveillance data to inform safety, effectiveness and reimbursement decisions for devices and procedures.
>
> **Recommendation 15**: That registers for high-risk implantable medical devices and/or procedures be established, with:
>
> (a) key stakeholders such as clinicians, health consumers and industry to participate in governance of and contribution to registries;
>
> (b) establishment of mechanisms to apply data from the register to future HTA;
>
> (c) the feasibility, benefits and methodologies for data linkage to be explored in a pilot project in regard to a particular device identified by the high-risk implantable devices register;
>
> (d) consideration of how developments in e-health and data linkage could improve the efficiency of the post-market surveillance of medical technology more generally; and
>
> (e) the development of criteria, the identification of opportunities and the consideration of strategies for improvements in public investment in medical devices.[103]

2.105 As noted above, while the Government has accepted all of the other thirteen recommendations made by the HTA Review, Recommendations 13-15 have not yet been accepted and are subject to further consideration due to the costs involved in their implementation.[104]

2.106 A number of submitters told the committee that these recommendations should be implemented. By way of example AusBiotech stated that:

> ...many of the issues addressed by the terms of reference of this Inquiry are well-addressed in the recommendations of the HTA Review and in their implementation and [Biotech] suggests that an outcome of the Senate Inquiry be the provision of opportunity for the HTA recommendations to be fully implemented and their effectiveness and impact on the regulatory standards associated with medical devices monitored.[105]

2.107 Similarly, the AHIA supported the implementation of the recommendations and noted that although DoHA has delayed these recommendations based on the cost

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103 Panel to Review the transparency of the Therapeutic Goods Association, *Review to improve the transparency of the Therapeutic Goods Administration, Final Report*, June 2011, available at http://www.tga.gov.au/pdf/consult/review-tga-transparency-1101-final-report.pdf, accessed 20 September 2011.

104 Therapeutic Goods Administration, *Submission 18*, p. 12.

105 AusBiotech, *Submission 16*, p. 8.

implications, there has been 'no cost benefit analysis flagged to allow the issue to progress'. AHIA also informed the committee that 'a number of the industry bodies including the AHIA have flagged a willingness to financially support their establishment'.[106]

2.108 The committee received evidence that there is 'currently limited reporting and visibility by the TGA in relation to post-market surveillance'.[107] Medibank Private explained that 'due to resource limitations, the TGA tends to be more reactive rather than proactive in post-market surveillance activities'. It submitted that this is 'a situation which could be addressed by prioritising implementation of HTA recommendations 13, 14 and 15' regarding post-market surveillance.[108]

2.109 The CHF noted that identifying prostheses with high revision rates relies on the post-market capture of information from consumers, health professionals and manufacturers. Drawing on consumer consultations, they emphasised the 'importance of ensuring that many avenues are available for the capture of such information, and then for its aggregation, public reporting and feedback into the review process'.[109]

Adverse event reporting

2.110 In addition to the HTA's consideration of adverse event reporting, the TGA Transparency Review identified a number of issues with the process:

- The current reporting system for adverse events is complex.
- Timely advice and the distribution of information regarding adverse drug reactions appear to be lacking.
- The regular provision of information to keep health practitioners, consumers and the media informed of the TGA's management of adverse events is needed.
- The lack of transparency regarding information on adverse events including events following immunisation.[110]

2.111 The TGA Transparency Review also made several recommendations regarding adverse event reporting:

106 Australian Health Insurance Association, *Submission 20,* p. 10.

107 Medibank Private, *Submission 1,* p. 6.

108 Medibank Private, *Submission 1,* p. 6.

109 Consumers Health Forum of Australia, *Submission 2,* p. 4.

110 Panel to Review the transparency of the Therapeutic Goods Association, *Review to improve the transparency of the Therapeutic Goods Administration, Final Report*, June 2011, p. 50, available at http://www.tga.gov.au/pdf/consult/review-tga-transparency-1101-final-report.pdf, accessed 20 September 2011.

Recommendation 19: The TGA more effectively facilitate the recognition and reporting of adverse events by health practitioners and consumers, and promote the adverse event reporting system.

Recommendation 20: The TGA make its Adverse Events Database available to, and searchable by, the public in a manner that supports the quality use of therapeutic goods.

Recommendation 21: The TGA work with State and Territory governments, stakeholders, and other relevant agencies, to improve the visible management of adverse event reporting in support of consumer safety and consistent with the findings of the Horvath Review into Immunisation.[111]

2.112 Submitters raised a number of issues in relation to adverse event reporting including that the Therapeutic Goods Regulations require a manufacturer to report adverse events to the TGA yet reporting of adverse events is optional for medical device users. The TGA encourages the reporting of adverse events and its website includes forms for 'medical device users (clinicians, patients or their relatives, etc) to report any suspected problems with a medical device which has or may present a health hazard' as well as a form for 'medical device manufacturers or authorised representatives for mandatory reporting of adverse events associated with a medical device'.[112]

2.113 Submitters also noted the importance of encouraging adverse event reporting by health practitioners and consumers.[113] The Cancer Council WA commented that:

> ...currently there is limited stakeholder access to post-market surveillance reporting systems, which provide vital information for monitoring of the safety and efficacy of devices. Consumers, patients and clinicians are a rich source of information as end-users of therapeutic products, and so should be encouraged to participate in the post-market surveillance process.[114]

2.114 The CHF further commented that 'consumers often report an adverse event to their doctor rather than the manufacturer or sponsor of a device' and 'often the sponsor is not aware of adverse events'. Yet, whereas the Act requires sponsors to report adverse events there is no requirement for doctors to do so.[115]

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111 Panel to Review the transparency of the Therapeutic Goods Association, *Review to improve the transparency of the Therapeutic Goods Administration, Final Report*, June 2011, available at http://www.tga.gov.au/pdf/consult/review-tga-transparency-1101-final-report.pdf, accessed 20 September 2011.

112 Reporting medical device problems, http://www.tga.gov.au/safety/problem-device.htm, accessed 16 September 2011.

113 Cancer Council WA, *Submission 19,* [p. 3]; Consumers Health Forum of Australia, *Submission 2,* p. 2.

114 Cancer Council WA, *Submission 19,* [p. 3].

115 Consumers Health Forum of Australia, *Submission 2,* p. 2.

2.115 A number of submitters indicated that greater clarity is required regarding what events need to be notified to the TGA. By way of example, the CHF submitted that regulations need to be strengthened 'so that sponsor judgement is not a factor in determining what is to be reported'.[116] Similarly, the Australian Private Hospitals Association (APHA) proposed that 'there should be clear criteria established around...what constitutes a notifiable issue and what does not'.[117]

2.116 The AMA provided suggestions about how to better facilitate reporting by medical practitioners:

> Medical software companies could incorporate the ability for medical practitioners to compile the adverse event report using their medical practice software. Relevant information could be electronically incorporated into the TGA form and emailed directly to the TGA. This would reduce the time for completing and dispatching the form, which in turn would encourage more reporting to the TGA. Further, it is important that medical practitioners can see the value of reporting adverse events to the TGA by receiving information directly from the TGA about the quantity of reports of the same nature and what action has been taken in respect of the product that has been reported as being associated with adverse events.[118]

2.117 Other submitters provided similar comments on the need for the TGA to provide feedback to stakeholders. The CHF suggested that the TGA make information on adverse event reports available in real time and provide formal feedback on the TGA response to stakeholders involved in adverse event reporting.[119] Similarly, Cancer Council WA submitted that:

> ...regular, public reporting on the nature of adverse events associated with therapeutic devices is essential. We recommend the TGA publically reports on adverse events associated with therapeutic devices, detailing associated TGA action. We submit that such a system would enhance the manner in which the general public is notified of potentially risky devices.[120]

2.118 The CHF submitted that initiatives need to be developed 'to build and support increased awareness of the Incident Report and Investigations Scheme [IRIS] and other post-market surveillance processes'.[121]

2.119 The CHF noted that when they carried out consultations for the HTA Review consumers expressed a strong view that:

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116 Consumers Health Forum of Australia, *Submission 2,* p. 2.

117 Australian Private Hospitals Association, *Submission 4,* [p. 2].

118 Australian Medical Association, *Submission 3,* p. 2.

119 Consumers Health Forum of Australia, *Submission 2,* p. 5.

120 Cancer Council WA, *Submission 19,* [p. 3].

121 Consumers Health Forum of Australia, *Submission 2,* p. 2.

> ...the post-market surveillance function should be the responsibility of an agency separate from the one that conducts the original assessment of health technologies.[122]

2.120 However, in the event that the TGA remains responsible for post-market surveillance as well as assessment, the CHF submitted that 'consumers argued that a separate division of the TGA should be created to conduct reviews, ensuring greater separation of assessment and review functions'.[123]

2.121 A number of submitters expressed specific concerns about adverse reporting as it relates to remanufactured devices. Further discussion of remanufactured devices is found below. Medtronic Australasia explained its concerns about this issue:

> Medical device manufacturers are required to keep records of, and report to regulatory authorities, all adverse events and complaints regarding their products. Medtronic has significant concerns about the ability of healthcare practitioners, consumers and companies to effectively identify original products from those that are likely to still bear the original manufacturers logos and model numbers but which have been reprocessed whether or not additional labelling is applied. Accurate recording of complaints, failures and adverse events is essential as a part of post-market surveillance and internal quality systems to ensure that the trending and reporting processes are not contaminated and skewed by inclusion of reprocessed devices. Similarly, where the original manufacturer identifies a quality issue with the original product and issues recalls and field actions to customers and consumers, it may not be possible to identify where reprocessed products have been supplied and thus to notify users. This potentially raises issues of concern with respect to ongoing patient safety.[124]

2.122 In the context of this inquiry, issues of post-market surveillance assume a particular importance for patients who experienced problems associated with implantation with the DePuy hip or hip resurfacing system. This is discussed further in chapter 4.

Clinical registries

2.123 The Centre of Research Excellence in Patient Safety (CREPS) explained that clinical registries are databases that systematically collect health-related information on specified groups of individuals. This includes those treated with a particular surgical procedure, device or drug (e.g. joint replacement); diagnosed with a particular illness (e.g. stroke); or managed via a specific healthcare resource (e.g. treated in an intensive care unit).[125]

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122 Consumers Health Forum of Australia, *Submission 2*, p. 2.

123 Consumers Health Forum of Australia, *Submission 2*, p. 2.

124 Medtronic Australasia, *Submission 14*, p. 9.

125 Centre of Research Excellence in Patient Safety, *Clinical Registries*, http://www.crepatientsafety.org.au/registries, accessed 21 October 2011.

2.124 In November 2010 the Australian Health Ministers' Conference (AHMC) endorsed principles for clinical registries, which had been drafted by CREPS and the National E-Health Transition Authority (NEHTA). Following this, the Australian Commission on Safety and Quality in Health Care (ACSQHC) announced that it will:

> Draft national arrangements, including data and clinical governance, for Australian clinical quality registries.
>
> Prepare a costed technical infrastructure plan to be provided to Health Ministers in 2011.[126]

2.125 The TGA submitted that there are a range of considerations in establishing and managing clinical registries:

- adequacy and reliability of funding–funding needs to cover infrastructure/core costs, data collection, analysis and reporting, operational requirements and the ability to support growth and innovation;
- agreement on the funding obligation – amongst beneficiaries of the data and information produced by the registry;
- definition of role and role clarity – the extent to which different stakeholders can access data and information and engage in registry governance and operations;
- the elements of central registry functions – data management, quality control, reporting and governance;
- the elements of peripheral registry functions – data collection and patient follow up which occur at a hospital level and rely upon the engagement and support of health service providers; and
- requirements for information technology and other infrastructure to support registry operations and governance.[127]

2.126 A number of submitters supported the role that clinical registries can play in post-market assessment.[128] The AMA observed that:

> Clinical registers allow medical practitioners to identify problems early, respond appropriately and support clinical decisions about which devices are delivering the best patient outcomes in particular clinical circumstances.[129]

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126 Australian Commission on Safety and Quality in Health Care, *Clinical Quality Registries: Project Overview*, http://www.health.gov.au/internet/safety/publishing.nsf/Content/PriorityProgram-08_clinical1, accessed 6 October 2011.

127 Therapeutic Goods Administration, *Submission 18,* pp 13–14.

128 Australian Medical Association, *Submission 3*, p. 2; Consumers Health Forum of Australia, *Submission 2*, p. 5; Australian Orthopaedic Association, *Submission 5*, [p. 2], Medical Technology Association of Australia, *Submission 12*, p. 6.

129 Australian Medical Association, *Submission 3*, p. 2.

2.127 The AOA argued that clinical registries provide a superior mechanism to 'reactive post-market surveillance driven by reports of adverse outcomes from sponsors' in ensuring that products continue to meet Australian standards.[130]

2.128 The National Joint Replacement Registry (NJRR), which is administered by the AOA, and has been collecting data on the revision of orthopaedic procedures since 1 September 1999, was singled out for praise by a number of submitters.[131]

2.129 The AMA described the NJRR as a 'premium example of a clinical registry that collects and provides high quality data on the performance of joint prostheses'. The AMA explained further that:

> The NJRR allows the Australian Orthopaedic Association to monitor the performance of surgeons against their peers. The NJRR information also assists the TGA to remove unsafe and non-performing devices from the ARTG.[132]

2.130 The AOA claimed that the NJRR has been very successful in changing the behaviour of orthopaedic surgeons, evidenced by a decline in the proportion of revision hip replacements and revision knee procedures. The AOA went on to state that the NJRR:

> ...has proven to be a world benchmark in the establishment and maintenance of rigorous post-market surveillance. It is pro-active, centrally driven, government funded, conflict free with professional ownership of the data and protected under Quality Assurance legislation for compliance.[133]

2.131 The AOA noted that the NJRR 'was the first to identify that the ASR was a prostheses that was associated with a higher than anticipated revision rate and this lead to the prostheses being withdrawn in Australia in 2009 almost a year earlier than the worldwide withdrawal'. AOA provided further information about the operation of the NJRR:

> Currently AOA NJRR reports regularly to TGA and to other government bodies regarding demographics, trends in prostheses usage and prostheses with a higher than anticipated revision rate. It has also provided TGA with secure internet access to its database that enables the TGA to obtain preliminary outcomes data on any joint replacement prostheses being used within the country. This data is updated daily and reflects the national situation as of six weeks earlier. The AOA NJRR also provides the TGA

130 Australian Orthopaedic Association, *Submission 5,* [p. 4].

131 Australian Medical Association, *Submission 3,* p. 2; Consumers Health Forum of Australia, *Submission 2,* p. 5; Medical Technology Association of Australia, *Submission 12,* p. 6; Sportsmed-SA, *Submission 15,* [pp 1–2], Name Withheld, *Submission 27,* [p. 2]; The Hon Dr Michael Armitage, Chief Executive Officer, Australian Health Insurance Association, *Committee Hansard* , 27 September 2011, pp 1, 2.

132 Australian Medical Association, *Submission 3,* p. 2.

133 Australian Orthopaedic Association, *Submission 5,* [p. 2].

> with ad hoc reports on request. These are sometimes requested if TGA have received adverse event notifications and want more in depth information on a particular prosthesis.[134]

2.132 The committee heard that although the ASR hip was withdrawn from the market in 2009, it continued to be sold in other parts of the world until August 2010. Professor Graves, NJRR, used this example to make a case for much greater international collaboration:

> There are now 20 or so registries around the world, and I think that there needs to be much more international collaboration. If we look at the ASR, in Australia we identified that it was an issue and it was withdrawn from the Australian market in 2009. It continued to be sold in other parts of the world until August 2010. The reason that the company gave for withdrawing it worldwide in 2010 was, they said, that the English and Wales registry had identified that there was a higher than anticipated rate of revision for these devices. Now, we had been identifying it for quite a few years at that point of time. But what that message really says is that two registries identifying an issue suddenly adds a lot more strength to the idea that there may be an issue with the device.[135]

2.133 Professor Graves, NJRR, provided further information on advantages that accrue in being able to link a number of similar registries at the international level. Professor Graves informed the committee that the US Food and Drug Administration (FDA) have formed a new organisation called the International Consortium of Orthopaedic Registries (ICOR). Professor Graves, who will chair ICOR, explained what the organisation will do:

> What they are doing is providing funding for registries to work together in a collaborative manner to identify issues with respect to joint replacement. We have talked about issues related to individual devices; however, there are classes of devices which are now being identified as an issue. The metal-on-metal group as a whole, particularly in conventional hip replacements and large-head metal on metal, is an issue of great concern worldwide. The Australian registry has been identifying another class where there have been devices that use what we refer to as exchangeable necks which appear to have over twice the risk of revision compared to devices that do not have those exchangeable necks. So there are a whole range of issues coming up that registries, if they work in collaboration, will identify very quickly and on which they will be able to provide very strong advice to regulatory bodies worldwide.[136]

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134 Australian Orthopaedic Association, *Submission 5*, [p. 2].

135 Professor Stephen Graves, National Joint Replacement Registry, *Committee Hansard*, 27 September 2011, p. 22.

136 Professor Stephen Graves, National Joint Replacement Registry, Australian Orthopaedic Association, *Committee Hansard*, 27 September 2011, p. 23.

2.134 A number of submitters proposed that more clinical registries need to be established,[137] with the CHF suggesting that the NJRR should be used as a model for further clinical registries.[138] The AMA described clinical registries as 'a valuable and cost-effective way to undertake post-market assessment', and submitted that:

> If we are to improve post-market assessment of medical devices and patient safety in Australia, it is essential that more clinical registries be established for a broader range of devices, such as neurological shunts and cardiac devices...The benefits to the Australian community, both in terms of individual health outcomes and overall health expenditure, and the public interest in guaranteeing independent governance of clinical registries, justifies Government funding for clinical registries.[139]

2.135 The MTAA supported the development of further clinical registries for higher risk devices but stressed that these should be 'developed in accordance with public health priority areas to ensure that the cost of the registry delivers maximum benefit to the healthcare system'.[140]

2.136 Noting the success of the NJRR, the AOA suggested 'the establishment of additional registries for things such as Anterior Cruciate Ligament (ACL) reconstructions, hip fractures, cardiac/cardio/thoracic devices and trauma registries', submitting that these registries should be 'established, funded and supported by similar professionally independent mechanisms as the AOA NJRR'.[141]

2.137 JJM submitted that clinical registries could benefit from a broader range of stakeholder involvement. They acknowledged that a consultative committee to the NJRR has been formed including stakeholders from the industry. However, JJM went on to comment that 'we would like to see broader implementation (including patients, administrators and industry) in the governance of the registry itself'.[142]

2.138 The AMA provided comment on the funding of clinical registries:

> We note that while the Commonwealth's costs of the NJRR are met by a levy on device suppliers, these costs are passed on to patients. The role of the TGA in post-market regulation will be sufficiently strengthened by the introduction of more clinical registries. We believe this is a cost that the Australian community is willing to share, rather than imposing it on the

137 Australian Medical Association, *Submission 3*, p. 2; Consumers Health Forum of Australia, *Submission 2*, p. 5; Australian Orthopaedic Association, *Submission 5*, [p. 2].

138 Consumers Health Forum of Australia, *Submission 2*, p. 5.

139 Australian Medical Association, *Submission 3*, p. 2.

140 Medical Technology Association of Australia, *Submission 12*, p. 6.

141 Australian Orthopaedic Association, *Submission 5*, [p. 3].

142 Johnson & Johnson Medical, *Submission 28*, p. 14.

> individuals whose lives have been saved or improved by medical devices.[143]

Other post-market mechanisms

2.139 The committee received information from submitters about how the billing code, in conjunction with other coding and identification processes, could be utilised to flag when a problem was occurring with a particular device. The AHIA submitted that:

> There is no flag or indicator to a billing code identified as being subject to an alert or recall and benefits are not adjusted based on industry feedback as to the device's performance. If this option were to be pursued, there is considerable scope for improvement, via the coding and identification processes between the TGA, PL and any patient data registers that would potentially pick up on these points.[144]

2.140 The way that these coding and identification processes could be better aligned was described by the AOA. The AOA submitted that there should be:

> ...simultaneous allocation of ARTG numbers, Private Health Insurance prostheses listing, and allocation of billing codes, catalogue numbers and [Medicare Benefits Schedule] CMBS item numbers for each device and/or technology.[145]

2.141 In addition to the post-market surveillance mechanisms already detailed, the TGA draws on advice from clinical and technical experts. The TGA provided details of the three expert committees that assist with pre- and post-market functions in the medical devices area of the TGA.

- The Advisory Committee on Medical Devices (ACMD) 'provides independent medical and scientific advice to the Minister for Health and Ageing and the TGA on safety, quality and performance of medical devices supplied in Australia including issues relating to premarket conformity assessment and post-market monitoring'.
- The Medical Devices Incident Review Committee (MDIRC) 'is established as a sub-committee of the ACMD. The major function of MDIRC is to advise the TGA and the ACMD on matters relating to the safety performance of medical devices supplied in Australia. It does this by reviewing reports received by the TGA through its medical device Incident Reporting and Investigation Scheme'.[146]

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143 Australian Medical Association, *Submission 3*, p. 2.

144 Australian Health Insurance Association, *Submission 20*, p. 4.

145 Australian Orthopaedic Association, *Submission 5*, [p. 2].

146 Therapeutic Goods Administration, *Submission 18*, p. 15.

- The Orthopaedic Expert Working Group (OEWG) 'is established as a sub-committee of the ACMD. This group consists of orthopaedic surgeons with expertise in joint replacement surgery. It has a crucial role to play in advising the TGA on appropriate actions to take in the regulation of orthopaedic devices. It is called upon to review available clinical data and other relevant information and provide advice to the TGA on whether an early revision (replacement) rate for orthopaedic devices is acceptable for the identified implant of concern'.[147]

2.142 In addition to operating the NJRR, the AOA explained that it has also recently established a system of web-based linkages for early notification of hazard alerts, enabling early and rapid dissemination to AOA surgeons. The AOA explained that 'this expediency precludes further devices being implanted during any 'lag' period of notification'.[148]

Committee comment

2.143 The committee notes that Recommendations 13, 14 and 15 of the HTA Review go to improved post-market surveillance by increasing the rate of reporting of adverse events, including by health service providers and consumers; facilitating the expansion and use of post-market surveillance data to inform safety, effectiveness and reimbursement decisions; and establishing further clinical registers for high risk implantable devices and procedures. The committee is of the view that implementing these recommendations will make an important, and timely, contribution to improved post-market surveillance.

2.144 The committee is of the view that implementing the recommendations of the TGA Transparency Review will also make an important, and necessary contribution to post-market monitoring and surveillance. Recommendations 15-21 of the TGA Transparency Review go to substantially improving the way that the TGA communicates with stakeholders in relation to post-market monitoring and compliance, and the way that it manages adverse events. Recommendations 1-14 of the TGA Review are also pertinent as they address the need for improved communication and information provision by the TGA for the benefit of, and with greater involvement by, stakeholders.

Safety standards and approval processes for devices that are remanufactured for multiple use

2.145 Single-use medical devices are medical devices 'intended to be used on an individual patient during a single procedure and then discarded...not intended to be reprocessed and used on another patient'. When a single-use device is 'remanufactured'

147 Therapeutic Goods Administration, *Submission 18*, pp 15–16.

148 Australian Orthopaedic Association, *Submission 5*, [p. 4].

a single-use device is either assembled, packaged, processed, fully refurbished, labelled or assigned a new intended purpose to supply for reuse.[149]

2.146 The TGA explained that the Australian Health Ministers' Advisory Council (AHMAC) had decided in 2001 that if reprocessing of single-use devices was to occur in Australia, it would be regulated as a manufacturing activity by TGA to the same requirements as the original manufacturer.[150]

2.147 The TGA outlined the regulatory framework for reprocessed single-use medical devices (SUD) and noted that under current therapeutic goods legislation, reprocessed SUDs are 'treated as new distinct medical devices, with the new manufacturer (the reprocessor) responsible for ensuring the reprocessed single-use devices are of acceptable safety, and perform as intended'.[151]

2.148 The TGA went on to explain the conformity assessment approval process, noting however that 'to date, the TGA has not issued a conformity assessment certificate to any manufacturer of reprocessed single-use medical devices'. The TGA stated that:

> ...[the approval process] requires a review of the information provided by the manufacturer to ensure that the manufacturer employs a QMS [Quality Management System] suitable for the class of device being manufactured, and the manufacturer holds adequate evidence to demonstrate the safety and performance of the reprocessed devices. Manufacturers assessed as meeting these regulatory requirements would be issued with a conformity assessment certificate, enabling the reprocessed medical devices to be included on the ARTG.[152]

2.149 Submitters provided a range of opinions to the committee on the acceptability of remanufacturing single-use devices for multiple use. A number of submitters supported the remanufacture of medical devices in certain circumstances. The AOA argued that many items that could be safely used more than once are disposed of as they are labelled single-use.[153] Sportsmed-SA contended that 'there is a financial incentive for a manufacturer to label all devices an SUD irrespective of whether it still is fit for purpose for subsequent use'.[154]

2.150 Stryker Australia submitted that 'the remanufacturing of specific and appropriate expensive medical devices that are marked for single-use only, can

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149 Therapeutic Goods Administration, Acronyms and glossary, http://www.tga.gov.au/about/glossary.htm#s, accessed 4 October 2011.

150 Therapeutic Goods Administration, *Submission 18,* p. 7.

151 Therapeutic Goods Administration, *Submission 18,* p. 7.

152 Therapeutic Goods Administration, *Submission 18,* p. 7.

153 Australian Orthopaedic Association, *Submission 5,* [p. 4].

154 Sportsmed-SA, *Submission 5,* [p. 2].

contribute to relieving costs in an overburdened health system'.[155] Stryker Australia distinguished between devices that can genuinely only be used once and those that have only been validated for a single-use, arguing that:

> ...there is a large range of products that can genuinely only be used once, there is also a significant number of products that the original equipment manufacturers (OEMs) have only validated for a single use, and that with the correct and validated remanufacturing processes in place, could be validated as safe and effective for an additional use.[156]

2.151 However, JJM contested the assertion that reprocessing of single-use medical devices provides economic benefits. JJM acknowledged that 'various studies show that reprocessing single-use devices is cheaper than using a single-use device'. Nevertheless, they submitted that:

> ...the analysis of economic benefits is often inadequate as it is based upon a comparison of the cost of reprocessing versus the price of a new single use device. This type of analysis does not take into account other significant costs to hospitals such as internal costs, regulatory compliance costs and the penalty costs of adverse events such as device failure or contamination.[157]

2.152 JJM noted that the regulatory approach to reprocessing single-use devices differs in different jurisdictions, and provided a summary of the differences. The United Kingdom prohibits the reprocessing of single-use devices due to fears of cross contamination with Creutzfeld-Jacob Disease (CJD) and variant CJD. However in the EU there is no uniform policy, with some countries not approving or prohibiting reprocessing of single-use devices. While the United States allows commercial reprocessing under the regulatory control of the United States Food and Drug Administration (FDA), Canada has no guidelines at a national level.[158]

2.153 St Jude Medical noted 'ongoing concerns about significant gaps in the *Australian Regulatory Guidelines for Medical Devices (ARGMD) on the Reuse of Single Use Devices*'. They noted that 'Australia has a regulatory system for medical devices that is harmonised with the European Medical Device Directives', yet submitted that 'remanufactured devices are not considered suitable for CE marking in Europe'.[159]

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155 Stryker Australia, *Submission 11*, [p. 1].

156 Stryker Australia, *Submission 11*, [p. 1].

157 Johnson & Johnson Medical, *Submission 28*, p. 19.

158 Johnson & Johnson Medical, *Submission 28*, p. 5.

159 St Jude Medical Australia, *Submission 8*, [p. 13]; see also Johnson & Johnson Medical, *Submission 28*, Appendix: *Reuse of single use medical devices in Australia: safety and performance imperatives and challenges to regulatory compliance*, p. 5.

2.154 A number of submitters raised the prospect that post-market surveillance will be compromised if remanufactured devices are unable to be traced.[160] For example, JJM noted that:

> ...it is problematic that many devices bear the CE mark directly on the device (in compliance with regulatory requirements). Unless the CE mark is physically removed (a process which may in itself damage the device) the reprocessed single use medical device is effectively misbranded.[161]

2.155 St Jude Medical explained further its concerns that the TGA is 'currently considering an application to 'remanufacture' products that the original manufacturer has designed to be used only once', arguing that a remanufacturer should not be able to supply a device, still bearing the original manufacturers branding, for a use for which it is not intended:

> Under the Australian regulatory system for medical devices, it is the responsibility of the designing manufacturer to determine the intended use of a device based on a thorough understanding of the design, materials, manufacturing processes and risk analysis. If the device cannot be guaranteed by the manufacturer to perform according to specification more than once, then it must be labelled as "Single Use Only"...It appears that the TGA is contemplating condoning 'off label' use.[162]

2.156 Several submitters raised concerns that remanufactured devices pose threats to patient health. AusBioTech noted risks from remanufactured devices including risks of contamination, material degradation and mechanical failure of the medical device, as well as that remanufacturers do not have 'access to the original design specifications which makes validating the safety and effectiveness of the reprocessed device difficult'.[163]

2.157 Similarly, St Jude Medical listed potential risks to patients from remanufactured devices including cross-infection from failure to remove micro-organisms (including prions), accumulation of unsafe levels of sterilisation chemicals, damage to the integrity of the materials and potential for mechanical failure.[164]

2.158 Medtronic Australasia raised concerns about 'whether a device designed for single-use can be effectively decontaminated and re-used whilst maintaining the same

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160 St Jude Medical Australia, *Submission 8,* [p. 13]; see also Johnson & Johnson, *Submission 28,* Appendix: *Reuse of single use medical devices in Australia: safety and performance imperatives and challenges to regulatory compliance,* p. 5.

161 Johnson & Johnson Medical, *Submission 28,* Appendix: *Reuse of single use medical devices in Australia: safety and performance imperatives and challenges to regulatory compliance,* p. 5.

162 St Jude Medical Australia, *Submission 8,* [pp 13–14].

163 AusBioTech, *Submission 16,* pp. 7–8.

164 St Jude Medical Australia, *Submission 8,* [p. 15]; see also Johnson & Johnson Medical, *Submission 28,* p. 33.

safety profile' as the original device. Medtronic Australia provided evidence of its experience with remanufactured devices:

> Results from Medtronic testing of US market sourced reprocessed/remanufactured Medtronic Octopus® tissue stabilisation product, used for beating heart surgery, in the US market, showed that all of the 14 reprocessed units tested were contaminated with unknown material, showed DNA and protein positive bio-contamination and exhibited physical defects.[165]

2.159 Stryker South Pacific provided additional information to the committee to clarify the difference between validated remanufacturing and other kinds of reuse. They explained:

> Remanufacturing devices using a validated remanufacturing process should not be confused with any other practice of reusing devices. There are many health care settings in which devices are reused without undergoing a validated remanufacturing process, for example a hospital may decide to clean and reuse devices without any external validation. This was common in Australian hospitals before being banned in 2003/04 and is still reportedly common in hospitals in some parts of the world. This ban stopped risky reuse practices but led to hospitals discarding many devices that could with appropriate and validated remanufacturing – be used safely more than once.[166]

2.160 Stryker South Pacific also sought to dispute the claims that remanufactured devices are unsafe. They informed the committee that:

> Comprehensive evidence from the USA supports the safety and quality of remanufactured devices and has identified no additional problems associated with validated remanufacturing processes over and above those recognized by the original manufacturer. The overwhelming majority of reports to the Food and Drug Administration (FDA) of adverse events associated with medical devices relate to the first use of 'single use' devices and the FDA has stated that it has not identified 'any adverse events that were actually related to the reprocessing of the SUD (single use device).'
>
> Furthermore, FDA's adverse event database contains over 6,500 reports of patient deaths associated with original (un-reprocessed) medical devices since 2004. According to the same database, no deaths have been associated with the use of reprocessed 'single use' medical devices.[167]

2.161 Issues of informed patient consent were raised by a number of submitters. St Jude Medical argued that patients 'need to be fully informed that a reprocessed

165 Medtronic Australasia, *Submission 14*, p. 9.

166 Stryker South Pacific, Additional Information provided on 7 October, 2011, pp 2–3.

167 Stryker South Pacific, Additional Information provided on 7 October, 2011, p. 4.

medical device may be used during the procedure' as remanufacturing of devices elevates risks to patients.[168] Similarly, JJM argued that:

> ...typically patients are not informed that reprocessed devices are to be used or their consent requested. Surgeons and other clinicians also are not normally aware if a device they are about to use is reprocessed.[169]

2.162 AusBiotech recommended consideration of an inquiry to address the safety concerns associated with the reprocessing of single-use medical devices in Australia.[170] Stryker South Pacific recommended 'that the TGA (or appropriate body) conduct an inquiry into the un-validated reprocessing of medical devices in Australian hospitals and health care settings'.[171]

Committee comment

2.163 The committee received a variety of evidence about whether remanufactured devices are safe, but was concerned by risks of contamination, material degradation and mechanical failure of medical devices. While the committee is aware of arguments that remanufacturing medical devices may contribute to reducing hospital's costs and waste, they note that these benefits may not be as substantial as claimed.

2.164 The committee notes that a prudent approach was taken by the Australian Health Ministers' Advisory Council in 2001 when it decided that, if reprocessing of single-use devices was to occur in Australia, it should be regulated to the same requirements as the original manufacture. The committee supports the prudent approach taken by the TGA to date, which has seen no conformity assessment certificate issued to any manufacturer of reprocessed single-use medical devices.

Other matters

The regulation of custom made dental prostheses

2.165 Although the placement of therapeutic goods on the ARTG is regulated by the TGA, there are limitations on the coverage of the Act and exceptions to the requirements that medical devices be placed on the ARTG. [172] The ADIA has raised the issue of how internet imports circumvent the protections put in place by the *Therapeutic Goods Act 1989.* The ADIA explained:

> It is possible to purchase from overseas sources (via websites such as eBay) most products that appear on the ARTG. There is evidence that healthcare

168 St Jude Medical Australia, *Submission 8,* [pp. 14–15].

169 Johnson & Johnson Medical, *Submission 28,* p. 33.

170 AusBiotech, *Submission 16,* p. 8.

171 Stryker South Pacific, Additional Information provided on 7 October, 2011, p. 10.

172 Therapeutic Goods Administration, *Submission 18,* p. 27.

> professionals are buying dental product[s] from overseas sources and using [these] in their practices...[173]

2.166 Similar concerns were expressed by Logic Appeal who informed the committee that up to 50 per cent of custom made dental prostheses such as crowns, bridges, dentures and some implants are sourced from overseas markets such as China, India and Vietnam. Logic Appeal stated that these medical devices are not validated by the TGA at the source of manufacture.[174]

2.167 Logic Appeal went on to explain that while 'the onus is on the practitioner using them to verify they that they are of an adequate standard', the practitioner is frequently unaware of the source of the prostheses, as they may have ordered the item from an Australian address. Logic Appeal also told the committee that 'Patients are similarly unaware of where their dental device is manufactured'.[175]

2.168 Logic Appeal informed the committee that in the United Kingdom patients receiving a dental appliance are offered a statement of manufacture. Logic Appeal explained that 'Practitioners are obligated to retain this statement for the lifetime of the prosthesis and record whether this was provided to the patient or not'.[176]

2.169 Both Logic Appeal and the ADIA submitted that legislative reform is required in relation to the importation of dental prostheses. Logic Appeal submitted that legislation is required to hold dentists and dental care professionals accountable if they sub-contract manufacture of a medical device overseas, with a statement of manufacture serving as proof to both patients and practitioners of where the device originated.[177]

2.170 The ADIA suggested that 'the medical devices personal importation provisions contained in the *Therapeutic Goods Act (Cth) 1989* be removed', and 'the Australian Government provide a budget appropriation to the TGA to fund activities associated with awareness of, and compliance with, regulatory standards for the importation of medical devices'.[178]

Committee comment

2.171 The committee notes that custom made dental devices appear to escape TGA scrutiny, with dental professionals and patients alike unaware that up to 50 per cent of custom made dental prostheses are manufactured overseas, with no validation at the source of manufacture. The model employed in the United Kingdom, whereby

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173 Australian Dental Industry Association, *Submission 30*, p. 3.

174 Logic Appeal, *Submission 33*, p. 1.

175 Logic Appeal, *Submission 33*, p. 1.

176 Logic Appeal, *Submission 33*, p. 1.

177 Logic Appeal, *Submission 33*, p. 1.

178 Australian Dental Industry Association, *Submission 30*, p. 3.

patients are offered a statement of manufacture, and practitioners are obliged to retain this statement for the lifetime of the prosthesis, and must record whether the statement was provided to the patient or not, appears to have merit.

2.172 The committee is also concerned that the issue of unregulated importation of dental devices via the internet may indicate a much broader problem of inadequate regulation of other medical devices purchased through the internet. The committee is of the view that this requires further investigation and assessment by the TGA.