

The Senate

Community Affairs
References Committee

The regulatory standards for the approval of
medical devices in Australia

November 2011

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43rd Parliament

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ABBREVIATIONS

ACL	Anterior Cruciate Ligament
ACMD	Advisory Committee on Medical Devices
ACSQHC	Australian Commission on Safety and Quality in Health Care
ADIA	Australian Dental Industry Association
AFSSAPS	Agence française de sécurité sanitaire des produits de santé
AHIA	Australian Health Insurance Association
AHMAC	Australian Health Ministers' Advisory Council
AHMC	Australian Health Ministers Conference
AHPRA	Australian Health Practitioner Regulation Agency
AIMD	Active Implantable Medical Devices
AMA	Australian Medical Association
AMC Code	Australian Medical Council Good Medical Practice: A Code of Conduct for Doctors in Australia
AOA	Australian Orthopaedic Association
APHA	Australian Private Hospitals Association
ARGMD	Australian Regulatory Guidelines for Medical Devices
ARTG	Australian Register of Therapeutic Goods
ASR	Articular Surface Replacement
AusPARs	Australian Public Assessment Reports for prescription medicines
BSC	Boston Scientific Australia New Zealand
CAB	Conformity Assessment Body
CAG	Clinical Advisory Group
CE	Conformité Européenne
CHF	Consumers Health Forum of Australia
CJD	Creutzfeld-Jacob Disease
MBS	Medicare Benefits Schedule
CMI	Consumer Medicine Information
CREPS	Centre of Research Excellence in Patient Safety, Monash University
DIISR	Department of Innovation, Industry, Science and Research
DoHA	Department of Health and Ageing
EC	European Community
EU	European Union

EU NB	European Union Notified Body
FDA	Food and Drug Administration (United States)
GHTF	Global Harmonisation Task Force
GMP	Australian code of good manufacturing practice for medicinal products
HCP	Healthcare Professionals
HTA	Health Technology Assessment
ICOR	International Consortium of Orthopaedic Registries
IEC	Independent Ethics Committee
IRIS	Incident Report and Investigation Scheme
JJM	Johnson & Johnson Medical Pty Ltd
MDD	Medical Device Directive
MDIRC	Medical Devices Incident Review Committee
MRA	Mutual Recognition Agreement
MSAC	Medical Services Advisory Committee
MTAA	Medical Technology Association of Australia
NEHTA	National E-Health Transition Authority
NJRR	National Joint Replacement Registry
OEM	Original Equipment Manufacturers
OEWG	Orthopaedic Expert Working Group
PDC	Prostheses and Devices Committee
PHI	Private Health Insurance
PI	Product Information
PLAC	Prostheses Listing Advisory Committee
PoCE	Panel of Clinical Experts
QMS	Quality Management System
RACS	Royal Australasian College of Surgeons
RSA	Radiostereometric analysis
SAS	Special Access Scheme
SUD	Single Use Device
TGA	Therapeutic Goods Administration
UPI	Unique Product Identifiers

RECOMMENDATIONS

Recommendation 1

5.16 The committee recommends that the Therapeutic Goods Administration make a list of the devices on the Australian Register of Therapeutic Goods publicly available.

Recommendation 2

5.17 The committee recommends that the Department of Health and Ageing fully implement Recommendation 8c of the Health Technology Assessment Review regarding the need for increased rigour of regulatory assessment of higher-risk medical devices.

Recommendation 3

5.18 The committee recommends that the level of assessment of Class III medical devices be increased.

Recommendation 4

5.19 The committee recommends that the Therapeutic Goods Administration investigate whether allowing an increasing number of medical devices onto the Australian market actually improves clinical outcomes; and whether a more judicious approach could improve pre-market assessment and post-market surveillance of higher risk medical devices, for the ultimate benefit of patients.

Recommendation 5

5.23 The committee recommends that the Therapeutic Goods Administration continue to consult widely with stakeholders, including consumer health organisations, on the amended proposals related to third party conformity assessment; and weigh carefully considerations of the advantages of streamlined international regulatory frameworks and patient safety.

Recommendation 6

5.28 The committee recommends that the Therapeutic Goods Administration continue its prudent approach to the regulation of reprocessed single-use medical devices, with due consideration for issues of informed patient consent and the need for suitable mechanisms to enable tracing of remanufactured medical devices in the case of adverse events.

Recommendation 7

5.39 The committee recommends that the Department of Health and Ageing implements Recommendations 13, 14, and 15 of the Health Technology Assessment Review in a timely manner. These recommendations address the need for 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.

Recommendation 8

5.40 The committee recommends that the Therapeutic Goods Administration put in place mechanisms to educate and encourage doctors to report adverse incidents associated with the use of medical devices. The committee further recommends that the Department of Health and Ageing introduce mandatory reporting for health practitioners to the Therapeutic Goods Administration on relevant issues, in certain circumstances including problems with medical devices.

Recommendation 9

5.41 The committee recommends that the Government implements the Recommendations of the Therapeutic Goods Administration Transparency Review in a timely manner.

Recommendation 10

5.42 The committee recommends that the Therapeutic Goods Administration consider simultaneously allocating or aligning the great variety of codes used to identify medical devices, in order to facilitate more efficient regulation and more rapid identification of devices when problems occur.

Recommendation 11

5.43 The committee recommends that the Department of Health and Ageing consider a mechanism for flagging billing codes in order to identify devices subject to an alert or recall; as well as a consequent adjustment to benefits paid, based on industry feedback as to the performance of the device.

Recommendation 12

5.46 The committee recommends that the Therapeutic Goods Administration consider whether custom made dental devices are adequately regulated; and whether the approach used in the United Kingdom of requiring a statement of manufacture to be provided to patients, and retained by the dental practitioner, has merit.

Recommendation 13

5.47 The committee recommends that the Therapeutic Goods Administration carry out an investigation to ascertain whether importation of medical devices via the internet is adequately regulated.

Recommendation 14

5.52 The committee recommends that the Therapeutic Goods Administration, in consultation with the National Joint Replacement Registry, investigate ways in which information provided by the National Joint Replacement Registry can be used and responded to in a more timely way for the benefit of patients, and to inform future evidence based decision making on the listing of prostheses on the Australian Register of Therapeutic Goods.

Recommendation 15

5.57 The committee recommends that the Department of Health and Ageing prepare, as a matter of priority, a comprehensive communications strategy to inform medical practitioners, patients and the general public about the issues associated with De Puy hip and hip resurfacing devices as well as options for treatment, obtaining further information, and reporting adverse outcomes. The committee further recommends that such a strategy be implemented as a standard process for any future adverse event reporting.

Recommendation 16

5.58 The committee recommends that the Department of Health and Ageing, as a matter of urgency, consider the best way of establishing a process for monitoring the levels of cobalt, chromium, and other toxic metals; and any possible health effects, in all patients who have received metal-on-metal hip replacements.

Recommendation 17

5.59 The committee recommends that the Government consider the best mechanism for initiating and advancing research on the health effects of cobalt, chromium, and other toxic metals, on the human body. The committee also recommends that consideration be given to ensuring adequate funding for that research is made available.

Recommendation 18

5.64 The committee recommends that the Department of Health and Ageing undertake further work to address the issue of inducements paid by pharmaceutical companies and medical device manufacturers to doctors and teaching hospitals, in line with the Physician Payment Sunshine provisions of the *Patient Protection and Affordable Care Act* of 2009 in the United States. The definition of inducements should include a commercial interest in a company or device; any cash payments or discounts offered to medical practitioners; and any other gifts provided to medical practitioners.

Chapter 1

Introduction

Terms of reference

1.1 On 16 June 2011 the Senate referred the following matter to the Senate Community Affairs References Committee for inquiry and report by 12 October 2011:

The regulatory standards for the approval of medical devices in Australia, with particular attention to devices with high revision rates, and in undertaking the inquiry the committee consider:

- (a) the role of the Therapeutic Goods Administration in regulating the quality of devices available in Australia;
- (b) the cost effectiveness of subsidised devices;
- (c) the effectiveness and accuracy of the billing code and prostheses list;
- (d) the processes in place to ensure that approved products continue to meet Australian standards;
- (e) the safety standards and approval processes for devices that are remanufactured for multiple use;
- (f) the processes in place to notify the relevant authorities and the general public of high revision rates or possible faulty devices;
- (g) the effectiveness of the current regimes in place to ensure prostheses with high revision rates are identified and the action taken once these devices are identified;
- (h) the effectiveness of the implemented recommendations of the Health Technology Assessment; and
- (i) any other related matter.

1.2 The reporting date was extended to 8 November 2011 and subsequently to 22 November 2011.

Conduct of the inquiry

1.3 The inquiry was advertised in *The Australian*, and through the internet. The committee invited submissions from the Commonwealth Government and interested organisations.

1.4 The committee received 34 public submissions. The list of individuals and organisations which made public submissions to the inquiry, together with other information authorised for publication by the committee, is at appendix 1. The committee held a public hearing in Canberra on 27 September 2011. The list of witnesses who gave evidence at the public hearing is available at appendix 2. In addition, the committee received responses in relation to potential adverse reflections. Following the public hearing on 27 September 2011, the committee received

correspondence from St Jude Medical raising concerns about evidence provided at the hearing by Ms Karen Carey.

1.5 Submissions, additional information, the Hansard transcript of evidence and responses to potential adverse reflection (contained in submissions or expressed at the public hearing) may be accessed through the committee's website at http://www.aph.gov.au/senate/committee/clac_ctte/index.htm

Acknowledgement

1.6 The committee thanks those organisations and individuals who made submissions and gave evidence at the public hearings.

Note on references

1.7 References in this report are to individual submissions as received by the committee, not to a bound volume. References to the committee Hansard are to the proof Hansard. Page numbers may vary between the proof and the official Hansard transcript.

Structure of the report

1.8 The report is structured as follows:

- Chapter 2 discusses issues related to the regulation of medical devices in Australia;
- Chapter 3 provides a background to the DePuy ASR hip system. It goes on to focus on the experience of consumers with DePuy ASR hip prostheses, and their associated revision surgery. It also examines the effectiveness of the current regime in place to ensure prostheses with high revision rates are identified; and the action taken once these devices are identified;
- Chapter 4 covers the cost effectiveness of subsidised devices and the effectiveness and accuracy of the billing code and Prostheses List; and
- Chapter 5 presents a summary of the committee's conclusions.

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

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:

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

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:

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

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 assessment³² 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

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 trials 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:

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

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.

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, Medtronic Australasia submitted that, in many respects, there is not much difference between the system for reimbursement of medical devices in Australia and France. Medtronic 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 Medtronic 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

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

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

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

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:

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

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

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

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.

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

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

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:

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

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

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

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

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

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

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

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

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.

Chapter 3

High revision rates: the consumer experience

Introduction

3.1 The previous chapter focussed on the role of the TGA in regulating the quality of medical devices in Australia. This examined both pre-market regulation and post-market surveillance.

3.2 This chapter commences with a background to the DePuy ASR hip system. The chapter then turns to the experience of consumers with DePuy ASR hip prostheses and associated revision surgery. Information was also provided to the inquiry regarding the DePuy LCS Duofix Femoral Knee Replacement Component (the DePuy knee replacement). The processes in place to notify the relevant authorities and the general public of high revision rates or faulty devices are also examined here. In particular, the effectiveness of the current regime in place to ensure prostheses with high revision rates are identified and the action taken once these devices are identified, will be discussed in detail.

3.3 A consistent theme of evidence provided to the committee was a need for the TGA to improve the way that it communicates with stakeholders as part of the fulfilment of its regulatory role. The submitters' comments frequently echoed the recommendations of the TGA Transparency Review. The need for improved communication has been discussed in general terms in the previous chapter. The call for greater transparency and better provision of information assumes critical importance when identifying and acting upon the high revision rate prostheses that are the subject of this chapter.

The DePuy ASR hip system

3.4 Issues around the De Puy ASR hip system were brought to light in May 2011 when ABC current affairs program 'Four Corners' broadcast a program detailing allegations regarding a relatively new type of hip replacement surgery used in Australia. The technology involved using metal-on-metal technology, including the metals cobalt and chromium.¹

3.5 Many individuals interviewed by Four Corners had received ASR, or Articular Surface Replacement, hips manufactured by DePuy Orthopaedics, part of the Johnson & Johnson company. The high revision rates of these devices, both in Australia and worldwide, eventually prompted a voluntary recall by DePuy.

1 ABC, Program Transcript, *Four Corners*, 'Joint Reaction', 16 May 2011.

Approximately 5500 people in Australia, and 93 000 worldwide, were the recipients of these metal-on-metal devices.²

3.6 During the course of the program, Four Corners interviewed numerous individuals who had received metal-on-metal devices, including interviews with those who had subsequently had revision surgery. Many interviewed reported systemic health problems extending beyond initial complications with the device. This included: vision impairment, tinnitus and heart palpitations. Professor Ross Crawford, an orthopaedic surgeon who has been involved with providing revision surgery theorised these complications are due to cobalt toxicity.³

3.7 The issues raised by the Four Corners program provided much of the impetus for this inquiry. The program also served to inform the public of something that should already have been much better known.

What is the DePuy ASR Hip System?

3.8 The hip is a ball-and-socket joint. The socket is formed by the acetabulum, which is part of the large pelvis bone. The ball is the femoral head, which is the upper end of the femur (thighbone). A slippery tissue called articular cartilage covers the surface of the ball and the socket. It creates a smooth, frictionless surface that helps the bones glide easily across each other.⁴

3.9 A total hip replacement, involves the removal and replacement of the head of the thighbone (femoral head) and the damaged socket (acetabulum) with metal, plastic, or ceramic components.⁵

3.10 Hip resurfacing is a newer technique, which does not involve the removal of the femoral head. The femoral head is instead capped, or 'resurfaced', with a hemispherical covering. The damaged bone and cartilage within the socket is removed and replaced with a shell made of metal, ultra-high molecular-weight polyethylene or a combination of polyethylene backed by metal, as in a total hip replacement.⁶

2 ABC, Program Transcript, *Four Corners*, 'Joint Reaction', 16 May 2011.

3 ABC, Program Transcript, *Four Corners*, 'Joint Reaction', 16 May 2011.

4 American Academy of Orthopaedic Surgeons, *Hip Arthroscopy*, <http://orthoinfo.aaos.org/topic.cfm?topic=A00572>, accessed 12 September 2011.

5 American Academy of Orthopaedic Surgeons, *Hip Resurfacing*, <http://orthoinfo.aaos.org/topic.cfm?topic=A00586>, accessed 12 September 2011.

6 American Academy of Orthopaedic Surgeons, *Hip Implants*, <http://orthoinfo.aaos.org/topic.cfm?topic=A00355>, accessed 12 September 2011.

3.11 DePuy Orthopaedics, a subsidiary company of JJM, is a provider of orthopaedic devices for hip, knee, extremities and trauma, in addition to bone cement and operating room products.⁷

3.12 There are two types of DePuy hip prostheses: the DePuy ASR resurfacing hip prosthesis; and the DePuy ASR XL femoral head prosthesis. These replaced some earlier models supplied by DePuy.⁸

3.13 The DePuy ASR XL System includes two components:

- a metal femoral head connected to a stem that is inserted in the femur; and
- a one-piece metal cup that lines the acetabulum.

3.14 With an ASR XL total hip replacement, a one-piece metal component known as an acetabular cup is placed in the acetabulum. The femoral head is replaced with a metal ball which is connected to a metal stem placed inside the femur.⁹

3.15 The DePuy ASR Hip Resurfacing System includes two components:

- a metal cap is placed over the natural femoral head; and
- a one-piece metal cup that lines the acetabulum.

3.16 With an ASR Hip Resurfacing System, a one-piece metal component known as an acetabular cup is placed in the acetabulum and a metal cap is placed over the femoral head.¹⁰

3.17 The ASR Hip Resurfacing System was first approved by the Therapeutic Goods Administration (TGA) for use in Australia in 2004 and the ASR XL System was approved in 2005.¹¹

3.18 The ASR Hip Resurfacing System was only approved for use outside the United States (US) and was not commercially available in the US.¹² The US Food and

7 Johnson & Johnson Medical, *Press Release*, 'DePuy Orthopaedics Voluntarily Recalls ASR Hip System', 26 August 2010, <http://www.jnj.com/connect/news/all/depuy-orthopaedics-voluntarily-recalls-asr-hip-system>, accessed 7 September 2011.

8 Therapeutic Goods Administration, *Recall of DePuy Orthopaedics hip replacement device*, 16 May 2011, <http://www.tga.gov.au/newsroom/btn-dupuy-recall.htm>, accessed 25 October 2011.

9 *DePuy ASR Hip Replacement Recall Guide* at: <http://www.depuy.com/asr-hip-replacement-recall>, accessed 7 September 2011.

10 *DePuy ASR Hip Replacement Recall Guide* at: <http://www.depuy.com/asr-hip-replacement-recall>, accessed 7 September 2011.

11 Therapeutic Goods Administration, *Recall of DePuy Orthopaedics ASR hip replacement device*, 16 May 2011, <http://www.tga.gov.au/newsroom/btn-dupuy-recall.htm>, accessed 7 September 2011.

Drug Administration (FDA) did not approve this implant because resurfacing was then a new procedure and it required DePuy Orthopaedics to test it in a clinical trial before it could be sold in the US. In late 2007, DePuy Orthopaedics submitted the study data on the resurfacing implant to the FDA for approval; however, the process was terminated when DePuy Orthopaedics withdrew its application in 2009.¹³

3.19 The ASR hip was included on the Australian Register of Therapeutic Goods after an evaluation by the British Standards Institute, an accredited European assessment body under the supervision of the British regulator, the Medicines and Healthcare products Regulatory Agency.¹⁴

Recall of DePuy ASR Hip System

3.20 In December 2009, in Australia, Johnson & Johnson Medical issued a recall of the ASR XL Acetabular Hip System and DePuy ASR Hip Resurfacing System used in hip replacement surgery.

3.21 In August 2010, DePuy Orthopaedics issued a worldwide voluntary recall of the same medical devices. The recall only applied to patients who had undergone hip surgery after July 2003.¹⁵ All components for the ASR XL Acetabular System and DePuy ASR Hip Resurfacing Platform were part of the recall.¹⁶

3.22 The worldwide recall followed receipt of new, then unpublished data from the national joint replacement registry in the UK that tracks implant performance and outcomes, indicating a higher number of patients than previously reported to DePuy requiring revision surgery.¹⁷ The DePuy Hip Replacement Recall Guide elaborated on the data:

The UK data indicated that within five years of having an ASR resurfacing device implanted, approximately 12 percent of patients had revision surgery and that within five years of having an ASR total hip replacement,

12 *DePuy ASR Hip Replacement Recall Guide* at: <http://www.depuy.com/asr-hip-replacement-recall>, accessed 7 September 2011.

13 Barry Meier, 'The Implants Loophole', *The New York Times*, 16 December 2010.

14 Therapeutic Goods Administration, *Recall of DePuy Orthopaedics ASR hip replacement device*, 16 May 2011, <http://www.tga.gov.au/newsroom/btn-dupuy-recall.htm>, accessed 7 September 2011.

15 *DePuy ASR™ Hip Recall Guide*, http://asrrecall.depuy.com/countries_list, accessed 2 September 2011.

16 *DePuy ASR Hip Replacement Recall Guide*, <http://www.depuy.com/asr-hip-replacement-recall>, accessed 7 September 2011.

17 *DePuy ASR Hip Replacement Recall Guide*, <http://www.depuy.com/asr-hip-replacement-recall>, accessed 7 September 2011.

approximately 13 percent of patients had revision surgery, which was not in line with data previously reported to DePuy.¹⁸

3.23 DePuy Orthopaedics also provided Australian data:

The 2010 Australian National Joint Replacement Registry reports five years after having an ASR hip implanted 7.8% of patients (1 in 13) who had an ASR total hip replacement and 10.9% of patients (1 in 10) who had the ASR resurfacing device needed to have revision surgery.¹⁹

3.24 The processes surrounding the recall of the ASR hip system are discussed in detail below.

Legal action in Australia

3.25 On 28 February 2011, Maurice Blackburn Lawyers commenced a class action in the Federal Court of Australia against DePuy International Ltd, which manufactured the ASR hip implants, and against Johnson & Johnson Medical Pty Limited, which distributed and sold the DePuy ASR hip implants within Australia.

3.26 This class action is being conducted on behalf of all patients who have had one or more DePuy ASR components surgically implanted by a doctor in Australia.²⁰

3.27 Shine Lawyers is also pursuing legal action against DePuy Orthopaedics seeking compensation for over 200 Australians who received an ASR hip.²¹

The consumer experience

3.28 The committee received a number of submissions, and heard evidence from, people whose lives had been deeply affected by their experience of the DePuy ASR XL Hip and DePuy ASR Hip resurfacing system, and the DePuy knee replacement, and associated revision surgery.

18 *DePuy ASR Hip Replacement Recall Guide*, <http://www.depuy.com/asr-hip-replacement-recall>, accessed 7 September 2011.

19 *DePuy ASR Hip System Recall Guide for Patients*, <http://asrrecall.depuy.com/aupatient>, accessed 7 September 2011.

20 Maurice Blackburn Lawyers, *DePuy ASR hip implants class action*, <http://www.mauriceblackburn.com.au/areas-of-practice/class-actions/current-class-actions/depuy-asr-hip-implants-class-action.aspx>, accessed 8 September 2011.

21 Shine Lawyers, *DePuy ASR hip replacement class action*, <http://www.shine.com.au/pages/depuyhipreplacement.aspx>, accessed 13 September 2011.

3.29 Although the circumstances of individual patients differed, the committee received evidence from consumers of devastating health problems that required:

- revision and other surgery;²²
- repeated or extended hospital stays;²³
- multiple and extended courses of antibiotics;²⁴
- major personal and family impact;²⁵ and
- significant financial loss.²⁶

3.30 Health problems cited by submitters included severe pain,²⁷ loss of mobility²⁸ and a complex of physical and psychological effects due to shedding of cobalt and chromium ions from the implanted device.²⁹

3.31 The majority of submitters who were recipients of either the DePuy hip or the DePuy hip resurfacing system have elevated cobalt, and sometimes chromium,

22 Name Withheld, *Submission 22*, pp 2, 3, 5–6 ; Name Withheld, *Submission 23*, p. 2 ; Name Withheld, *Submission 24*, [p. 1] ; Name Withheld, *Submission 25*, p. 1; Mr Robert Lugton, *Submission 29*, [pp 1–2]; Name Withheld, *Submission 31*, [p. 1]; Mr Stuart Cain, *Submission 32*, [p. 1]; Name Withheld, *Submission 34*, [p. 1].

23 Name Withheld, *Submission 22*, pp 3, 5, 6, 7; Name Withheld, *Submission 23*, p. 2; Name Withheld, *Submission 25*, pp 1–2; Name Withheld, *Submission 26*, [p. 1]; Name Withheld, *Submission 31*, [p. 1]; Mr Stuart Cain, *Submission 32*, [p. 1].

24 Name Withheld, *Submission 22*, pp 6–7; Name Withheld, *Submission 25*, p. 4.

25 Mrs Therese Wood, *Submission 9*, [p. 1]; Name Withheld, *Submission 22*, pp 4, 8–15; Name Withheld, *Submission 23*, pp 1, 2, 4; Name Withheld, *Submission 26*, [p. 1]; Mr Robert Lugton, *Submission 29*, [pp 1–2 and 13]; Name Withheld, *Submission 31*, [p. 1]; Mr Stuart Cain, *Submission 32*, [p. 2]; Name Withheld, *Submission 34*, [p. 1].

26 Mrs Therese Wood, *Submission 9*, [p. 1]; Name Withheld, *Submission 22*, p. 9; Name Withheld, *Submission 25*, pp 2–3, Mr Robert Lugton, *Submission 29*, [p. 2].

27 Mrs Therese Wood, *Submission 9*, [p. 1]; Name Withheld, *Submission 22*, pp 4–8, 11–15; Name withheld, *Submission 23*, p. 1; Name withheld, *Submission 25*, p. 1; Name Withheld, *Submission 26*, [p. 1]; Mr Robert Lugton, *Submission 29*, [p. 1]; Name Withheld, *Submission 31*, [p. 1]; Mr Stuart Cain, *Submission 32*, [p. 1]; Name Withheld, *Submission 34*, [p. 1].

28 Name withheld, *Submission 22*, [p. 1]; Name Withheld, *Submission 23*, p. 2; Name Withheld, *Submission 25*, pp 1–4; Name Withheld, *Submission 26*, [p. 1]; Mr Robert Lugton, *Submission 29*, [p. 2]; Name Withheld, *Submission 31*, [p. 1]; Mr Stuart Cain, *Submission 32*, [p. 1]; Name Withheld, *Submission 34*, [p. 1].

29 Name Withheld, *Submission 22*, pp. 5, 8; Name Withheld, *Submission 23*, pp 1, 2, 4; Name Withheld, *Submission 24*, [p. 1]; Name Withheld, *Submission 25*, p. 5; Name Withheld, *Submission 26*, [p. 1]; Mr Robert Lugton, *Submission 29*, [p. 2]; Name Withheld, *Submission 31*, [p. 1]; Mr Stuart Cain, *Submission 32*, [p. 1]; Name Withheld, *Submission 34*, [p. 1].

levels.³⁰ Submitters stated that the excessive amounts of cobalt and chromium in their body have produced symptoms such as bone loss,³¹ extensive damage to bone and soft tissues,³² hip dislocation,³³ pus coloured fluid and pseudo tumours,³⁴ and depression.³⁵ As a result of ensuing problems and complications, one submitter's condition is now terminal.³⁶

3.32 Information in the *DePuy ASR Hip Replacement Recall Guide* advised that ASR patients requiring revision surgery experienced a variety of symptoms, including pain, swelling and problems walking, on a recurrent or continuing basis. These symptoms may be caused by the following problems:

- loosening – when the implant does not stay attached to the bone in the correct position;
- fracture – where the bone around the implant may have broken; and
- dislocation – where the two parts of the implant that move against each other are no longer aligned.³⁷

3.33 The Department of Health and Ageing (DoHA) provided information to the committee on the symptoms of, and limited treatment options for, cobalt toxicity. They stated that:

Heavy metals, such as cobalt and chromium, have been associated with hypothyroidism, cardiac toxicity and nerve damage. In general, where possible, treatment involves attempting to minimise exposure to the heavy metal and treating any associated organ damage.³⁸

3.34 The DePuy ASR Hip Replacement Recall Guide also advised on the effects of metal leaching into the body:

ASR Hip is made up of ball and socket components that move against each other. These metal components wear over time and generate very small particles that can only be seen with a microscope. This is an expected process. These particles do not cause problems for most patients, but a

30 Name Withheld, *Submission 22*, p. 5; Mr Robert Lugton, *Submission 29*, [p. 2]; Name Withheld, *Submission 31*, [p. 1]; Mr Stuart Cain, *Submission 32*, [p. 1]; Name Withheld, *Submission 34*, [p. 1].

31 Mr Robert Lugton, *Submission 29*, [pp 1 and 7].

32 Name Withheld, *Submission 23*, p. 2; Mr Robert Lugton, *Submission 29*, [pp 1–2].

33 Name Withheld, *Submission 31*, [p. 1].

34 Name Withheld, *Submission 26*, p. 1.

35 Name withheld, *Submission 22*, pp 4 and 13; Name Withheld, *Submission 27*, [p. 1].

36 Name Withheld, *Submission 23*, p. 2.

37 *DePuy ASR Hip Replacement Recall Guide*, <http://www.depuy.com/asr-hip-replacement-recall>, accessed 7 September 2011.

38 Department of Health and Ageing, Answers to questions on notice, 25 October 2011.

small number of patients may react to these particles, causing fluid to collect in the joint and in the muscles around the joint. While this condition may initially be painless, if left untreated, this reaction may cause pain and swelling around the joint and could damage some of the muscles, bones, and nerves around the hip.³⁹

Case studies

3.35 The following cases are illustrative of consumers' experiences of the DePuy ASR hip and hip resurfacing system provided to the committee.

3.36 Case Study A received an ASR total hip replacement in January 2008 at the age of 63. He told the committee that:

It is difficult as a victim to come to terms with the fact that, if I had received one of the many, many proven hips that are available, I would be enjoying life without the pain and suffering that will follow me for the rest of my life. It would have been that easy. No second five-hour operation, no bone grafts, no splitting of my femur open and putting it together with clamps and wire-caging, no pneumonia, no renal failure, no second stay in intensive care, no pain, no pain-killing drugs, no stress for my wife and family and no loss of what will amount to a minimum of \$80, 000 to myself and the community—all because someone wanted, for whatever inducement, to use me in a medical trial, and I am one of the lucky ones. They value the quality of our lives too cheaply.⁴⁰

3.37 Case Study B, Mr Stuart Cain, received an ASR total hip replacement in June 2007. He subsequently experienced major physical problems including pain, mobility loss, anaemia, fatigue, weakness, and cobalt and chromium toxicity. The hip was revised in November 2010. However, this was not the end of his ordeal. In a supplementary submission received by the committee he detailed the subsequent 'catastrophic failure of the right total hip replacement':

Fortunately I was able to successfully undergo surgery on Saturday October 8 and after 4.5 hours of surgery I now have received my last possible hip replacement and have had my femoral bone wired together to repair the damage caused through the removal of the ten month old implant that had broken. The main cause of concern for me, and I think a very relevant issue for this inquiry is what the surgeons discovered upon performing the osteotomy (splitting of the bone to access the interior of it) to separate my femoral bone to remove the broken elements of my previous implant.

There was an approximately 10cm area within the bone that had developed severe necrosis (tissue death) as a result of metallosis caused by the original ASR implant degrading whilst it was insitu as there was no visible degradation on the surface of the 'new' implant I received in November

39 *DePuy ASR Hip Replacement Recall Guide* at: <http://www.depuy.com/asr-hip-replacement-recall>, accessed 7 September 2011.

40 Name Withheld, *In Camera Committee Hansard*, 27 September 2011, p. 1.

2010. This 'dead' area had not allowed my new implant to grow or adhere to the bone, this allowed the femoral stem to have flex which in the course of time caused it to snap in half. I also had to undergo 4 blood transfusions post-surgery to try to assist me to recover even a low Haemoglobin level, this was directly related to the Anaemia that I developed as a result of having the ASR implant in my hip in the first place. This was effectively a time bomb that was ticking away within my leg, it would eventually fail and as there is no other way to determine the extent of metallosis within the bone (except for regular bone biopsies which are not a standard follow up procedure for hip replacement patients), this is now a risk that I have come across, but more importantly, potentially there are many other Australian patients out there who could be unknowingly in the same situation.⁴¹

3.38 Case Study C received an ASR hip resurfacing device in November 2008. The consumer explained their subsequent experience to the committee:

My recovery following the surgery was slow and painful during the first six weeks post-op. From then I became ill with a whole range of different general symptoms and my hip remained sore, the pain increasing with time and the hip began "clicking and crunching". I consulted many different Doctors over the following fifteen months as I attempted to discover what was causing my general malaise. At no time did I consider that my worsening illnesses may be attributable to the hip implant. At no time did my Surgeon suggest my illness could be related to the hip implant.

Following a television current affairs programme, my partner and I realised that "Heavy Metal Poisoning (Cobalt and Chromium)" seemed to account for all of the symptoms I had experienced between the day of my operation and then.

I arranged for an appointment with my GP and for a Cobalt and Chromium blood test. The results revealed extremely high levels of Cobalt and Chromium toxicity in my blood. I then attended for my next scheduled follow-up appointment where I informed the replacement surgeon of my blood test results. Further blood tests were arranged and the results showed a significant increase in the already enormous level of toxicity in my blood.

[Name Redacted] then refused to see me again and referred me to the [Name Redacted] for assessment and possible treatment at some time in the future. Since that time I have been refused all orthopaedic treatment in South Australia.

Realising that the part needed to be revised urgently, my partner attempted to locate a Surgeon somewhere in the world who was willing to operate and remove the device. Eventually a Surgeon in Melbourne contacted us and I travelled to Melbourne, where the implant was removed on 11th November 2010.

The damage to my bone and soft tissues was horrendous and extensive. This meant that a Total Hip Replacement was required as described in the

41 Mr Stuart Cain, *Supplementary Submission 32*, [pp 1–2].

operation notes. Follow-up blood tests have indicated a dramatic reduction in Cobalt levels, but Chromium levels remain extremely high and static to the present time.

I am at this stage, despite medical expectations, still alive. I have been told that my death from the damage caused by the level of Cobalt and Chromium toxicity in my body will be horrific and will occur sooner rather than later. My partner and my family are extremely distressed.⁴²

3.39 Consumers and their advocates were highly critical of a regulatory system that they consider has failed. Issues raised with the committee by submitters go to shortcomings at all stages of the regulatory process for medical devices. Submitters raised the inadequacy of pre-market testing of devices; potential conflicts of interest of, and inducements for, surgeons and hospitals; the lack of information provided to patients to enable them to make informed decisions prior to surgery; problems with the adverse event reporting regime; the failure of the TGA to act upon information that it had available to it; the failure of the TGA to enforce the legislation and regulations that they are responsible for administering; and the lack of information and follow up provided to patients and the public once prostheses had been identified as problematic.

Pre-market clinical testing

3.40 Many of the consumers who provided evidence to the committee questioned why their hip and knee replacements were not adequately tested prior to being listed on the ARTG, and indeed whether the TGA should have listed these devices without clinical evidence.⁴³ Some consumers consequently felt that they were themselves unwittingly part of an unofficial clinical trial.

3.41 Ms Karen Carey, CHF, argued that the listing, and subsequent implantation, of medical devices without adequate pre-market clinical testing meant that patients were being treated as 'guinea pigs'. She explained further:

In a normal clinical trial, before a device would be put into common use, you would have a trial population. They would be the guineapigs and you would try it out on them. With medical devices, when a product comes to market without the clinical evidence they are really using normal patients as guinea pigs, because the evidence is not there. And they do not do it within a clinical trial environment in which those patients are closely monitored. They are simply putting the devices in, and patients are rarely told that there is only a small amount of evidence.⁴⁴

42 Name Withheld, *Submission 23*, [pp 1–2].

43 Mrs Therese Wood, *Submission 9*, [p. 1]; Mr Robert Lugton, *Submission 29*, [p. 6]; Name Withheld, *Submission 22*, p. 11; Name Withheld, *Submission 23*, p. 2; Name Withheld, *Submission 26*, [p. 1].

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

3.42 Ms Carey went on to submit that this process also failed in other ways. She told the committee that:

I have to say it does not even effectively constitute a trial, because they do not collect data and then use that data to make decisions. It is even worse than that: they trial it on patients and do not collect the data.⁴⁵

3.43 Another consumer raised concerns that patients are unaware that they are receiving clinically untested prostheses, effectively constituting unofficial trials, and further that those who have suffered as a result don't have an avenue of complaint. This consumer explained these concerns to the committee:

I am here because I have a duty to represent the thousands of people who have been unknowingly involved in trials with untested hip prostheses that have consequently failed and are unable to have their plight heard because of many reasons and circumstances. The vast majority of them will not even be aware that they have been part of a medical trial.⁴⁶

3.44 This sentiment was echoed by another submitter who stated that:

I find it hard to accept that the Australian trials for this device relied on data from overseas – and there were, in actual fact, no Australian trials and investigations into the suitability of this prosthesis. Obviously the patient was the trial.⁴⁷

3.45 Mr Robert Lugton highlighted that the AOA have similar concerns about the adequacy of pre-market testing.⁴⁸ He drew the committee's attention to the AOA submission to the TGA Consultation on Reforms in the Medical Devices Framework. In this submission, the AOA stated:

Currently there are no standards that define what is required for pre-market assessment of hip and knee replacement prostheses and the approach to the assessment by both manufacturers and regulators is ad hoc. It is likely that the type and amount of information that is required to undertake a pre-market assessment needs to be re-evaluated and clarified. Regulators must develop more stringent approaches to both product approval and post market surveillance. Finally it is also clear that orthopaedic surgeons need to be more discriminatory and evidence based in their approach to prostheses choice.⁴⁹

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

46 Name Withheld, *In Camera Committee Hansard*, 27 September 2011, p. 1.

47 Name Withheld, *Submission 26*, [p. 1].

48 Mr Robert Lugton, *Submission 29*, [p. 6].

49 Australian Orthopaedic Association, AOA Submission, Discussion Paper– Reforms in the Medical Devices Regulatory Framework, 17 December 2010, appended to Mr Robert Lugton, *Submission 29*.

3.46 Mr Lugton drew the committee's attention to JJM's opposing position regarding pre-market scrutiny in a submission the company had made to the TGA Consultation on Reforms in the Medical Devices Framework.⁵⁰ JJM stated that:

...JJM acknowledges the TGA's concern about the adequacy of review of higher risk devices. However we do not believe that the proposed increase in pre-market scrutiny is the most appropriate model for ensuring the quality, safety and performance of medical devices supplied in Australia. The nature of complex medical technology is that some unexpected outcomes of devices use only manifest with extensive post approval clinical use and post market surveillance is essential to identify these.⁵¹

3.47 Mr Lugton submitted that this statement from JJM shows that:

...they would like to rely heavily on "risk management" and "post market surveillance". What this actually means is that manufacturers would like to be allowed to continue supplying clinically untested devices into the market and let the patients take the risks, and then watch and see what happens.⁵²

Committee comment

3.48 The committee notes the significant and substantiated concerns of patients as well as the AHIA and the AOA regarding inadequate pre-market clinical testing, which was discussed in chapter 3 of this report. The committee considers that implementing Recommendation 8c of the HTA to increase the rigour of assessment of high risk medical devices is paramount. In this regard, introducing a requirement for two years minimum clinical evidence prior to a device being listed on the ARTG would appear to have significant merit.

Informed consent

3.49 Many of the consumers who submitted evidence to the inquiry did not feel they were provided enough information to give informed consent to the implantation of these devices. They did not feel they were informed by their surgeons of the known problems that were being experienced, particularly with the DePuy ASR hip, DePuy ASR hip resurfacing device and the DePuy Femoral Component. They also did not feel that their surgeons' or hospitals' financial interest in using that specific device was disclosed to them, meaning that informed consent was not possible.⁵³

50 Mr Robert Lugton, *Submission 29*, [p. 4].

51 Johnson & Johnson Medical, Reforms in the Medical Devices Framework, Submission in Response to the TGA Discussion Paper of 25 October 2010, 7 January 2001, appended to Mr Robert Lugton, *Submission 29*.

52 Mr Robert Lugton, *Submission 29*, [p. 4].

53 Mrs Therese Wood, *Submission 9*, [p. 1]; Ms Karen Carey, Board Director, Consumers Health Forum of Australia, *Committee Hansard*, 27 September 2011, p. 33; Name Withheld, *Submission 24*, [p. 1].

3.50 Ms Karen Carey, Board Director, CHF outlined a range of informed consent issues with the committee:

In the first instance the obligation is to tell the patient what their options are. Therefore when you are discussing options, whoever has the conflict needs to say that if in relation of one of those options they have a financial interest or a research interest that needs to be told to the patient so that they can take that into account when they are making the choice between the treatment options. If patients are properly informed, and that is that they know their treatment options, they know the potential outcomes, including complications, and they know the rates of incidence, it is a format in which proper disclosure can occur. It should always be disclosed.⁵⁴

Product information

3.51 The CHF explained that a variety of information is available about medicines including Consumer Medicine Information (CMI), Product Information (PI) and Australian Public Assessment Reports for prescription medicines (AusPAR). However, CHF has expressed concern that the information about medical devices is currently inadequate, compared to that available for medicines. They argue that having such information available for medical devices is even more important, 'as their use cannot be ceased in the way that medications can be when a problem occurs', and that this information needs to be available prior to a device being implanted.⁵⁵

Committee comment

3.52 The committee notes that on 23 September 2011 the TGA announced a 'proposed course of action' in relation to Proposal 4 of the *Reforms in the Medical Devices Regulatory Framework Discussion Paper*⁵⁶ which addresses this issue:

The TGA considers that it is important to be more transparent and will explore the possibility of posting manufacturer's Instructions for Use (or an abstract thereof) and Australian Public Assessment Reports (AusPAR) equivalents on the TGA in the first instance.⁵⁷

54 Ms Karen Carey, Board Director, Consumers Health Forum of Australia, *Committee Hansard*, 27 September 2011, p. 33.

55 Consumers Health Forum of Australia, *Submission 2*, p. 5; Mrs Therese Wood, *Submission 9*, [p. 1].

56 Department of Health and Ageing, Therapeutic Goods Administration, *Reforms in the Medical Devices Regulatory Framework: Discussion Paper 25 October 2010*, p. 24.

57 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.

Disclosure of known problems

3.53 A number of submitters told the committee that if they had been informed that the prosthesis chosen by their surgeon was already known to be causing patients problems, they would not have agreed to it being implanted in their bodies.⁵⁸

3.54 Of particular note is the patient who received an ASR hip resurfacing device in November 2008: the NJRR had reported to the TGA on several occasions since September 2007 that there was a statistically significant rate of revisions of this device.⁵⁹ Further, the minutes of the OEWG meeting held on 21 May 2008 show that the TGA noted that the manufacturer of the ASR resurfacing hip implant had approached the TGA recognising that the revision rate was unacceptable.⁶⁰

3.55 It should also be noted that the TGA does not have access to information regarding specific patients who have received implants. When a recall of a device is undertaken, the TGA contacts industry and health professional bodies, with information about the action.

Committee comment

3.56 It appears to the committee that ASR hip devices were in use after a higher than expected revision rate had been identified. The committee believes that insufficient information was provided to consumers regarding the concerns with the device. This is regrettable.

Conflicts of interest

3.57 Some submitters believed that the choice of implants by doctors may have been subject to conflicts of interest or inducements of a financial nature.⁶¹ Mr Richard Bartlett, First Assistant Secretary, Medical Benefits Division, DoHA addressed the issue of disclosing commercial interests between the manufacturer of the device and the doctor:

In terms of the patient actually giving informed consent, they need to be fully informed. If the surgeon has an interest in the device and they are not told of that, they are not actually giving fully informed consent. There is

58 Name Withheld, *In Camera Committee Hansard*, 27 September 2011, p. 2; Name Withheld, *Submission 23*, p. 1.

59 Professor Stephen Graves, National Joint Replacement Registry, *Committee Hansard*, 27 September 2011, p. 20.

60 Department of Health and Ageing, Answers to questions on notice, 25 October 2011, *Minutes of the Orthopaedic Expert Working Group*, 21 May 2008, p. 5.

61 Name Withheld, *Submission 22*, p. 2.

also a professional and ethical element to this that one would expect the relevant college to have a level of interest in.⁶²

3.58 Ms Carol Bennett, Chief Executive Officer, CHF, also addressed this issue and submitted there was room for improved disclosure:

The codes of professional conduct should cover those sorts of issues. Whether or not it happens, certainly consumers report to us that it does not often happen and they do not feel as though they have received fully informed consent. Clearly there is a limitation there, but that is around how the profession manages those sorts of conflicts, and it needs to be improved.⁶³

3.59 Submitters stated that they were not given a choice of hip or knee implants. The committee also received evidence that in a number of cases the consumer had specifically asked for a different device to be implanted, however the request was refused by their doctor.⁶⁴ As one submitter told the committee:

I was a recipient of a metal-on-metal hip replacement in January 2008. My surgeon was the partner of [Name redacted], one of the researchers into the technology and the development of the De Puy ASR XL Hip implant. [Name redacted] insisted upon fitting the De Puy device, despite my wish for [Name redacted] to use a ceramic device.⁶⁵

3.60 Another submitter noted that JJM sponsor the fellowship programme at the hospital where the operation was performed and stated that in their view, this is why the hospital uses JJM's products.⁶⁶

3.61 In the May 2011 Budget Estimates hearing Senator Xenophon asked the TGA two questions on this matter:

In September 2007, De Puy Orthopaedics agreed to pay \$84.7million to the US Government as part of an agreement to avoid criminal prosecution over financial inducements the company paid to surgeons for the use of their products

a) Was the TGA aware of this case at the time?

b) Was De Puy, or De Puy's products, subject to additional scrutiny because of this?⁶⁷

62 Mr Richard Bartlett, First Assistant Secretary, Medical Benefits Division, Department of Health and Ageing, *Committee Hansard*, 27 September 2011, p. 52.

63 Ms Cathy Bennett, Chief Executive Officer, Consumers Health Forum of Australia, *Committee Hansard*, 27 September 2011, p. 33.

64 Name Withheld, *Submission 24*, [p. 1].

65 Name Withheld, *Submission 24*, [p. 1].

66 Name Withheld, *Submission 22*, p. 2.

67 Senate Community Affairs Legislation Committee, Answers to questions on notice, Health and Ageing Portfolio, Budget Estimates 2011–2012, 31 May 2011, Question E11–018.

And

In addition, De Puy has recently paid 4.8 million pounds in a further settlement after De Puy's Director of Marketing, Robert Dougall, was convicted of paying bribes to secure contracts in Greece.

- a) Was the TGA aware of this conviction?
- b) What impact did this have on the TGA's dealings with De Puy?

3.62 In both cases the TGA answered it was unaware of the cases.⁶⁸

Codes of conduct

3.63 Information was provided to the committee on a range of codes of conduct and internal guidelines that address the need to provide patients with full disclosure in the event that a doctor has a financial or other interest in a medical device.

3.64 The AOA provided the committee with information on their code of conduct:

AOA has had a professional code of conduct for members for a number of years. However, following the USA FDA investigation of device companies during 2004/05, the AOA Code of Conduct was reviewed and strengthened.

The code of conduct since at least 2006 has outlined the requirement for members to disclose any financial interest in the sale of drugs, prostheses, or appliances that he/she may have when recommending that particular item to a patient.

AOA believes the previous code of conduct also outlined the same requirement but due to a change of website that occurred in that year the file format used previously is unreadable.

The code of conduct has been reviewed in 2006, 2008 and 2010.⁶⁹

3.65 The AOA also provided information on sanctions for breaching the AOA code of conduct:

Firstly the complaint has to be a written complaint directly to AOA to initiate the process. The complaint would be referred to the AOA Professional Conduct Committee for assessment and review. Sanctions include counselling of the member through to removal of the member from the Association. If the complaint involved anything of a criminal nature it would be referred to the relevant authority (ie police,[Australian Health Practitioner Agency] AHPRA).⁷⁰

68 Senate Community Affairs Legislation Committee, Answers to questions on notice, Health and Ageing Portfolio, Budget Estimates 2011–2012, 31 May 2011, Question E11–019.

69 Australian Orthopaedic Association, Answer to question on notice, 17 October 2011.

70 Australian Orthopaedic Association, Answer to question on notice, 17 October 2011.

3.66 Finally, the AOA provided information on complaints made to the AOA regarding breaches of the code:

There have been no complaints to AOA that were progressed through to invoking sanctions. AOA received one written complaint in 2010 but it was not progressed internally as it was regarded as raising issues outside AOA charter. The complainant was advised to report the matter to AHPRA.⁷¹

3.67 JJM provided information to the committee on their International Health Care Business Integrity Guide:

As with other affiliate companies, Johnson & Johnson Medical Pty Limited (JJM) is required to comply with an internal International Health Care Business Integrity Guide (the Guide) that contains enterprise-wide standards for compliance with a number of legal regimes. It is intended to supplement national and international legislation and applicable industry codes.

The Guide sets out how Johnson & Johnson Medical Pty Limited (JJM) interacts with healthcare professionals (HCP) including the following principles:

When engaging a HCP to act on behalf of the company, the services paid for by the Johnson & Johnson Medical Pty Limited (JJM) must fill a legitimate, documented business need and such services must be obtained from individuals who possess demonstrable special knowledge or capabilities to perform the services;

These services must be properly documented in a written agreement, and that agreement must specify the complete compensation arrangements. Compensation paid must be fair market value for the services provided. Johnson & Johnson Medical Pty Limited (JJM) must document how fair market value was determined;

Performance of services received must be documented and invoices from service providers must have sufficient detail to enable proper recordkeeping; and

The agreement must contain a representation and warranty by the HCP that, in the event the HCP is or attains a position to influence purchasing decisions by a government entity or the HCP's employer, the HCP shall notify the purchase decision-maker of the HCP's financial relationship with Johnson & Johnson Medical Pty Limited (JJM) and otherwise comply with applicable requirements of local law. In such circumstances, the agreement will also permit Johnson & Johnson Medical Pty Limited (JJM) to terminate the agreement.

The Guide also sets out the requirements for arrangements under a Product Development Agreement or a licence for intellectual property rights. Again, such arrangements must be properly documented in a written contract that includes the complete compensation arrangements with the healthcare

71 Australian Orthopaedic Association, Answer to question on notice, 17 October 2011.

professional. In addition, if royalties are to be paid, the healthcare professional's contribution to the development of the product at issue must be documented. Further, the Guide requires that purchases by the applicable healthcare professional be excluded in the calculation of appropriate royalties to avoid the potential for improper influence.

The Guide does not require that Johnson & Johnson Medical Pty Limited (JJM) should ensure that healthcare professionals notify patients that they have a commercial relationship.⁷²

3.68 In addition JJM provided information to the committee that the company expected 'the doctors and orthopaedic surgeons with whom it interacts to abide by their professional standards of conduct and ethics, including':

- The Australian Medical Council Good Medical Practice: A Code of Conduct for Doctors in Australia (the AMC Code) which applies to all doctors nationally registered within Australia. Section 8.11 sets out the requirements of a doctor to adhere to when a conflict of interest arises which may affect their care of a patient.
- The Royal Australasian College of Surgeons (RACS) has a Code of Conduct (the RACS Code), which defines the standards of professional behaviour applicable to surgeons who are fellows of RACS. Section 8.1(4) specifies that surgeons will be honest and transparent with respect to any potential conflicts of interest.
- The Australian Orthopaedic Association also has a Code of Conduct for members, which reflects appropriate professional standards and professional expectations for orthopaedic surgeons, above and beyond the requirements of the AMC Code, due to its unique discipline. Section 6.4 of the AOA Code requires that orthopaedic surgeons declare any conflicts of interest, in particular, financial relationships with prosthetic companies or hospitals and other corporate entities or persons.⁷³

Committee comment

3.69 The committee notes that in the US, JJM have agreed to pay a '\$21.4 million criminal penalty as part of a deferred prosecution agreement for improper payments by J&J subsidiaries to public health care providers in Greece, Poland and Romania in violation of the Foreign Corrupt Practices Act (FCPA)'.⁷⁴

72 Johnson & Johnson Medical, Answer to question on notice, 14 October 2011.

73 Johnson & Johnson Medical, Answer to question on notice, 14 October 2011.

74 Tom Moylan, LexisNexis, 'Johnson & Johnson, DePuy Pay \$76.9M To Settle Foreign Bribery Claims', <http://www.lexisnexis.com/community/corpsec/blogs/fcpa-law-blog/archive/2011/04/12/johnson-amp-johnson-depuy-pay-76-9m-to-settle-foreign-bribery-claims.aspx>, accessed 25 October 2011.

3.70 Similarly, the committee notes that the UK Serious Fraud Office obtained a Civil Recovery Order against DePuy International Limited, in recognition of unlawful conduct relating to the sale of orthopaedic products in Greece between 1998 and 2006.⁷⁵

3.71 The committee further notes that public disclosure of payments to physicians and teaching hospitals by medical manufacturers and pharmaceutical companies is now the subject of legislation in the United States. The Physician Payment Sunshine provisions were included in the *Patient Protection and Affordable Care Act* of 2009 (H.R. 3590, section 6002) which was signed into law on 23 March 2010, and will come into effect on 1 January 2012.

3.72 The committee notes with interest legislative developments in another jurisdiction, designed to address the insidious problem of the payment of inducements by pharmaceutical companies and medical device manufacturers to doctors and teaching hospitals. The practice of paying inducements in this way is anathema to principles of informed consent and improved patient safety. The committee is of the view that there is merit for Australia in developing a similar approach.

Notifying authorities, patients and the general public about faulty devices

3.73 One of the critical issues that has been raised by consumers, their advocates and industry bodies relates to the timeliness of notification of those affected by the ASR DePuy hip and ASR DePuy hip resurfacing system, and the adequacy of subsequent action.

3.74 These matters are pertinent to the TGA as regulator of medical devices in Australia, and JJM as the manufacturer of these devices. Some submitters have also raised the question of whether the NJRR could play a more active role in the provision of information to consumers and the medical profession.

Identifying the problem

3.75 It has been reported that between 2003 and 2010, surgeons implanted the DePuy ASR hip and ASR hip resurfacing device in 93 000 patients around the world – 5500 of whom were Australians.⁷⁶ The ASR hip and hip resurfacing devices were withdrawn in Australia by the company in December 2009, and worldwide in August 2010.

75 Serious Fraud Office, 'DePuy International Limited ordered to pay 4.829 million pounds in Civil Recovery Order', <http://www.sfo.gov.uk/press-room/latest-press-releases/press-releases-2011/depu-international-limited-ordered-to-pay-4829-million-pounds-in-civil-recovery-order.aspx>, accessed 25 October 2011.

76 ABC, Program Transcript, *Four Corners*, 'Joint Reaction', 16 May 2011.

3.76 The committee sought details of when the NJRR, the TGA and JJM became aware that there was a problem:– first with the ASR hip resurfacing system; and subsequently with the ASR hip replacement system itself.

3.77 The DoHA has provided a helpful timeline regarding events associated with the ASR hip. This can be found at appendix 5.

The NJRR and the TGA

3.78 The committee received evidence about how problems with joint replacements are identified by the NJRR, and subsequently reported to the TGA. Professor Stephen Graves, NJRR, informed the committee that for a device to be considered an 'outlier', or statistically significant, it must have 'at least twice the rate of revision of any other device'. He went on to provide more detail on how the NJRR identified outlier prostheses:

Those outliers have gone through a very rigorous process of identification, which includes statistical analysis that says that they are an outlier. As part of the process, it is also reviewed by an independent group of orthopaedic surgeons. It is that independent group of surgeons that makes recommendations to the registry to identify those particular devices as being outliers.⁷⁷

3.79 Dr Michael Armitage pointed out that a device that requires revision at at least twice the rate of revision of any other device, may in fact need revising at five or six times the rate of any other device.⁷⁸

3.80 It is unclear to the committee how the algorithm of 'at least twice the rate of revision of any other device' was arrived at by the NJRR, and has the appearance of being somewhat arbitrary.

3.81 Professor Graves went on to explain that there are a number of ways that the NJRR provides information to the TGA including by giving the TGA direct access to the NJRR database, by providing more detailed reports on request, and through identification of outlier prostheses in the Annual Report. He noted that prior to the annual report being released detailed reports on each device are provided to the TGA.⁷⁹

3.82 Professor Graves went on to explain what happens after the NJRR notifies the TGA that there are outlier prostheses:

77 Professor Stephen Graves, National Joint Replacement Registry, *Committee Hansard*, 27 September 2011, p. 18.

78 The Hon Dr Michael Armitage, Australian Health Insurance Association, *Committee Hansard*, 27 September 2011, p. 1.

79 Professor Stephen Graves, National Joint Replacement Registry, *Committee Hansard*, 27 September 2011, p. 18.

When we notify the TGA, what happens is that they then go through a process of providing that information to companies and getting responses from companies. That is then reviewed by the orthopaedic expert working group, which again is a further independent group that the TGA has gathered. That group then provides advice to the TGA about what should happen with those particular devices. That advice is then taken on board by the TGA, with the TGA then making its own decisions as to what it will do.⁸⁰

3.83 Professor Graves emphasised to the committee that the role of the NJRR and the TGA are distinct, noting that 'the responsibility for regulation of devices rests solely with the TGA'. He explained further:

It is important to separate the regulatory functions and the information gathering and reporting functions. There is no infrastructure within the registry to determine whether a device is suitable or not suitable for use within the Australian market. What we do is identify devices that are performing differently from other devices.⁸¹

3.84 The NJRR first reported higher than usual revision rates for the ASR resurfacing device in 2006, although it did not meet the threshold of twice the normal rates of revision, and thus was not considered statistically significant. Professor Graves, NJRR, explained that at that time there was no formal notification process between the NJRR and the TGA.⁸²

3.85 However, in mid-September 2007 the NJRR informed the TGA that the ASR resurfacing device was experiencing revisions at a statistically significant rate. By July 2008 the NJRR was aware that the hip replacement itself was experiencing significant revision rates, and informed the TGA in September 2008.⁸³

3.86 Professor Graves told the committee that in September 2008 when the NJRR informed the TGA that the hip replacement itself was a problem, they 'also re-emphasised at that point in time that the resurfacing was still an outlier as well'. He then told the committee that 'In 2009 we again emphasised that both the conventional hip and the resurfacing were outliers'.⁸⁴

80 Professor Stephen Graves, National Joint Replacement Registry, *Committee Hansard*, 27 September 2011, p. 18.

81 Professor Stephen Graves, National Joint Replacement Registry, *Committee Hansard*, 27 September 2011, p. 18.

82 Professor Stephen Graves, National Joint Replacement Registry, *Committee Hansard*, 27 September 2011, p. 20.

83 Professor Stephen Graves, National Joint Replacement Registry, *Committee Hansard*, 27 September 2011, p. 20.

84 Professor Stephen Graves, National Joint Replacement Registry, *Committee Hansard*, 27 September 2011, p. 20.

3.87 Professor Graves also explained that a correlation was not immediately made between there being problems with the ASR hip resurfacing device and potential problems with the ASR hip replacement. However, he explained that there is a nexus, telling the committee that 'The devices are similar in one respect, in that the acetabular or the cup is the same, but the femoral component is quite different'.⁸⁵

3.88 Dr Hammett explained the responses of the TGA to the receipt of information from the NJRR: first regarding the hip resurfacing device, and subsequently the hip replacement itself. Dr Hammett informed the committee that as a result of the 2007 NJRR report, the TGA established the OEWG, as a subcommittee of the TGA's Medical Device Evaluation Committee, in order to 'bring in some expert independent clinical advice to review the data of the joint replacement registry and work out what regulatory action was appropriate based on that data'.⁸⁶ The OEWG met for the first time on 8 August 2007.⁸⁷

3.89 Dr Hammett reported to the committee that the advice provided by the OEWG in 2007 was that the higher revision rate 'may be due to the technical complexity of implanting this particular joint prosthesis'. Dr Hammett further commented that the OEWG recommendation 'was that surgeons should be required to undertake additional training regarding insertion of the ASR hip'.⁸⁸ DePuy Orthopaedics agreed to provide the training.⁸⁹

3.90 The training program on the ASR hip was instituted between 2007 and 2008.⁹⁰ Dr Hammett reported that in 2008 the OEWG was consulted again and they agreed that the monitoring and training program that had been put in place was appropriate for the ASR hip.⁹¹

3.91 The OEWG met on 21 May 2008, and considered the ASR resurfacing hip implant. The minutes of this meeting state that:

85 Professor Stephen Graves, National Joint Replacement Registry, *Committee Hansard*, 27 September 2011, p. 20.

86 Dr Rohan Hammett, National Manager, Therapeutic Goods Administration, *Committee Hansard*, 27 September 2011, p. 47.

87 Department of Health and Ageing, Answers to questions on notice, 27 September 2011.

88 Dr Rohan Hammett, National Manager, Therapeutic Goods Administration, *Committee Hansard*, 27 September 2011, p. 48.

89 Therapeutic Goods Administration, *Recall of DePuy Orthopaedics ASR hip replacement device*, 16 May 2011, <http://www.tga.gov.au/newsroom/btn-dupuy-recall.htm>, accessed 7 September 2011.

90 Dr Rohan Hammett, National Manager, Therapeutic Goods Administration, *Committee Hansard*, 27 September 2011, p. 48.

91 Dr Rohan Hammett, National Manager, Therapeutic Goods Administration, *Committee Hansard*, 27 September 2011, p. 49.

The TGA noted that the manufacturer of the ASR resurfacing hip implant had approached the TGA recognising that the revision rate is unacceptable. The manufacturer advised that supply of the implant will no longer be possible unless the surgeon undergoes a training and mentoring program. It appears that many surgeons are reluctant to undertake this training, and the company reports that sales have decreased sharply since this measure began.⁹²

3.92 At the same meeting the OEWG advised that:

The Working Group endorsed the actions taken by the ASR resurfacing hip implant's sponsor towards requiring surgeons to undertake specific training for this implant as a condition of sale. The Working Group advised that the performance and revision rate of the ASR resurfacing hip implant should continue to be observed.⁹³

3.93 The OEWG met on 18 June 2008 and again on 9 December 2009.⁹⁴ Professor Graves confirmed that the TGA were sent information by the NJRR, on higher revision rates of both the ASR hip resurfacing device and the hip replacement itself, in September 2008. Yet, the OEWG did not meet again until December 2009, a period of over a year between receiving this information and meeting again.⁹⁵

3.94 At the December 2009 meeting of the OEWG it was noted that:

The TGA reported that there have been approximately 30 implants identified in the 2008 and 2009 report that have a higher than average revision rate. Due to the slow response rate from the manufacturers, of the 30 implants, 10 will be discussed at this meeting and the remaining 20 will be discussed at subsequent meetings to be held early in 2010.⁹⁶

3.95 According to additional information provided to the committee by Professor Graves, the NJRR originally provided the 2007 report to the TGA in September 2007

92 Department of Health and Ageing, Answers to questions on notice, 25 October 2011, *Minutes of the Orthopaedic Expert Working Group*, 21 May 2008, p. 5.

93 Department of Health and Ageing, Answers to questions on notice, 25 October 2011, *Minutes of the Orthopaedic Expert Working Group*, 21 May 2008, p. 5.

94 Department of Health and Ageing, Answers to questions on notice, 25 October 2011, *Meeting Record and Outcomes of the Orthopaedic Expert Working Group*, 18 June 2008; Department of Health and Ageing, Answers to questions on notice, 25 October 2011, *Draft Meeting Record and Outcomes of the Orthopaedic Expert Working Group*, 9 December 2009.

95 Professor Stephen Graves, National Joint Replacement Registry, *Committee Hansard*, 27 September 2011, pp 20, 24; Department of Health and Ageing, Answers to questions on notice, 25 October 2011, *Draft Meeting Record and Outcomes of the Orthopaedic Expert Working Group*, 9 December 2009.

96 Department of Health and Ageing, Answers to questions on notice, 25 October 2011, *Draft Meeting Record and Outcomes of the Orthopaedic Expert Working Group*, 9 December 2009.

and then again in February 2008 when the TGA requested that the data be resent.⁹⁷ This data was not reviewed until May and June 2008, a delay of over nine months.⁹⁸ This is concerning.

3.96 Dr Hammett explained that during this period that the OEWG did not meet that 'the TGA was reviewing the processes of gathering information and responding to it from the NJRR data'. Dr Hammett went on to state:

The NJRR data, while it is widely acknowledged as incredibly useful for post-market monitoring, has had some challenges in the interpretation of that data over the years, and not long before the period in question I think there had been questions raised about the way this information was handled and about the processing of data from the NJRR and whether the mechanisms by which that information was utilised by the regulator was appropriate and whether it accorded appropriate natural justice to sponsors of companies and to the general community.⁹⁹

3.97 The OEWG met on 9 December 2009 and considered the ASR Acetabular Cup. The minutes of the meeting state that:

The TGA reported that the rate of revision for this device due to metal sensitivity is high. The Sponsor is taking steps to withdraw the product from the market but wishes to retain some components on the ARTG. Approximately 4000 devices were implanted and access to components will be beneficial when revision surgery is required...

A member commented on ASR being problematic and the ongoing incidents reported to the Medical Devices Incident Reporting Scheme (MDIRC).

Members agreed that the ASR should no longer be available on the market, but that some components such as the femoral heads should be available for revision surgery. The TGA together with the company will make a decision as to what components will remain on the ARTG.¹⁰⁰

3.98 Dr Hammett told the committee that once devices are identified as having a high revision rate it is not the case that they are just withdrawn from the market, noting that 'That actually would not help patients. There are many useful devices contained within the Joint Replacement Registry data that do have a real role'. Dr Hammett went on to explain how the OEWG conduct their considerations and why the process takes time:

97 Professor Stephen Graves, National Joint Replacement Registry, Answers to questions on notice, 25 October 2011, [p. 2].

98 Professor Stephen Graves, National Joint Replacement Registry, Answers to questions on notice, 25 October 2011, [p. 3].

99 Dr Rohan Hammett, National Manager, Therapeutic Goods Administration, *Committee Hansard*, 27 September 2011, p. 50.

100 Department of Health and Ageing, Answers to questions on notice, 25 October 2011, *Minutes of the Orthopaedic Expert Working Group*, 9 December 2009, p. 5.

They have to consider each of the devices that have been shown to have higher revision rates and there is a process whereby the information is conveyed to the companies, and they are asked to respond to it to try to explain what might be causing that. That is reviewed by the clinical experts, and that takes some time. There are now 76 separate devices that have been identified within the Joint Replacement Registry as having higher rates of revision. Of those 76, after they have all been considered by experts and by the regulator, only 15 have been removed from the market. There is a lengthy process of understanding what might be contributing to this data.¹⁰¹

3.99 Once the NJRR identifies prostheses being revised at greater than twice the usual rate it does not necessarily mean that those implants are removed from the market. Dr Michael Armitage pointed out that the implants may stay on the market, only to be identified once again in the following year's report. To illustrate this point Dr Armitage drew the committee's attention to the 2010 National Joint Replacement Registry annual report:

...there were 16 hips that needed replacement at a rate greater than a standard algorithm, at twice the rate of revision of others. It says 'more than' so it might be a five or six times greater failure rate. Sixteen were identified but seven of those had been identified in the previous report and were still being used. In the case of knee replacements, nine failed more than twice as often as another standard knee replacement but, in fact, five of those had been identified the year before. We think that is cause for action to be taken on behalf of Australians.¹⁰²

3.100 Professor Graves gave evidence to the committee regarding the timeliness of the TGA in responding to issues about devices that have been flagged by the NJRR:

Have I been happy with the timeliness of action over the whole period? The answer is no. Am I currently happy with the approach that the TGA is using? The answer is yes. There have been times when I have thought the timeliness could have been better.¹⁰³

3.101 Further evidence that the OEWG also had concerns about the timeliness of the TGA's response to devices showing high revision rates was apparent in the minutes of the 9 December 2009 OEWG meeting:

A member voiced their concerns on the slow action being taken on some of the recommendations made by the working group at previous meetings. There was robust discussion regarding timeframes and some of the prosthesis identified in previous meetings that were still on the ARTG.

101 Dr Rohan Hammett, National Manager, Therapeutic Goods Administration, *Committee Hansard*, 27 September 2011, p. 53.

102 The Hon Dr Michael Armitage, *Committee Hansard*, 27 September 2011, p. 1.

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

The Chair expressed concern at the lack of meetings for the past 18 months of the working group and stated that this group will need to meet on a more regular basis to be of any benefit.

The TGA referred the OEWG to the Out of Session Item that was distributed prior to the meeting and included with the papers for consideration, highlighting the actions already taken by the TGA on previous OEWG recommendations. Some members felt that the actions had been too weak and too slow.

The TGA explained that there had been an internal review of the process for re-assessment of implants that had been identified as having higher than expected revision rates, and that the process had been halted during the review. But the process has now been cleared to continue. TGA expects to be able to process the implants that were identified in the 2008 and 2009 NJRR reports quite quickly, provided that the OEWG can meet a couple of times early in 2010.¹⁰⁴

3.102 Dr Hammett responded to apparent criticisms about the TGA's timeliness:

...what I would say is we have worked very hard over the last couple of years to improve the timeliness of review of data from the NJRR and to improve the links with the NJRR to the point where we have access to the database and can make specific inquiries. I think...the relationship and the communications between the NJRR and the TGA currently is better than it ever has been.¹⁰⁵

Committee comment

3.103 The committee notes that both the NJRR and the TGA assert that the TGA is currently responding to NJRR data with improved timeliness. The committee notes that Australia was the first country to remove the ASR devices from the market. However, the committee is of the view that response to the emerging problem could have been more timely. Additionally, more could have been done to understand the extent and nature of the problem including consumer experience post-implant of the devices. The committee also considers there could have been better communication with stakeholders as events unfolded.

The manufacturer

3.104 The committee also sought to ascertain when JJM became aware of a higher than usual rate of revision for the ASR hip resurfacing system and the hip replacement. JJM submitted answers to questions on notice but in response to the question about when the company first became aware of these issues, its reply was

104 Department of Health and Ageing, Answers to questions on notice, 25 October 2011, *Draft Meeting Record and Outcomes of the Orthopaedic Expert Working Group*, 9 December 2009, p. 2.

105 Dr Rohan Hammett, National Manager, Therapeutic Goods Administration, *Committee Hansard*, 27 September 2011, p. 49.

decidedly opaque. In its response, JJM correctly identified that in 2006 the NJRR annual report said that 'The ASR has a higher revision rate when compared to the [Birmingham Hip Resurfacing] but it is not significant'.¹⁰⁶ JJM went on to note that:

The revision rates reported in 2010 by the UK National Joint Registry were higher than expected, which resulted in DePuy Orthopaedics Inc (DePuy) issuing a voluntary recall of the ASR Hip System on 24 August 2010.¹⁰⁷

3.105 The committee drew on answers to questions on notice provided by DoHA, to ascertain when JJM would have been informed that there were problems with the hip resurfacing device firstly, and subsequently the hip replacement.

3.106 DoHA provided details of contact between the TGA and JJM in relation to the ASR hip, but not documentation supplied by JJM. DoHA explained that, while the Department has no objection to the release of documentation provided by JJM to the committee, it has not been supplied because:

...it is claimed by J&J to be commercial in confidence. Following a recent Freedom of Information request, release of this information is currently the subject of a review by the Office of the Information Commissioner.¹⁰⁸

3.107 Details of discussions between the TGA and JJM, and information provided by JJM to the TGA, were provided to the committee are as follows:

The Therapeutic Goods Administration (TGA) met with the manufacturer, Johnson & Johnson Medical (J&J) in September 2007 to discuss high early revision rates for the ASR Surface Replacement device. J&J tabled a submission which proposed surgeons be required to undergo specific training on the ASR implant as a means of reducing the number of revisions...

On 1 May 2008 the TGA received an update report from J&J on the actions undertaken in September 2007 in relation to the ASR Surface Replacement device (see preceding paragraph)...

Individual early revisions (revisions that take place <10 years after implantation) are considered to be reportable adverse events. To date the TGA has received 401 adverse event reports from J&J about ASR implants. Of these:

69 were received prior to December 2009 (the date of the withdrawal of the implant in Australia)

139 were received between January 2010 and December 2010

193 were received as a batch of summary reports covering the period January - March 2011.¹⁰⁹

106 Johnson & Johnson Medical, Answers to questions on notice, 27 September 2011, p. 1.

107 Johnson & Johnson Medical, Answers to questions on notice, 27 September 2011, p. 2.

108 Department of Health and Ageing, Answers to questions on notice, 25 October 2011.

109 Department of Health and Ageing, Answers to questions on notice, 25 October 2011.

Committee comment

3.108 The committee notes that JJM did not provide clear answers to information sought by the committee about when it first became aware of a higher than usual revision rate. The committee considers it highly unlikely that the company was not aware of the issue before 2010 given that a withdrawal was issued in Australia in 2009. In particular the committee notes that the TGA was meeting with JJM on this issue from at least September 2007 onwards.

3.109 The committee is deeply disturbed by what appears to be tardiness on the part of JJM to act on known problems with these devices. Many people could have avoided considerable pain, suffering and diminished quality of life if the company had acted in a responsible manner to known problems with these devices. In failing to respond to the committee's requests for information on this matter, JJM have only served to confirm the committee's views.

Removal of DePuy ASR hip products from the Australian market

3.110 JJM, through DePuy withdrew the DePuy hip resurfacing system and the DePuy hip from the Australian market in December 2009. Ms Robyn Chu, Director, Health Outcomes, JJM, described in general terms what happens after such a withdrawal:

...my understanding is that when a product is withdrawn from the market there is a conversation with the TGA about what has occurred, and then the process is that the communication is drafted and approved by the TGA, and that communication is then provided to healthcare professionals who deal with patients.¹¹⁰

3.111 The TGA, on their website, advise that:

In 2009, after ongoing monitoring of the performance of both types of ASR hip prosthesis for a reasonable period to evaluate the effects of the enhanced training program, data from the NJRR revealed that the rate of hip revisions remained of concern. The TGA took immediate action with the sponsor regarding this ongoing, higher-than-anticipated revision rate and subsequently DePuy Orthopaedics agreed to remove the ASR resurfacing hip implant from the Australian market in December 2009.¹¹¹

3.112 Clarification on the TGA's role in the removal of the ASR device from the Australian market was sought by Senator Xenophon through the Budget Estimates 2011–12 process. Senator Xenophon asked the following question on notice:

110 Ms Robyn Chu, Director, Health Outcomes, Johnson & Johnson Medical, *Committee Hansard*, 27 September 2011, p. 40.

111 Therapeutic Goods Administration, *Recall of DePuy Orthopaedics ASR hip replacement device*, 16 May 2011, <http://www.tga.gov.au/newsroom/btn-dupuy-recall.htm>, accessed 7 September 2011.

The DePuy ASR hip device was eventually withdrawn from the market by DePuy. Dr Hammett, in an interview with Four Corners, you state that the device was withdrawn: "as a result of the TGA, and its expert clinical groups analysing data and presenting that to the company, making it quite clear that we regarded the performance of this device as no longer acceptable".

a) So the TGA did not require DePuy to remove the device from the market, it merely provided information and allowed the company to make that decision?¹¹²

3.113 The Department of Health and Ageing answered:

a) The TGA, through bringing the company to a point where it understood that the data was showing that there was a problem, achieved removal of this device from the Australian marketplace ten months before it had been removed anywhere else in the world.¹¹³

Following through

3.114 Given that it appears that so many consumers are experiencing ill health as a result of being implanted with either the DePuy hip resurfacing device or the DePuy hip replacement, the committee endeavoured to understand what actions have been taken by the TGA and the manufacturer, subsequent to the withdrawal of the devices.

3.115 The following section considers provision of information and provision of assistance to consumers. It also considers follow up of cobalt and chromium toxicity in patients.

The TGA and orthopaedic surgeons

3.116 The TGA website described what happened following the removal of the ASR implant from the Australian market. The website stated that:

...the TGA worked with DePuy and the Australian Orthopaedic Association (AOA) to ensure that all Australian orthopaedic surgeons were aware of the recall and the appropriate advice provided to patients.

3.117 However, consumers who provided evidence to the inquiry were not informed once problems had been identified with their particular prosthetic devices. Additionally, although both the ASR hip and ASR hip resurfacing system were withdrawn by the manufacturer in Australia in 2009, it appears this information was not conveyed to patients in a systematic or consistent manner.

112 Senate Community Affairs Legislation Committee, Answers to questions on notice, Health and Ageing Portfolio, Budget Estimates 2011–2012, 31 May 2011, Question E11–017.

113 Senate Community Affairs Legislation Committee, Answers to questions on notice, Health and Ageing Portfolio, Budget Estimates 2011–2012, 31 May 2011, Question E11–017.

3.118 A number of submitters described how they only became aware that there was a problem with their device through the media. Mr Stuart Cain received a hip replacement in June 2007 and started experiencing major physical problems in December 2008. He visited his doctor, but as he noted, neither he nor his doctor considered his implant could be a cause. He explained how he found out that the device could be causing his problems:

It was only when the media enlightened me to the issues around the dePuy implant and my Orthopaedic Surgeon requested that I have a blood test for Cobalt and Chromium Ion poisoning as well as a Nuclear Bone Scan to assess the integrity of the implant, that my true situation became clear.¹¹⁴

3.119 The consumer in Case Study C had a similar experience. She received a DePuy hip resurfacing device in November 2008, even though the device had been reported as having a statistically significant rate of revisions since September 2007. She told the committee that it was only following a television current affairs program that she identified the cause of her symptoms.¹¹⁵

3.120 Another consumer also commented that the only information they had received was through the media:

Unfortunately I recently became aware of the problems that lay ahead for me when [I saw] the Australian Broadcasting Co[sic] on a Television show "4 Corners"...This programme made it quite clear what a very poor outlook [there is for] any folk who like me had a Cobalt – Metal to Metal Hip reconstruction implanted in their body.¹¹⁶

3.121 Mr Robert Lugton, described how after constantly raising symptoms with his surgeon, he finally realised the source of his ill-health, through searching on the internet. Mr Lugton explained:

I was a fit and active 63 year old when I had a DePuy ASR total hip replacement in January 2008. In June 2010 and after 2 years of pain with continual surgery visits, I was informed by my surgeon that the ASR had been withdrawn from the market.

My surgeon informed me that it was also subject to a high failure rate of around 12%. After examining my x-rays he said that everything looked good and for me to come back for another check-up in a year's time. I again, as I had many times before, asked him about my thigh and groin pains. His reply was, as before, that I must have a lower back problem. I left the surgery unconvinced and worried! I decided to look on the internet to try and determine what symptoms patients, who had already undergone revisions had experienced before having to have their ASR implants removed. Their symptoms were similar to what I was experiencing. The

114 Mr Stuart Cain, *Submission 32*, [p. 1].

115 Name Withheld, *Submission 23*, p. 1.

116 Name Withheld, *Submission 31*, [p. 1].

amount of information on the ASR failure around the world on the internet was staggering. The Metal-on-metal hip was leaching Cobalt and Chromium into patients' bloodstreams in huge quantities.¹¹⁷

3.122 Another submitter described how, after significant ill health and a test indicating seriously elevated cobalt levels, his wife was only informed on 10 October 2010 by her original surgeon at her annual review of the DePuy ASR hip's withdrawal.¹¹⁸ The submitter went on to describe the surgeon's response, prior to providing a referral to another surgeon:

The surgeon told us not to worry about [her] blood toxicity, as this alone was not significant to warrant revision surgery. He mentioned he had twelve other patients in a similar position.¹¹⁹

3.123 Dr Michael Armitage, Chief Executive Officer, Australian Health Insurance Association was critical of the processes in place to notify the relevant authorities and the general public of high revision rates, stating:

...this simply does not occur, and we think that is one of the key failings. The Australian public are not stupid and they deserve to be told when there are high revision rates.¹²⁰

3.124 In relation to the effectiveness of the current regimes in place to ensure prostheses with high revision rates are identified, Dr Armitage went on to say that:

...we actually believe that there should be a lot more action taken in this matter. We think there should be identified any potential problems with the devices and those should be made public for Australians to make their own decisions as to whether they want to have the device or prosthesis inserted into them.¹²¹

3.125 The AOA contended that in the case of high revision rates or possible faulty devices 'the ideal method of dissemination of information to patients and consumers is through the surgeons who implant the devices and informed medical practitioners'. It asserted that 'to do otherwise promotes patient, media and legal mischief and misinformation' and that 'it would appear to AOA that there is a role for TGA to advise the public directly'.¹²²

117 Mr Robert Lugton, *Submission 29*, [p. 1].

118 Name Withheld, *Submission 34*, [p. 2].

119 Name Withheld, *Submission 34*, [p. 2].

120 The Hon Dr Michael Armitage, Australian Health Insurance Association, *Committee Hansard*, 27 September 2011, p. 1.

121 The Hon Dr Michael Armitage, Australian Health Insurance Association, *Committee Hansard*, 27 September 2011, p. 1.

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

3.126 St Jude Medical noted their support for the recommendations of the TGA Transparency Review report which recommended processes:

...for ensuring that information related to deficiencies in the quality, safety, or performance of medical devices will be made available to health care professionals and the public as early as possible.¹²³

3.127 The AOA also provided information about a recently established system of web-based linkages for early notification of hazard alerts, enabling early and rapid dissemination to AOA surgeons. They explain that 'this expediency precludes further devices being implanted during any "lag" period of notification'.¹²⁴

Committee comment

3.128 The committee is of the view that provision of information to patients regarding the withdrawal of the ASR hip devices, and the known associated problems with the devices, has been lacking and should be addressed as a matter of urgency.

3.129 It appears to the committee that industry has been very good at promoting medical devices to surgeons and hospitals but utterly remiss in informing them in a timely manner of problems with those same devices.

The manufacturer

3.130 The committee heard from Mr Anthony Bishop, Area Vice President, Australia and New Zealand, JJM, that 'the recall has had an enormous impact upon patients, their loved ones and their healthcare professionals'. Mr Bishop went on to state that:

...our company profoundly and deeply regrets the impact that this recall has had on patients. We are doing what we can to minimise the impact that this recall is having.¹²⁵

3.131 Mr Bishop explained that the company's first priority in response to the recall was 'the care and well-being of all ASR patients'. Mr Bishop told the committee that:

We are trying to ensure that no ASR patient is without information and that they receive appropriate support during this time. We are working to ensure that no ASR patient suffers financial detriment related to this recall. To this end, Crawford and Company, an independent third-party claims processor, has been engaged to appropriately evaluate claims and reimburse individuals for the eligible expenses they incur in the course of their treatment arising from the ASR recall. At the date of this hearing, we have

123 St Jude Medical Australia, *Submission 8*, [pp 15–16].

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

125 Mr Anthony Bishop, Area Vice President, Australia and New Zealand, Johnson & Johnson Medical, *Committee Hansard*, 27 September 2011, p. 34.

reimbursed over \$21 million in approved claims, and at the date of this recall we have over 3½ thousand patients registered with Crawford.

3.132 JJM provided additional information to the committee about assistance the company is providing for patients with the ASR hip devices through the Crawford & Company Scheme. JJM explained that:

Crawford & Company has been engaged to process the funding of reasonable and customary expenses incurred by patients for tests and treatment (including revision surgery) associated with ASR hip devices. The expenses funded include hospital charges, surgeon and anaesthetist fees, surgical assistant fees and implant costs, and out-of-pocket costs for reasonable and documented expenses, such as travel expenses, subject to review by Crawford & Company.¹²⁶

3.133 JJM also told the committee that in some circumstances, patients who are assessed to be eligible for funding under the Crawford & Company Scheme may be considered by JJM to be eligible for additional compensation. JJM explained that:

Such consideration is likely to be most appropriate for patients whose conditions have stabilised. Those individuals (or someone on their behalf) should approach Johnson & Johnson Medical Pty Limited (JJM) directly. Any compensation provided beyond the Crawford & Company process would be on a full and final settlement basis and covered by a settlement agreement.¹²⁷

Monitoring and evaluating the effects of cobalt and chromium

3.134 The committee received details of cobalt toxicity in some patients who received the ASR hip. The Medical Journal of Australia has called for more research into this issue for patients with metal-on-metal hip prosthesis as a result of a recent report¹²⁸ on this issue:

Mao and colleagues report the first Australian patients with ASR prostheses to show a potential association between high serum metal ion levels and systemic toxicity. Their report also highlights the difficulties in understanding the relevance and significance of these high metal ion levels. To date, there have only been anecdotal case reports of potential toxicity, and this is another such publication. The authors have been clear in stating that it is not possible to draw conclusions because there is not enough evidence to determine if the problems these patients have experienced are coincidental rather than causal. What this and other reports have done, however, is highlight the urgent need to undertake comprehensive research to examine the relationship between high serum metal ion levels after total

126 Johnson & Johnson Medical, Answers to questions on notice, 14 October 2011.

127 Johnson & Johnson Medical, Answers to questions on notice, 14 October 2011.

128 Xinzhan Mao, Andrew A Wong and Ross W Crawford, Cobalt toxicity – an emerging clinical problem in patients with metal-on-metal hip prosthesis, *Medical Journal of Australia*, 2011; 194(12): pp 649–651.

hip replacement and the risk of toxicity. It is critical to determine at what concentration elevated cobalt and chromium serum levels may cause toxicity, and how the extent and severity of toxicity varies with the level. This is important because surgeons currently have no information on whether a hip should be revised based simply on the patient's serum metal ion levels. Revision surgery has significant morbidity and mortality risks and should not be undertaken without good indications to do so.¹²⁹

3.135 The committee received evidence from Dr Hammett, of the TGA, Professor Graves, of the NJRR, and the DoHA that research and publication on the effects of cobalt and chromium in the human body is nascent.¹³⁰ Professor Graves, NJRR, told the committee that:

At this point in time, there have been two reports of metal toxicity published in the literature. Both of those are on two patients, so we have four patients worldwide that have been reported with cobalt systemic toxicity.¹³¹

3.136 However, Professor Graves went on to state that cobalt systemic toxicity 'is potentially a major concern'. He explained further:

I think that the jury remains out as to what the extent of this problem is. I am not saying it is not a problem; I am saying that we do not know the extent of it. But what we are saying is that we need to look at this quickly and we need to get an understanding of the extent of the problem.¹³²

3.137 Dr Hammett appeared more equivocal on the problems posed by metal ion toxicity in patients who have received metal-on-metal implants, stating that 'We share concerns about the need to understand whether metal ion toxicity is a real thing'.¹³³ Dr Hammett went on to explain that:

So if there are about a million people out there who have had these cobalt based implants and all of those have high levels of cobalt-and we do not know that, so no-one knows that-and a million of them less four are walking around asymptomatic with no problems, then it would suggest-on the balance of those numbers-that there may not be an issue. But we do not

129 Stephen E Graves, 'What is happening with hip replacement?', *Medical Journal of Australia*, 2011; 194(12): pp 620–621.

130 Professor Stephen Graves, National Joint Replacement Registry, *Committee Hansard*, 27 September 2011, p. 24; Dr Rohan Hammett, National Manager, Therapeutic Goods Administration, *Committee Hansard*, 27 September 2011, p. 56; Department of Health and Ageing, Answers to questions on notice, 25 October 2011.

131 Professor Stephen Graves, National Joint Replacement Registry, *Committee Hansard*, 27 September 2011, p. 24.

132 Professor Stephen Graves, National Joint Replacement Registry, *Committee Hansard*, 27 September 2011, p. 24.

133 Dr Rohan Hammett, National Manager, Therapeutic Goods Administration, *Committee Hansard*, 27 September 2011, p. 56.

know that. As I started by saying, I am not trying to downplay this; I am just saying that there is a gap in the scientific knowledge.¹³⁴

3.138 Professor Graves informed the committee that the NJRR has been approached by the TGA 'as to whether a study like that could be undertaken in Australia'. Professor Graves went on to recommend that:

...there needs to be a careful, systematic review of what is actually happening. We believe that those studies would be best undertaken by being embedded in registries, where we know what the outcome is with respect to revision.¹³⁵

3.139 Similarly, Dr Hammett provided evidence on the TGA's plans to address the issue of metal ion toxicity:

At this stage we are just working out what is feasible in terms of doing research on this and what the appropriate and best ways of doing it are. We are certainly talking with experts from the orthopaedic expert working group, the AOA and the joint replacement registry about whether it is possible in some way to track people who have had these metal-on-metal hips and to assess whether there are any impacts. But this is all very nascent work at present and we are still in discussions about whether there is a feasible mechanism of undertaking that sort of research.¹³⁶

3.140 DoHA has advised the committee that 'the TGA has reviewed the scientific literature regarding blood levels of cobalt and chromium'. DoHA went on to state that:

The TGA is not a research body but will examine research results when they become available to determine any regulatory significance.¹³⁷

3.141 The committee endeavoured to establish what the acceptable range in Australia and internationally for the presence of cobalt and chromium in blood, and whether the range had been changed. DoHA informed the committee that:

There is no established reference (normal) range for serum cobalt and chromium. Serum cobalt and chromium level testing is performed only in a few Australian pathology laboratories and the quoted reference ranges vary.¹³⁸

3.142 DoHA stated that different pathology companies and the academic literature suggest different reference ranges for cobalt and chromium. DoHA explained that:

134 Dr Rohan Hammett, National Manager, Therapeutic Goods Administration, *Committee Hansard*, 27 September 2011, p. 57.

135 Professor Stephen Graves, National Joint Replacement Registry, *Committee Hansard*, 27 September 2011, p. 24.

136 Dr Rohan Hammett, National Manager, Therapeutic Goods Administration, *Committee Hansard*, 27 September 2011, p. 57.

137 Department of Health and Ageing, Answers to questions on notice, 25 October 2011.

138 Department of Health and Ageing, Answers to questions on notice, 25 October 2011.

For instance, one large pathology company suggests a reference range for cobalt (0–20 nmol/L) and for chromium (10–100 nmol/L). In an article published in 2011 in the Medical Journal of Australia, the reference range for chromium was 0–100nmol/L {Mao et al MJA 2011;194(12):649–651}. The Sandwell and West Birmingham Hospitals, Birmingham UK, Trace Elements Laboratory quote reference ranges of <40 nmol/L for Chromium and <10 nmol/L for Cobalt in patients without hip replacements.¹³⁹

3.143 DoHA also submitted that:

...there is acceptance that serum cobalt and chromium levels will be elevated in patients who have undergone well functioning metal-on-metal hip replacement relative to those without hip replacements. As well, the metal ion levels will vary over time even in patients who have well functioning implants and no symptoms suggesting any health problem.¹⁴⁰

Committee comment

3.144 The committee received compelling and distressing evidence from consumers of serious ill health and complications associated with metal toxicity, caused by the leaching of cobalt and chromium ions from the hip replacements into patients' bodies. The committee is of the view that this is being treated by health authorities and professionals with an inadequate sense of urgency. The committee recommends that a process for monitoring the levels of cobalt and chromium, and any possible health effects, should be established as a matter of urgency for all patients who have received metal-on-metal hip replacements.

139 Department of Health and Ageing, Answers to questions on notice, 25 October 2011.

140 Department of Health and Ageing, Answers to questions on notice, 25 October 2011.

Chapter 4

Subsidised devices

Introduction

4.1 This chapter discusses cost effectiveness of subsidised devices and the effectiveness and accuracy of the billing code and Prostheses List.

Subsidised devices

4.2 The *Private Health Insurance Act 2007* (PHI Act) provides for mandatory benefits to be paid by private health insurers for a range of prostheses that are provided as part of an episode of hospital treatment (or hospital substitute treatment) where a Medicare benefit is payable for the associated professional service (surgery).

4.3 The prostheses for which a benefit must be paid by a private health insurer are listed on the Prostheses List. The Prostheses List is made under the PHI Act and the Private Health Insurance (Prostheses) Rules which require private health insurers to pay benefits for those prostheses. The arrangements for including products on the Prostheses List help to ensure that benefits paid by insurers are 'relative to clinical effectiveness'.¹

4.4 The Prostheses List Advisory Committee (PLAC) advises the Minister about the listing of prostheses and their appropriate benefits in the Prostheses List. In making its recommendations to the Minister about which products should be included on the Prostheses List, PLAC considers the clinical effectiveness of the product including comparative cost and comparative safety.

4.5 The Prostheses List arrangements, the PLAC and its predecessor, the Prostheses and Devices Committee (PDC), were established to control inflation in private health insurance benefits paid for prostheses.²

4.6 The PHI Act provides for two categories of prostheses:

- no-gap prostheses: these prostheses are listed with a single benefit which health insurers are required to pay; and
- gap-permitted prostheses: these prostheses have both a minimum and maximum benefit listed. For these prostheses private health insurers are required to pay at least the minimum benefit.

1 Department of Health and Ageing, *Prostheses List: Guide to listing and setting benefits for prostheses, Part 1 – Understanding the Prostheses Arrangements*, July 2010, p. 7.

2 Department of Health and Ageing, *Prostheses List Advisory Committee*, www.health.gov.au/internet/main/publishing.nsf/content/health-privatehealth-PLAC, accessed 12 October 2011.

4.7 The TGA noted that between 1999 and 2002, the growth of the cost of prostheses significantly increased the benefits paid by private health insurers. In response, the Government introduced a package of reforms to private health insurance that included new arrangements for listing products on the Prostheses List that provide for an evidence-based assessment of products and a centralised benefit negotiation process.³ The PLAC terms of reference and business rules state that:

The Prostheses List arrangements, the PLAC and its predecessor, the Prostheses and Device Committee, were established to control inflation in private health insurance benefits paid for prostheses. The Prostheses List plays an important role in ensuring the sustainability of the Australian private health insurance system, and helps to achieve the Government's policy objective of ensuring private health insurance remains affordable and accessible to all Australians.⁴

The Prostheses List

4.8 The Prostheses List contains 9 645 prostheses including cardiac pacemakers and defibrillators, cardiac stents, hip and knee replacements and intraocular lenses, as well as human tissues such as human heart valves, corneas, bones (part and whole) and muscle tissue.⁵ The Prostheses List does not include external devices such as external breast prostheses, only surgically implanted prostheses.

4.9 The Prostheses List is managed by the DoHA which is also accountable for grouping devices and determining the benefit to be paid.

4.10 The Prostheses List is divided into two parts: Part A for prostheses and Part B for human tissue. A new Part C is being developed as a consequence of the Doyle Review. Part C will include items currently on the Prostheses List which do not meet the listing criteria but have proven clinical benefit, for example, insulin pumps. Part C items will include clinically effective and cost effective devices, such as those that are:

- not surgically implanted but with an internal part that is integral to the effectiveness and designed to combat a pathological process or modulate a physiological process; and
- surgically implanted devices to monitor a pathological or physiological process.⁶

4.11 The Prostheses List contains information on devices including billing code, product category, sponsor, product name and benefit(s). The billing code is a reference code allocated to a listed prosthesis and facilitates hospital invoicing

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

4 Therapeutic Goods Administration, *Submission 18, Attachment 5*, p. 1.

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

6 Department of Health and Ageing, *Prostheses List: Guide to listing and setting benefits for prostheses, Part 1 – Understanding the Prostheses Arrangements*, July 2010, p. 15.

procedures and the payment of benefits by insurers. The billing code may be allocated to a single piece product, a system or set, or a pack containing different sizes of otherwise identical items. Sponsors are required to provide catalogue numbers for each component of a billing code. This allows users of the Prostheses List to understand what each billing code covers.

Prostheses List Advisory Committee

4.12 The PLAC was established on 4 October 2010 and replaced the PDC in response to the HTA Review recommendations. The PLAC is comprised of an independent chair, with members having expertise in current clinical practice, health insurance, consumer health, health economics, health policy, private hospitals and the medical device industry. In making recommendations, the PLAC considers advice from Clinical Advisory Groups (CAGs) and members of the Panel of Clinical Experts (PoCE).⁷

4.13 The main roles of the PLAC are to provide advice to the Minister about whether prostheses should be included on the Prostheses List. In doing so, the PLAC considers:

- whether a submitted or listed product is a 'prosthesis';
- whether the prosthesis under consideration has similar clinical function, effectiveness and safety compared with other prostheses included on the Prostheses List intended to treat similar clinical conditions;
- whether the cost of the prosthesis under consideration is similar to other prostheses included on the Prostheses List intended to treat similar clinical conditions; and
- whether the prosthesis under consideration should only be listed on a conditional basis, and, if so, appropriate conditions that should be applied to its listing.⁸

4.14 The PLAC also provides advice about grouping and description of prostheses. Grouping of prostheses enables a single (benchmark) benefit to be established for prostheses with similar clinical function, effectiveness and safety. Groups are being progressively developed by DoHA in response to recommendation 12 of the HTA Review (see below). The PLAC provides advice about appropriate benefits that are to be paid by private health insurers for prostheses included on the Prostheses List. Determination of the benefit is based on clinical effectiveness of the prosthesis compared with other listed prostheses providing similar clinical outcomes for comparable clinical circumstances. In addition, the PLAC refers concerns about the

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

8 Therapeutic Goods Administration, *Submission 18, Attachment 5*, p. 2.

intrinsic safety of prostheses to the TGA and provides advice about other matters as requested by the Minister for Health and Ageing.⁹

Reviews of the listing and setting of benefits for prostheses

4.15 There have been two reviews of the prostheses arrangements for private health insurance. The first review was undertaken in 2007 by Mr Robert Doyle. The findings of the Doyle Review were overtaken by the HTA Review. The HTA Review commented that the Review provided 'an opportunity to revise current arrangements which impede progress for reform of Prostheses List activities to develop a more sustainable model for the future, as recommended by the Doyle Review to reduce regulatory burden (including costs) imposed on the medical devices industry'.¹⁰ The HTA Review made three recommendations aimed at simplify administration of the Prostheses List by streamlining administrative processes and removing duplication:

Recommendation 10:

That in order to reduce regulatory costs:

- (a) the terms of reference for the PDC and its subcommittees be revised by July 2010 so that it is clear that its assessments of prostheses only consider clinical effectiveness (including comparative cost and comparative safety); and
- (b) channels of communication between the TGA and PDC should be formalised to ensure that any concerns the PDC encounters regarding the intrinsic safety of prostheses are immediately referred to the TGA and dealt with appropriately.

Recommendation 11:

That the PDC be restructured by July 2010 to ensure that its membership is balanced and:

- (a) includes individuals with expertise in current clinical practice, health policy and health economics;
- (b) includes representation from health consumers, health service providers, and the health insurance and health technology industries; and
- (c) has an independent chair.

Recommendation 12:

That the arrangements for the Prostheses List be changed by 2011, with appropriate consultation, to:

9 Therapeutic Goods Administration, *Submission 18, Attachment 5*, pp 3–4.

10 Department of Health and Ageing, *Review of Health Technology Assessment in Australia*, December 2009, p. 18.

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- (a) accept applications on a continuous basis, but still make the Prostheses List every six months;
 - (b) establish and maintain groups of products with similar clinical effectiveness;
 - (c) abolish the negotiation of benefits for individual listed products, and instead establish and maintain a single (benchmark) benefit for the products included in each group, with sponsors being required to accept this benefit in order to be listed;
 - (d) abolish the negotiation, setting or publication of maximum benefits, to eliminate the potential for gap payments for patients who have Private Health Insurance (PHI); and
 - (e) permit the establishment of new product groups (or sub-groups) where a sponsor establishes clear superiority of their product compared to those in an existing group.¹¹

4.16 The Government accepted these recommendations. As noted above, the following matters have since been implemented:

- Recommendation 10: the PLAC has been established to replace the PDC, with revised terms of reference and new membership (recommendation 10a); and a communication protocol for the referral from the PLAC to the TGA of concerns regarding the intrinsic safety of prostheses or devices has been implemented (recommendation 10b);
- Recommendation 11: the PLAC replaced the PDC, with revised terms of reference and new membership; and
- Recommendation 12: the continuous acceptance of applications for the Prostheses List commenced on 2 August 2010 (recommendation 12a). A stakeholder consultation meeting was held in June 2010 and general agreement on the approach to implementation of recommendation 12b-e was reached. The Minister has approved this approach, including the establishment of a Consultative Committee, and phased implementations which will occur throughout 2010 and 2011. The Consultative Committee is continuing to meet to consider the proposed groupings and group benefits of products.¹²

11 Department of Health and Ageing, *Review of Health Technology Assessment in Australia*, December 2009, p. 19.

12 Therapeutic Goods Administration, *Submission 18*, pp 11–12; Department of Health and Ageing, *Achievements since the release of the Health Technology Assessment Review*, www.health.gov.au/internet/hta/publishing.nsf/Content/achievements-1, accessed 12 October 2011.

Public health system

4.17 In the public health system, medical devices are supplied under agreements or tender arrangements between the supplier and the public hospital. Public hospitals also receive payments from health insurers for private patients who elect to be treated in a public hospital.

Issues

4.18 Submitters noted that the reimbursement of medical devices has been addressed in the HTA Review with the Review's recommendations being progressively implemented. Medtronic Australasia, for example, commented that 'some positive changes have been made'.¹³ AusBiotech added that:

With its revised membership and terms of reference, PLAC should assist with developing clinical evidence requirements for new Prostheses List applications as well as the development of procedures and models for assessing the cost effectiveness of medical devices in a more rigorous and transparent way.¹⁴

4.19 However, submitters also argued that a number of issues still remained to be addressed including addressing comparative cost effectiveness mechanisms, limitation of listing on the Prostheses List to implantable devices and the influence of gap payments on choice of device. Medtronic Australasia, for example, commented:

Medtronic commends MSAC [Medical Services Advisory Committee] on the work it has done to develop a new framework for the MSAC assessment processes. However, we believe MSAC is experiencing significant teething problems with the new processes, resulting in a great deal of uncertainty for applicants who have applications in progress. This includes significant examples of "shifting goalposts", undocumented processes, partially implemented processes, poor communication of changes and processes, and expectations and lack of transparency. There are further improvements to be made here if Australia is to deliver internationally recognised good HTA practice.¹⁵

Cost effectiveness of subsidised devices

4.20 The cost effectiveness of medical devices is a significant issue for both the private and the public health care sectors. The benefits paid by private health insurers for prostheses for the 12 months to March 2011 were \$1.3 billion, which represented 10.6 per cent of total benefits paid by health insurers during that period.¹⁶

13 Medtronic Australasia, *Submission 14*, p. 8.

14 AusBiotech, *Submission 16*, p. 6.

15 Medtronic Australasia, *Submission 14*, pp 8–9.

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

4.21 The Medical Technology Association of Australia (MTAA) commented that prior to the implementation of the recommendations of the HTA Review, cost effectiveness of implantable devices was assessed relative to comparator devices already on the Prostheses List. However, following the HTA Review, the grouping of products and the application of a benchmark benefit for each group of like products has been gradually implemented. The MTAA noted that the grouping mechanism employed to enable comparisons is 'a simpler and more appropriate approach than evidence-based assessments for reimbursements of products on the Prostheses List'.¹⁷

4.22 Other submitters raised the issue of the lack of comparative cost effectiveness of devices in relation to total benefits and costs. JJM commented that the cost effectiveness of devices should not be limited only to the device itself. Rather, total benefits and costs should be taken into account both within sectors and across sectors, for example, the utilisation of medical technology within the private sector may accrue savings to the Pharmaceutical Benefits Scheme.¹⁸ JJM went on to state that it supported evidence-based medicine to achieve objectives including enhanced healthcare decision-making, access to appropriate technologies and optimal use of healthcare resources. JJM commented that:

Individual patient needs should supersede short-term cost considerations, especially for the use of new treatments that potentially address unmet medical need and that may change the paradigm of therapy.¹⁹

4.23 JJM concluded that medical technology costs 'should not be judged in isolation or in silos for budget setting and budget holding'. However, JJM argued that this does not currently occur in the Australian healthcare sector and as a result there is 'non-realisation of cost savings within the overall expenditure on the healthcare system'.²⁰

4.24 AusBiotech put a similar view and commented that the 'current system provides no incentive for medical practitioners and healthcare providers to look at the entire cost of the treatment over multiple admissions'.²¹

4.25 The need to assess comparative effectiveness was raised by the AHIA. The AHIA argued that assessment of effectiveness should consider both cost and clinical effectiveness of devices, with only devices which have been proven to be both more clinically effective and more cost effective should be listed. Dr Michael Armitage, Chief Executive Officer, AHIA, explained further:

At the moment if someone brings in, for argument's sake, a stent to be put into a cardiac artery it is usually compared with another stent. It is,

17 Medical Technology Association of Australia, *Submission 12*, p. 7.

18 Johnson & Johnson Medical, *Submission 28*, p. 20 and p. 24.

19 Johnson & Johnson Medical, *Submission 28*, p. 22.

20 Johnson & Johnson Medical, *Submission 28*, p. 24.

21 AusBiotech, *Submission 16*, p. 7.

however, not compared on a comparative cost-effectiveness, or indeed comparative clinical effectiveness, basis with, for argument's sake, a coronary artery bypass graft. More importantly, it is not compared against, in this particular case, the use of optimal medical treatment—in other words, standard drugs that are used every day, and there is a trial in America, called the COURAGE trial, which seems to indicate that optimal medical treatment is better than either of those other two things. So there is a need for comparative cost-effectiveness.²²

4.26 The AHIA concluded that:

...the medical devices should be competitively contestable to ensure ongoing growth. However, in ensuring an informed consumer, information should be readily available on comparing the best available HT alternatives.²³

4.27 In relation to cost effectiveness, Medibank Private commented that within the Australian healthcare sector there is a fragmented approach with separate processes for medicines, procedures and devices. Thus the healthcare sector does not benefit from a global approach. In addition, Medibank Private noted that the take up of new technologies relies on suppliers introducing specialists to new medical devices or direct supply or hospitals. This, Medibank Private argued, is undertaken 'without any clinical evidence other than Therapeutic Goods Approval (TGA), or formal industry accepted process for reimbursement (such as that that exists for prostheses)'. A further matter raised was the change to the regulatory regime to contain costs. As a consequence, Medibank Private commented that approval, funding and use of new medical devices are 'complex and highly regulated'.²⁴

4.28 While acknowledging the work of the HTA Review, Medibank Private argued that there are features of the current system which have 'led to unintended and unwanted outcomes for the Australian health system' and continue to affect the success of changes to existing arrangements. Medibank Private pointed to excessive costs for the health system as there is a lack of genuine competitive pressure; product selection that is predominantly determined by clinical choice without reference to cost effectiveness; and different classes of prostheses with widely differing benefits may be used with no clinical justification for the higher cost.²⁵

4.29 Medibank Private outlined the features which are contributing to adverse outcomes. First, the scale and size of the Prostheses List is inhibiting attempts to group products on the basis of clinical effectiveness. For example, a review that involves around 2 500 products remains incomplete after almost two years. Medibank

22 The Hon Dr Michael Armitage, Chief Executive Officer, Australia Health Insurance Association, *Committee Hansard*, 27 September 2011, p. 1.

23 Australia Health Insurance Association, *Submission 20*, p. 3.

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

25 Medibank Private, *Submission 1*, p. 4.

Private also noted that there is a major backlog of reviews of listings and benefits intended to be undertaken by the PDC, resulting in inconsistent benefits set for products with similar clinical effectiveness.²⁶ However, the AHIA commented that the 'grouping exercise is on technical rather than relative clinical effectiveness grounds'.²⁷

4.30 Medibank Private went on to comment on practices in the private and public sectors and noted that the differing benefit setting arrangements for prostheses between the public and private hospitals sectors result in private health insurers having to reimburse prostheses at much higher levels in the private hospital sector where clinicians are not required or encouraged to consider cost effectiveness. While some differences reflect the level of training and product support between public and private hospitals, benchmarking indicates variation that exceeds this justification. In addition, there is a lack of emphasis given to considerations of cost effectiveness in the private sector which makes it difficult to encourage device suppliers (or sponsors) to develop and support generic prostheses. Medibank Private commented that 'while the regulatory framework needs to ensure that there are appropriate incentives for sponsors to invest in prostheses, innovations to develop generic products where they achieve the same or better results in more cost effective ways are similarly important'.²⁸ However, the AOA also commented that the price differential between the public and private sectors is not as great as it has previously been as procurement arrangements have now been undertaken by the States rather than individual hospitals.²⁹

4.31 Medibank Private pointed to three further features which effect the current system:

- the encouragement of market competition between sponsors will help offset the market failures which exist in relation to prostheses, for example, information gaps for consumers who rely on clinical guidance, which is not required to reflect cost effectiveness considerations in any meaningful way;
- there is a paucity of information regarding clinical best practice to guide the choice of prostheses despite the work of the NJRR. As a consequence, the substitution of certain devices for more cost effective selections where clinical effectiveness is maintained is undermined; and
- there is a significant degree of discounting on prices actually paid by parties along the supply chain (sponsors, private hospitals, and possibly clinicians). Medibank Private argued that private health insurers, and ultimately the

26 Medibank Private, *Submission 1*, p. 4.

27 Australian Health Insurance Association, *Submission 20*, p. 9.

28 Medibank Private, *Submission 1*, p. 4.

29 Australian Orthopaedic Association, *Submission 5*, p. 2.

consumer, miss out on sharing in the discounts and no price disclosure or other comparable mechanism exists for sharing discounts.³⁰

4.32 A final matter raised by the AOA in relation to costs generally is that there is no mechanism to take account of any increase in the value of the Australia dollar. Such a mechanism would ensure that the purchase cost of imported devices can be adjusted as the value of the dollar increases, thus providing benefits for consumers and the health sector.³¹

Prostheses List

4.33 As noted above, the Prostheses List was considered by both the Doyle Review and the HTA Review. The HTA Review recommended changes to the Prostheses List process. The Australian Private Hospitals Association (APHA) was of the view that 'it is too early in the process to make any definitive statements about how the new list is working'.³² However, other submitters, while acknowledging that some changes have been implemented, argued that problems still remain. For example, Medibank Private indicated that there are 'inherent problems' in present prostheses systems which include:

- errors in prostheses listing of legislated requirements – Medicare Benefits Schedule/Australian Register of Therapeutic Goods (ARTG) numbers are absent, generic or incorrect;
- benchmarked benefits are generally overpriced compared to overseas examples and Australian public market;
- the constructs of the list are overly complicated with individual components of a prostheses being listed;
- no common identifier or coding system is in use. In addition, billing code identifiers for manufacturer codes are not publicly available;
- there is no audit of performance as a commercial instrument which creates unnecessary error rates and acceptance of poor practice;
- no benefit setting processes have been investigated or proposed post the HTA review; and
- the list has an inadequate classification system in that substitutable devices cannot be easily identified.³³

4.34 These problems were also raised by other submitters with the AOA commenting on the accuracy of Prostheses List descriptors. The AOA stated that the

30 Medibank Private, *Submission 1*, p. 4.

31 Australian Orthopaedic Association, *Submission 5*, p. 2.

32 Australian Private Hospitals Association, *Submission 4*, p. 4.

33 Medibank Private, *Submission 1*, p. 5; see also Australian Health Insurance Association, *Submission 20*, p. 4.

relevant Clinical Advisory Groups are still identifying products that have been incorrectly listed in higher paying groups 'which companies rarely volunteer as an issue'. The AOA concluded that 'there are no penalties to ensure effective compliance and from the evidence it would seem that companies are not good at self-regulation'.³⁴

4.35 Medtronic Australasia commented on the lack of sufficiently clear and detailed guidelines on the clinical evidence requirements for listing products on the Prostheses List. Medtronic Australasia argued that as there are no clear guidelines, there have been instances of what appears to be an inconsistent assessment of product application which 'greatly increases uncertainty for companies'. In addition, Medtronic Australasia stated that company requests for higher benefits for certain products due to clinical superiority are not currently being assessed as the criteria for superior clinical performance have yet to be developed.³⁵ The AHIA also commented that the grounds for superiority are inconsistent, not transparent and should be based on patient register performance.³⁶

4.36 Issues with the billing codes were raised by the AHIA which argued that identification and coding standards remain fragmented across the industry and need to be addressed so that there is an effective link in the HTA information chain and that opportunities provided by the implementation of e-Health and the push towards a national product catalogue are captured.³⁷

4.37 Dr Armitage, AHIA, commented that there is no billing code to catalogue link so that funders are unsure of what they are paying for. Dr Armitage called for action to be taken so that there is a link between the billing code and the Prostheses List.³⁸ This concern was supported by the AOA which argued that billing codes and catalogue numbers should be linked, 'as any one billing code can cover a multitude of catalogue numbers with inherent capacity for new technologies to be introduced into the billing code without scrutiny'. The AOA concluded:

This linkage would not only enable more accurate auditing of devices and technology, but would enable device and technology companies to more accurately access their data through independent bodies such as registries. It would also bring a level of transparency to billing practices.³⁹

4.38 The MTAA noted that DoHA is continuing in its efforts to ensure that product descriptions contained in individual billing codes are appropriately descriptive of the approved listing and that all entries have current registration with the ARTG. The

34 Australian Orthopaedic Association, *Submission 5*, p. 2.

35 Medtronic Australasia, *Submission 14*, p. 8.

36 Australia Health Insurance Association, *Submission 20*, p. 10.

37 Australia Health Insurance Association, *Submission 20*, p. 4.

38 The Hon Dr Michael Armitage, Chief Executive Officer, Australia Health Insurance Association, *Committee Hansard*, 27 September 2011, p. 1.

39 Australian Orthopaedic Association, *Submission 5*, p. 2.

MTAA commented that 'this is a burdensome task in respect to a list with over 9 000 entries but a necessary task which MTAA supports'.⁴⁰

4.39 The Australian Private Hospitals Association commented that no concerns have been raised by its members in relation to billing codes.⁴¹

4.40 Submitters raised a range of other issues concerning the Prostheses List including the type of devices that may be listed. The MTAA, St Jude Medical and Boston Scientific Australia New Zealand (BSC) commented on the criteria for listing that requires the device to be implantable. It was argued that this requirement is unnecessarily restrictive and does not take into account new technologies. St Jude added that that the 'rigid and anachronistic' rules of the Prostheses List resulted in the most cost saving and effective clinical treatment is not delivered to patients.⁴² As a result there is a cost to the health system. In addition, the MTAA argued that 'private patients do not always receive the benefits of technologies which are otherwise available on the Australian market'.⁴³

4.41 BSC noted that 'increasingly technologies are being designed such as radiofrequency ablation, which if used, prevents the need for implantable devices, such as a defibrillator' which is a less invasive treatment.⁴⁴ St Jude Medical provided the example of its pressure wire which is used during coronary angiography. Where the pressure wire is used, the average number of coronary stents used is lower. However, as private hospitals do not receive any additional benefit for using a pressure wire, St Jude Medical stated that there is financial disincentive to use the device despite the significant decrease in heart attacks, death and overall cost. In the public sector, the uptake of this technology is higher as 'there are different financial drivers'.⁴⁵

4.42 The MTAA acknowledged that the HTA Consultative Committee has terms of reference that will include examination of funding for cost-effective technologies that are not eligible for listing on the Prostheses List.⁴⁶ While BSC concluded that it:

...shares the concerns of health funds that we do not want to address these perverse incentives by listing every possible device. However, there is an opportunity to create an alternative list of surgical treatments requiring non-implantable devices to provide patients and doctors with the same certainty they enjoy from the Prostheses List.

40 Medical Technology Association of Australia, *Submission 12*, p. 7.

41 Australian Private Hospitals Association, *Submission 4*, p. 3.

42 St Jude Medical, *Submission 8*, p. 3; see also Medical Technology Association of Australia, *Submission 12*, p. 7.

43 Medical Technology Association of Australia, *Submission 12*, p. 7.

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

45 St Jude Medical, *Submission 8*, p. 6.

46 Medical Technology Association of Australia, *Submission 12*, p. 7.

BSC is working with the MTAA on a principled-based approach to creating a "Schedule C" for non-prostheses device treatments. As technologies evolve, there will be increasing need for an explicit list that enable doctors to provide the most appropriate treatment option for their patients. To do this, Australia will have to eliminate the perverse incentives inherent in the Prostheses List definition.⁴⁷

4.43 St Jude also recommended that Part C of the Prostheses List should be revised to allow for devices such as the pressure wire to be listed.⁴⁸

4.44 Two matters which affect the choice of medical devices were raised by AusBiotech. First, AusBiotech stated that the size of the gap payment required to be paid by a patient can influence the choice of device made by the medical practitioner. As a consequence, the sale of 'unselected' medical devices is impeded. Secondly, the revision of the Prostheses List twice per year can similarly effect the utilisation of devices. AusBiotech stated that when a new device is listed, benefits established for medical devices can universally change due to the new product being listed 'subsequently altering the gap payment required by the patient'.⁴⁹

4.45 Medtronic Australasia noted that the development of a review and appeal processes for both the Prostheses List and for MSAC are progressing very slowly. As a consequence there is currently no mechanism for internal appeal and review of decisions and concluded that 'it is imperative that this be addressed as a matter of urgency'.⁵⁰

4.46 Finally, the AHIA commented that there is no process proposed post the HTA review and no constructive papers have been commissioned or information released around which the industry can base decisions in regards to an ongoing process. The AHIA stated that 'this would include how benefit setting would work into the future, what would be the mechanisms for controlling benefit growth, and any indications of the establishment of further registries to ensure quality and safety'.⁵¹

Committee comment

4.47 A significant issue raised during the inquiry was the lack of assessment of comparative cost effectiveness of devices. It was argued that as a consequence, savings in other areas such as the PBS are not being identified. Evidence pointed to the fragmentation of the approval system across pharmaceuticals, devices and processes working against a global approach. The committee considers that more rigorous comparative cost effectiveness would benefit the healthcare sector, and there

47 Boston Scientific Australia New Zealand, *Submission 13*, p. 9.

48 St Jude Medical, *Submission 8*, p. 6.

49 AusBiotech, *Submission 16*, p. 7.

50 Medtronics Australasia, *Submission 14*, p. 8.

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

is some way to go before this can be implemented. However, the committee considers that once the recommendations of the HTA Review have been fully implemented, the strengthening and streamlining of processes will allow for comparative clinical and economic evaluations by MSAC. These issues of clinical effectiveness were also considered in chapter 3

4.48 The committee notes the changes being made to the Prostheses List as a result of the HTA Review. While there remain some concerns with the Prostheses List, the committee considers that many will be addressed as further changes are made. In relation to the restriction of listing of implantable devices on the Prostheses List, the committee notes that a new part to the Prostheses List (Part C) is being developed which may address some of these concerns.

Chapter 5

Conclusion and recommendations

5.1 This inquiry addresses the regulation of medical devices in Australia. This is a complex and evolving area of regulation. The inquiry examined the role of the TGA in regulating the quality of devices in Australia, including the processes in place to ensure that single use and remanufactured products continue to meet Australian standards. It also examined issues related to subsidies for medical devices.

5.2 More importantly, the inquiry focused on the consumer experience of those approximately 5500 Australians who have received DePuy metal on metal hip replacements, including total hip replacements and hip resurfacing systems. Many of the consumers who received the DePuy metal on metal hip devices subsequently needed one or more revision surgeries. They also reported serious and systemic health problems extending beyond initial complications with the device.

5.3 In association with these concerns, the committee scrutinised the processes in place to notify the relevant authorities and the general public of high revision rates or possible faulty devices; and the effectiveness of the current regimes in place to ensure prostheses with high revision rates are identified and action taken once the devices are identified. The committee found that, in practice, these processes should be improved.

5.4 The committee was shocked by the intolerable, and unacceptable, experiences of patients who received the DePuy hip and hip resurfacing system. These very personal experiences serve to underline the need for improved pre-market clinical testing and post-market surveillance systems for medical devices, as well as improved timeliness and decisiveness when acting upon the information that is available.

5.5 These experiences brought home to the committee that the TGA could have done more in response to the concerns with the device and that Johnson & Johnson Medical did not serve patients well.

5.6 This inquiry is being conducted in parallel with the Government's implementation of the recommendations of the HTA Review, and consideration of the recommendations of the TGA Transparency Review. Many of the recommendations of these reviews are material to the considerations of the inquiry.

5.7 The committee notes the regulatory balance that the TGA attempts to achieve between ensuring safety of medical devices and the encouragement of new technologies that may provide benefit to patients. It also noted the balance the TGA seeks to strike in allocation of resources to pre-market assessment and post-market surveillance of medical devices.

5.8 The committee heard evidence about the TGA's approach to global harmonisation, and its efforts in concluding a range of bilateral agreements. The committee received evidence regarding the leading role that the TGA has played in

the Global Harmonisation Task Force (GHTF) for medical devices. The committee commends the ongoing work of the TGA in seeking to raise the standard of regulation of medical devices in the international arena.

Pre-market assessment

5.9 The committee received a range of evidence regarding the adequacy of the TGA's approach to pre-market assessment of medical devices. In particular, the committee examined the current approach to assessing clinical evidence prior to listing on the ARTG.

5.10 The committee notes that the HTA Review recommended increasing the rigour of regulatory assessment of higher risk medical devices, and that the TGA has subsequently carried out consultations on proposals designed to address this matter. The TGA announced its intention to implement a 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. However, the TGA has announced that it will conduct further consultation on a proposal to increase the level of assessment of Class III devices.

5.11 While the committee commends the TGA for reclassifying joint replacement devices from Class IIb to Class III, it is also of the view that a higher level of assessment of Class III medical devices is required. The committee is mindful of statements by some submitters that there is a material difference in carrying out clinical trials on pharmaceuticals and medical devices due to the extra complications of a device being inserted in a patient's body.

5.12 However, the committee is concerned that an emphasis on post-market surveillance may mean that medical devices are, in a sense, being trialled unofficially, without the protections associated with registered clinical trials. 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.

5.13 The committee also received evidence about the increasing number of medical devices, in a wide variety of combinations, entering the Australian market. The committee was not entirely convinced by the argument from DoHA that this represents better consumer and practitioner choice. Such an approach will make assessing the available clinical evidence more onerous and resource intensive. A larger number of devices also makes assessment of post-market surveillance data more complex, with a possibly longer lead time before problems become apparent.

5.14 The committee was disturbed by evidence from the AOA that its research indicates that many prosthetic devices entering the market actually perform worse than, or no better than, those that are currently available.

5.15 The committee was persuaded by the AOA that the development of a publicly available list of approved devices on the ARTG is vital. 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.

Recommendation 1

5.16 The committee recommends that the Therapeutic Goods Administration make a list of the devices on the Australian Register of Therapeutic Goods publicly available.

Recommendation 2

5.17 The committee recommends that the Department of Health and Ageing fully implement Recommendation 8c of the Health Technology Assessment Review regarding the need for increased rigour of regulatory assessment of higher-risk medical devices.

Recommendation 3

5.18 The committee recommends that the level of assessment of Class III medical devices be increased.

Recommendation 4

5.19 The committee recommends that the Therapeutic Goods Administration investigate whether allowing an increasing number of medical devices onto the Australian market actually improves clinical outcomes; and whether a more judicious approach could improve pre-market assessment and post-market surveillance of higher risk medical devices, for the ultimate benefit of patients.

5.20 The committee heard evidence about current TGA consideration of third party conformity assessment, in relation to global harmonisation of regulatory frameworks for medical devices. On the one hand, the committee heard that accepting clinical evidence from overseas, in particular where there is a very high degree of regulatory alignment, would reduce the time and costs associated with regulatory compliance and listing of a device, without compromising patient safety. On the other hand, the committee heard of the potential for mistakes made in other jurisdictions to be replicated in the Australian context through this mechanism, with one submitter raising concerns about such a system being 'a race to the bottom'.

5.21 The committee was sympathetic to the concerns of Australian medical device manufacturers that they are subjected to a more onerous regulatory regime than overseas manufacturers. Similarly, the committee acknowledges the concerns raised by medical device manufacturers about the increasing timeframes for the TGA to carry out conformity assessments.

5.22 The committee notes that the HTA Review, and a number of consultations by the TGA, examined the issue of third party conformity assessment. The TGA recently circulated proposals in relation to this matter for comment, and has now decided to undertake further consultations on a series of amended proposals. The committee recognises this is a complex issue and urges the TGA to consult as widely as possible with all stakeholders in their continuing consideration of this matter.

Recommendation 5

5.23 The committee recommends that the Therapeutic Goods Administration continue to consult widely with stakeholders, including consumer health organisations, on the amended proposals related to third party conformity assessment; and weigh carefully considerations of the advantages of streamlined international regulatory frameworks and patient safety.

5.24 The committee received conflicting evidence from submitters in relation to whether remanufactured devices are safe. While Stryker South Pacific argued that their remanufacturing processes were sufficiently rigorous to ensure patient safety, other submitters raised concerns about the potential health effects of remanufactured single-use devices including risks of contamination, material degradation and mechanical failure of medical devices. The committee also received evidence that the remanufacturing of single-use medical devices raises issues related to tracking of those medical devices, as well as issues of informed patient consent.

5.25 The committee is mindful of the argument that remanufacturing medical devices may, in part, address the growing environmental impact of the disposal of hospital waste, and the financial burden on hospitals of only using devices once. However, the committee heard that as yet there is no adequate evidence on whether an assessment of the entire reprocessing cycle would yield such apparently positive environmental results.

5.26 The positions of submitters fell fairly neatly into medical device manufacturers who stand to gain from continuing to market single-use devices; and those who stand to gain if they are approved to carry out validated remanufacturing by the TGA, at some point in the future.

5.27 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. A similarly prudent approach by the TGA has, to date, seen no conformity assessment certificate issued to any manufacturer of reprocessed single-use medical devices.

Recommendation 6

5.28 The committee recommends that the Therapeutic Goods Administration continue its prudent approach to the regulation of reprocessed single-use medical devices, with due consideration for issues of informed patient consent and the need for suitable mechanisms to enable tracing of remanufactured medical devices in the case of adverse events.

Post-market surveillance

5.29 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.

5.30 Similarly, 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.

5.31 The committee is of the view that consideration should be given to attaching a flag or an indicator to the billing code of devices subject to an alert or recall. Additionally, this would allow an adjustment to benefits paid, based on industry feedback regarding the device's performance. This would be facilitated by the simultaneous allocation of ARTG numbers, Private Health Insurance prostheses listing, and allocation of billing codes, catalogue numbers and Medicare Benefits Schedule (MBS) item numbers for each device.

5.32 The committee received evidence about the need for improved adverse event reporting. It is clear that doctors, rather than manufacturers, are the front line for consumers reporting problems with their medical devices. Yet, the system is currently limited by the lack of mandatory adverse event reporting by doctors. Similarly, it is evident that there is a lack of awareness among consumers about the possibility of, and the mechanism for, reporting adverse events to the TGA.

5.33 Information received by the committee that many prosthetic devices approved for use in Australia are performing worse than those already available highlighted the need for evidence-based decision making of the type anticipated by Recommendation 14 of the HTA Review.

5.34 The committee received considerable amounts of evidence about the important work that the NJRR does in monitoring joint replacement revisions, and identifying those medical devices or procedures with a statistically higher rate of revision. Information received about the way that this monitoring and identification

role will be enhanced through participation in the newly established International Consortium of Orthopaedic Registries (ICOR) is encouraging.

5.35 The committee found the evidence that establishing other clinical registries for high-risk devices and procedures, modelled on the NJRR, would make a critical contribution to improving post-market surveillance in Australia compelling. The committee noted, however, that establishing quality clinical registries is a costly undertaking, and registries should be prioritised according to identified health needs.

5.36 The committee notes that Recommendations 13, 14 and 15 of the HTA Review have not been accepted by Government due to cost considerations and that the TGA Transparency Review is still under consideration.

5.37 While the financial implications of implementing the HTA recommendations are not insignificant, the committee considers that it is a worthwhile investment in the future health of all Australians. The committee is of the view that such an investment stands to reduce health costs over the longer term by reducing the need for costly interventions, as HTA decisions are increasingly evidence based.

5.38 Similarly, many submitters raised issues related to the provision of, and ease of access to, information available from the TGA. These issues are not new. For this reason the committee believes that the Government should support the recommendations of the TGA Transparency Review.

Recommendation 7

5.39 The committee recommends that the Department of Health and Ageing implements Recommendations 13, 14, and 15 of the Health Technology Assessment Review in a timely manner. These recommendations address the need for 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.

Recommendation 8

5.40 The committee recommends that the Therapeutic Goods Administration put in place mechanisms to educate and encourage doctors to report adverse incidents associated with the use of medical devices. The committee further recommends that the Department of Health and Ageing introduce mandatory reporting for health practitioners to the Therapeutic Goods Administration on relevant issues, in certain circumstances including problems with medical devices.

Recommendation 9

5.41 The committee recommends that the Government implements the Recommendations of the Therapeutic Goods Administration Transparency Review in a timely manner.

Recommendation 10

5.42 The committee recommends that the Therapeutic Goods Administration consider simultaneously allocating or aligning the great variety of codes used to identify medical devices, in order to facilitate more efficient regulation and more rapid identification of devices when problems occur.

Recommendation 11

5.43 The committee recommends that the Department of Health and Ageing consider a mechanism for flagging billing codes in order to identify devices subject to an alert or recall; as well as a consequent adjustment to benefits paid, based on industry feedback as to the performance of the device.

Custom made dental devices and internet purchasing

5.44 The committee is concerned by evidence that, in Australia, 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 committee was also informed that in the United Kingdom patients are offered a statement of manufacture; and practitioners are obliged to retain this statement for the lifetime of the prosthesis. In addition, practitioners must record whether the statement was provided to the patient or not.

5.45 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.

Recommendation 12

5.46 The committee recommends that the Therapeutic Goods Administration consider whether custom made dental devices are adequately regulated; and whether the approach used in the United Kingdom of requiring a statement of manufacture to be provided to patients, and retained by the dental practitioner, has merit.

Recommendation 13

5.47 The committee recommends that the Therapeutic Goods Administration carry out an investigation to ascertain whether importation of medical devices via the internet is adequately regulated.

Identification of high risk prostheses

5.48 The committee received evidence that the NJRR clearly identified the higher than usual revision rates of the DePuy hip resurfacing system in 2007 and the DePuy hip in 2008.

5.49 The committee notes that the TGA convened meetings of the OEWG commencing in 2007, albeit with a substantial gap between June 2008 and December 2009.

5.50 The committee received evidence from Professor Stephen Graves, of the NJRR, that although he is now happy with the current timeliness of the TGA's response to new reports of increased rates of revision from the NJRR, this had not always been the case. Similarly, the minutes of the Orthopaedic Expert Working Group express similar concerns regarding the timeliness of the TGA in responding to information available regarding the high revision rates of the ASR hips. Although the committee notes the reasons for delays offered by the TGA, the failure of the TGA to act in a more timely and decisive manner is regrettable.

5.51 The NJRR provided evidence to the committee that it is not only the DePuy devices that are experiencing higher rates of revision. The committee was informed that there is new information that there are further classes of devices which are now being identified as an issue. This includes the metal-on-metal group as a whole, particularly in conventional hip replacements and large-head metal-on-metal devices. The NJRR has also identified another class which use 'exchangeable necks' which appear to have over twice the risk of revision compared to devices that do not have those exchangeable necks.

Recommendation 14

5.52 The committee recommends that the Therapeutic Goods Administration, in consultation with the National Joint Replacement Registry, investigate ways in which information provided by the National Joint Replacement Registry can be used and responded to in a more timely way for the benefit of patients, and to inform future evidence based decision making on the listing of prostheses on the Australian Register of Therapeutic Goods.

Notification and follow up

5.53 The processes used by the TGA for communicating adverse events to patients and medical practitioners have previously been identified as needing substantial improvement. The evidence received by the committee that consumers suffering complications from their DePuy hip and hip resurfacing devices did not receive adequate information from their doctors, despite repeated visits, indicates that something is seriously wrong with the management of adverse event reporting and follow up.

5.54 Many consumers only became aware that their medical device had been withdrawn from the market when they heard about it through the media or through internet searches. Some consumers were provided information about the ASR hip withdrawal by their doctors only when it came time for their annual review. The committee believes that there may be many thousands of Australians who continue to be unaware of these issues. This is clearly unacceptable.

5.55 At a minimum, as noted above at Recommendation 8, the committee recommends the implementation of the TGA Transparency Review Recommendations.

5.56 The committee received substantial evidence from consumers of serious ill health and complications associated with metal toxicity, caused by the leaching of cobalt and chromium ions from the hip replacements into patients' bodies. It appears from evidence received that research or monitoring of this issue is at best nascent. The committee believes that this matter should be considered more urgently by health authorities and professionals. The committee is also of the view that research on the health effects of cobalt and chromium, as well as other metals producing toxicity in the human body; should be made a research priority, with adequate funding provided for the conduct of such research.

Recommendation 15

5.57 The committee recommends that the Department of Health and Ageing prepare, as a matter of priority, a comprehensive communications strategy to inform medical practitioners, patients and the general public about the issues associated with De Puy hip and hip resurfacing devices as well as options for treatment, obtaining further information, and reporting adverse outcomes. The committee further recommends that such a strategy be implemented as a standard process for any future adverse event reporting.

Recommendation 16

5.58 The committee recommends that the Department of Health and Ageing, as a matter of urgency, consider the best way of establishing a process for monitoring the levels of cobalt, chromium, and other toxic metals; and any possible health effects, in all patients who have received metal-on-metal hip replacements.

Recommendation 17

5.59 The committee recommends that the Government consider the best mechanism for initiating and advancing research on the health effects of cobalt, chromium, and other toxic metals, on the human body. The committee also recommends that consideration be given to ensuring adequate funding for that research is made available.

Inducements

5.60 The committee received evidence from consumers about their concerns that there may have been inducements paid to doctors or hospitals to favour particular prostheses. The committee also received information about a range of voluntary codes of conduct that regulate such behaviour. The committee notes that Johnson & Johnson Medical have been required to pay high civil penalties in other jurisdictions for illegal conduct related to paying inducements to doctors.

5.61 The committee was interested to hear of legislative developments in the United States under the Physician Payment Sunshine provisions, included in the *Patient Protection and Affordable Care Act* of 2009, requiring disclosure of all payments made to physicians and teaching hospitals by medical manufacturers and pharmaceutical companies. The committee considers that a legislative, rather than voluntary, approach to this matter may have some merit in Australia as well.

5.62 The committee further notes that public disclosure of payments to physicians and teaching hospitals by medical manufacturers and pharmaceutical companies is now the subject of legislation in the United States. The Physician Payment Sunshine provisions were included in the *Patient Protection and Affordable Care Act* of 2009 (H.R. 3590, section 6002) which was signed into law on 23 March 2010, and will come into effect on 1 January 2012. The committee is of the view that this approach is also merited in Australia.

5.63 The committee will continue to monitor the issue of inducements that may be paid to doctors or hospitals.

Recommendation 18

5.64 The committee recommends that the Department of Health and Ageing undertake further work to address the issue of inducements paid by pharmaceutical companies and medical device manufacturers to doctors and teaching hospitals, in line with the Physician Payment Sunshine provisions of the *Patient Protection and Affordable Care Act* of 2009 in the United States. The definition of inducements should include a commercial interest in a company or device; any cash payments or discounts offered to medical practitioners; and any other gifts provided to medical practitioners.

5.65 In conclusion, the committee would like to thank all witnesses who provided evidence to the committee. In particular the committee extends their thanks to the patient witnesses, many suffering extremely poor health, who gave their time to provide such compelling evidence.

**Senator Rachel Siewert
Chair**

Additional Comments by Independent Senator Nick Xenophon

1.1 I would like to join the committee in acknowledging the witnesses who provided evidence about their personal experiences of the regulatory failure relating to the DePuy ASR hip replacements and other devices. This evidence was vital to the committee's understanding of the real life impact of the failure of these devices, and I thank these witnesses (many of whom are in very poor health) for taking the time to provide this information to the committee.

1.2 I would also like to acknowledge the other individuals who have contacted me since the committee hearing to share their stories, not just of the DePuy ASR hips but also of other metal-on-metal devices. It is important to note that the problems caused by the ASR are not restricted to these two devices, but have also been found to occur where other types of metal-on-metal devices have been implanted in patients. I note that the committee has made reference to this in the majority report.

1.3 Australian health consumers have been subject to a serious failure of regulatory standards, not just on the part of the device manufacturer, but on the part of the Therapeutic Goods Administration. As Australia's regulator, it is not unreasonable to expect the TGA to be meticulous not only in its original approval of devices, but in the area of post-market monitoring.

1.4 Instead, evidence provided to the committee by the TGA and by Professor Stephen Graves of the Australian Orthopaedic Association and National Joint Replacement Registry shows that the TGA was unacceptably slow in examining data relating to revision rates of hip and knee replacements provided to them by the National Joint Replacement Registry.

1.5 In one instance, data supplied to the TGA by the NJRR in September 2008 was not discussed by the TGA's Orthopaedic Expert Working Group until December 2009, after the NJRR had also supplied the TGA with the 2009 report¹. Even then only ten of the thirty devices flagged in the 2008 and 2009 reports were addressed².

1.6 In this same meeting, members of the OEWG, including the Chair, raised concerns about the lack of meetings and the delays in addressing some of the devices flagged in previous meetings that were still on the Australian Register of Therapeutic Goods and therefore approved for use in Australia. Concerns were also expressed in

1 Professor Stephen Graves, National Joint Replacement Registry, further answers to questions on notice, 21 October 2011, (received 25 October 2011), pp 2-3

2 Department of Health and Ageing, answers to questions on notice, 27 September 2011, (received 25 October 2011), Minutes of the Orthopaedic Expert Working Group, 9 December 2009, p 2

relation to the TGA's lack of action in responding to recommendations made by the OEWG³.

1.7 The TGA's response to these concerns, as stated in the minutes, indicates that that some implants identified in the 2008 and 2009 NJRR reports had still not been processed by early 2010. Given that some of these implants were identified in 2008, and some may possibly have been identified as early as 2007⁴, this seems an excessive and unacceptable delay, which has compromised the health of patients.

1.8 According to additional information provided to the committee by Professor Graves, the NJRR originally provided the 2007 report to the TGA in September 2007, and then again in February 2008, when the TGA requested that the data be resent⁵. The TGA's lack of timely action is unacceptable. This data was not reviewed until May and June of 2008, a delay of over nine months⁶. This is very concerning.

1.9 However, it is important to note that Professor Stephen Graves of the AOA and NJRR stated in the committee hearing that, while he was not happy with the timeliness of action over the whole period of OEWG meetings, he is now happy with the approach the TGA is currently using⁷.

1.10 In relation to the ASR resurfacing device, it is also important to note the comments made by Dr Rohan Hammett, National Manager of the TGA, regarding the TGA's actions. During the committee hearing, Dr Hammett indicated that, at first, it was considered that the technical complexity of implanting this device was responsible for the higher than expected rate of revision, and that a training program for surgeons was put in place to try and address these issues.

He stated:

Their [the expert working group] recommendation to the TGA... was that surgeons should be required to undertake additional training regarding insertion of the ASR hip. That was the advice of the clinical experts, which the TGA accepted, and a training program was put in place...⁸

He continued:

3 Ibid

4 Ibid

5 Professor Stephen Graves, National Joint Replacement Registry, further answers to questions on notice, 21 October 2011, (received 25 October 2011), p 2

6 Department of Health and Ageing, answers to questions on notice, 27 September 2011, (received 25 October 2011), Minutes of the Orthopaedic Expert Working Group, May 2008 and June 2008

7 Professor Stephen Graves, National Joint Replacement Registry, Committee Hansard, 27 September 2011, p 22

8 Dr Rohan Hammett, TGA, Committee Hansard, 27 September 2011, p 48

So, in fact, the utilisation of that hip was reduced by the risk mitigation that was put in place by the TGA. The Joint Replacement Registry said there was a problem. The experts said the right mitigation is to have better training and then, as a result of that, we saw a slower uptake in the use of that hip as people were required to train.⁹

The advice from the OEWR minutes, however, states:

The Working Group endorsed the actions taken by the ASR resurfacing hip implant's sponsor towards requiring surgeons to undertake specific training for this implant as a condition of sale. The Working Group advised that the performance and revision rate of the ASR resurfacing hip implant should continue to be observed.¹⁰

Dr Hammett's statements seem to infer that the TGA was responsible for implementing the training program, when in fact it had already been put in place by the manufacturer.

Dr Hammett's statements also imply that the TGA acted on notification from the National Joint Replacement Registry. However, the minutes specifically state:

The TGA noted that the manufacturer of the ASR resurfacing hip implant had approached the TGA recognising that the revision rate is no longer acceptable.¹¹

1.11 Dr Hammett's evidence also states that the training program led to a drop in the use of this prosthesis. However, information provided to the committee by Professor Stephen Graves states that:

...a decline in use was evident prior to the company initiated focus on training, which did not commence until early 2008. The most significant decline in the use of the ASR resurfacing hip occurred in 2007.¹²

1.12 While it is understandable that Dr Hammett was simply providing evidence to the committee based on the information he had at the time, it would have been useful for the TGA to clarify Dr Hammett's statements once the OEWR minutes and Professor Graves' information showed that Dr Hammett's comments could be considered to be confusing and clouding the key issues.

1.13 Questions were also raised in relation to the TGA's withdrawal process. The current process seems to be that, if or when the TGA becomes aware of a problem

9 Ibid

10 Department of Health and Ageing, answers to questions on notice, 27 September 2011, (received 25 October 2011), Minutes of the Orthopaedic Expert Working Group, 21 May 2008, p 5

11 Ibid

12 Professor Stephen Graves, National Joint Replacement Registry, further answers to questions on notice, 21 October 2011, (received 25 October 2011), p 1

with a device, the TGA approaches the company to discuss the withdrawal process^{13,14}. This process could be considered to be allowing manufacturers to make a 'voluntary withdrawal' rather than being subject to a forced recall.

1.14 In the evidence provided at the committee hearing, the Hon. Dr Michael Armitage of the Australian Health Insurance Association pointed out the important role of forced recalls as a type of sanction¹⁵; a withdrawal conducted by the manufacturer obviously does not have the same impact.

1.15 This relationship between the TGA and manufacturers, where the TGA allows manufacturers to 'withdraw' rather than 'recall' devices, needs to be investigated and these issues addressed as a matter of urgency.

1.16 It is also important to note that information provided by Johnson & Johnson Medical in response to questions on notice from the committee did not attempt to clarify when JJM first became aware of the problems with either of the ASR devices¹⁶. I endorse the committee's comments in relation to this.

1.17 Overall, the TGA's response to the failure of these devices has been unacceptable. Australians have had their health severely compromised because of a systemic failure on the part of Australia's regulator.

1.18 It remains unclear whether the TGA fully understands its failures in this area and acknowledges the need for greater action and change on its part. This raises serious concerns that this manifestly inadequate response could be replicated in the future.

1.19 If the TGA does not undertake a major systemic reform, the DOHA needs to require the TGA take action.

1.20 The DOHA needs to act on Recommendations 7, 8, 9 and 10 in the majority report within the next six months.

1.21 It is also useful to note the processes involved in approving medical devices in France. For a device to be eligible for rebates, French authorities require proof that the device will have equal or better outcomes than the devices currently approved. Evidence was given in relation to this by The Hon. Dr Michael Armitage of the Australian Health Insurance Association¹⁷. I note the comments made by the

13 Ms Robyn Chu, Director, Health Outcomes, Johnson & Johnson Medical, Committee Hansard, 27 September 2011, p. 40.

14 Therapeutic Goods Administration, Recall of DePuy Orthopaedics ASR hip replacement device, 16 May 2011, <http://www.tga.gov.au/newsroom/btn-dupuy-recall.htm>

15 The Hon. Dr Michael Armitage, AHIA, Committee Hansard, 27 September 2011, p 4

16 Nicholas Campbell, JJM, answers to questions on notice, 27 September, (received 14 October), pp 1-2

17 The Hon. Dr Michael Armitage, AHIA, Committee Hansard, 27 September 2011, p 3

committee in the majority report; it would also be useful for the DOHA to conduct a further investigation on the French model and any relevance it may have to the process for approving devices in Australia. Based on the evidence provided to the committee, it appears to be a stronger system that would provide better patient outcomes.

1.22 In relation to the remanufacture of devices, it is vital that the issues of patient consent and legal liability are addressed in the form of legislation or regulations. The current application for approval to remanufacture devices is the first to come close to approval in Australia, and it is vital that the TGA and the DOHA ensure that appropriate safeguards are in place.

1.23 Patients have the right to be provided with accurate, unbiased, comprehensive information about the medical device their practitioner is going to use on them. This information should include any interest (financial or otherwise) or involvement the practitioner has in the device or the company manufacturing the device. This information should also include whether the device has been remanufactured, details of the remanufacturing process, and any risks or benefits this may have. This information should also be provided in writing, so that patients are able to study it at their leisure.

1.24 There also needs to be clear regulatory or legislative guidelines in place relating to legal liability and 'ownership' of the device in case of patient injury or device failure. Stryker Australia made useful comments in relation to this in their supplementary submission to the inquiry¹⁸; however, it is vital that the regulatory guidelines in place are examined and tested before remanufacturing is approved.

1.25 Issues of patient consent in relation to medical practitioners' interests (financial or otherwise) in particular devices were also raised during the committee hearing. I acknowledge the committee's comments in the majority report regarding this, particularly in relation to the use of DePuy devices that had already been flagged as having higher than expected revision rates in previous NJRR reports. It is reasonable to assume that, if the patients in question had been made aware that issues had been raised in relation to these devices, they would have not consented to have them implanted.

1.26 The DOHA should act on Recommendation 18 of the committee's majority report and introduce and implement legislation within the next 12 months.

1.27 In relation to the importation of dental prostheses, the TGA should carry out Recommendations 12 and 13 of the majority report within the next six months. The lack of regulation in this area is very concerning and should be addressed as a matter of urgency.

18 Chris Szeleczyk, Stryker Australia, *Supplementary Submission 11*, p 4

Amended Recommendation 2:

The committee recommends that the Department of Health and Ageing fully implement Recommendation 8c of the Health Technology Assessment Review regarding the need for increased rigour of regulatory assessment of higher-risk medical devices within the next six months.

Amended Recommendation 4:

The committee recommends that the Therapeutic Goods Administration investigate whether allowing an increasing number of medical devices onto the Australian market actually improves clinical outcomes; and whether a more judicious approach could improve pre-market assessment and post-market surveillance of higher risk medical devices, for the ultimate benefit of patients. This investigation should include consideration of the system currently in place in France, and should be completed within the next 12 months.

Amended Recommendation 7:

The committee recommends that the Department of Health and Ageing implements Recommendations 13, 14, and 15 of the Health Technology Assessment Review in a timely manner, and in any event within the next six months. These recommendations address the need for 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.

Amended Recommendation 8:

The committee recommends that the Therapeutic Goods Administration put in place mechanisms to educate and encourage doctors to report adverse incidents associated with the use of medical devices. The committee further recommends that the Department of Health and Ageing introduce mandatory reporting for health practitioners to the Therapeutic Goods Administration on relevant issues, in certain circumstances including problems with medical devices. These mechanisms should be in place within the next 12 months.

Amended Recommendation 9:

The committee recommends that the Government implements the Recommendations of the Therapeutic Goods Administration Transparency Review in a timely manner, and in any event within the next six months.

Amended Recommendation 10:

The committee recommends that the Therapeutic Goods Administration consider simultaneously allocating or aligning the great variety of codes used to identify medical devices, in order to facilitate more efficient regulation and more rapid identification of devices when problems occur. This should take place within the next six months.

Amended Recommendation 12:

The committee recommends that the Therapeutic Goods Administration consider whether custom made dental devices are adequately regulated; and whether the approach used in the United Kingdom of requiring a statement of manufacture to be provided to patients, and retained by the dental practitioner, has merit. A report in relation to this should be provided to the Department of Health and Ageing by the TGA within the next 12 months.

Amended Recommendation 13:

The committee recommends that the Therapeutic Good Administration carry out an investigation to ascertain whether importation of medical devices via the internet is adequately regulated. A report in relation to this should be provided to the Department of Health and Ageing by the TGA within the next 12 months.

Amended Recommendation 15:

The committee recommends that the Department of Health and Ageing prepare, as a matter of priority, a comprehensive communications strategy to inform medical practitioners, patients and the general public about the issues associated with De Puy hip and hip resurfacing devices as well as options for treatment, obtaining further information, and reporting adverse outcomes. The committee further recommends that such a strategy be implemented as a standard process for any future adverse event reporting, and should be implemented within the next 12 months.

Amended Recommendation 16:

The committee recommends that the Department of Health and Ageing, as a matter of urgency and in any event within the next six months, consider the best way of establishing a process for monitoring the levels of cobalt, chromium, and other toxic metals; and any possible health effects, in all patients who have received metal-on-metal hip replacements.

Amended Recommendation 17:

The committee recommends that the Government consider the best mechanism for initiating and advancing research on the health effects of cobalt, chromium, and other toxic metals, on the human body. The committee also recommends that consideration

be given to ensuring adequate funding for that research is made available within the next 12 months.

Senator Nick Xenophon
Independent Senator for South Australia

APPENDIX 1

Submissions and Additional Information received by the Committee

Submissions received by the Committee

- 1 Medibank Private
- 2 Consumers Health Forum of Australia
- 3 Australian Medical Association
- 4 Australian Private Hospitals Association
- 5 Australian Orthopaedic Association Limited
- 6 NHMRC
- 7 Brandwood Biomedical Pty Ltd
- 8 St Jude Medical Australia Pty Ltd
- 9 Mrs Therese Wood
- 10 Max Boccardo Associates Pty Ltd
- 11 Stryker Australia, Supplementary Submission
- 12 Medical Technology Association of Australia
- 13 Boston Scientific Australia New Zealand
- 14 Medtronic Australasia Pty Ltd, Supplementary Submission
- 15 Sportsmed-SA
- 16 AusBiotech Ltd
- 17 IVD Australia Limited
- 18 Therapeutic Goods Administration
- 19 Cancer Council WA
- 20 Australian Health Insurance Association
- 21 Department of Innovation, Industry, Science and Research
- 22 Name Withheld
- 23 Name Withheld
- 24 Name Withheld
- 25 Name Withheld
- 26 Name Withheld
- 27 Name Withheld
- 28 Johnson & Johnson Medical Pty Ltd
- 29 Mr Robert Lugton, Attachment 1, Attachment 2, Supplementary Submission,
- 30 Australian Dental Industry Association

- 31 Name Withheld
- 32 Mr Stuart Cain, Supplementary Submission
- 33 Logic Appeal
- 34 Name Withheld

Additional Information Received

- 1 Medical Technology Association of Australia, Opening Statement tabled at the public hearing in Canberra on 27 September 2011
- 2 Consumers Health Forum of Australia, Opening Statement tabled at the public hearing in Canberra on 27 September 2011
- 3 Johnson & Johnson Medical Pty Ltd, Opening Statement tabled at the public hearing in Canberra on 27 September 2011
- 4 Stryker South Pacific, Additional Information received 7 October 2011
- 5 Clerk's Advice, dated 18 October 2011.

Correspondence

- 1 Response from Australian Orthopaedic Association to potential adverse comment (sub 29). Received 9 September 2011
- 2 Response from St Jude Medical to potential adverse comment arising from evidence of Ms K Carey at public hearing of 27 September 2011

Answers to Questions on Notice

- 1 Consumers Health Forum of Australia, Answers to Questions on Notice following the public hearing on 27 September 2011, received 4 October 2011
- 2 Medical Technology Association of Australia, Answers to Questions on Notice following the public hearing on 27 September 2011, received 14 October 2011
- 3 Johnson & Johnson Medical Australia, Answers to Questions on Notice following the public hearing on 27 September 2011, received 14 October 2011
- 4 Australian Orthopaedic Association, Answers to Questions on Notice following the public hearing on 27 September 2011, received 17 October 2011
- 5 Australian Orthopaedic Association, Additional Answers to Questions on Notice following the public hearing on 27 September 2011, received 19 October 2011
- 6 Department of Health and Ageing, Answers to Questions on Notice following the public hearing on 27 September 2011, received 25 October 2011
- 7 Department of Health and Ageing, Answers to Questions on Notice asked on 17 October 2011, received 27 October 2011
- 8 Department of Health and Ageing, Answers to Questions on Notice asked on 17 October 2011, received 31 October 2011
- 9 National Joint Replacement Registry, Australian Orthopaedic Association Limited, Answers to Questions on Notice asked on 21 October 2011, received 25 October 2011.

APPENDIX 2

Public Hearing

*Tuesday, 27 September 2011
Parliament House, Canberra*

Committee Members in attendance: Senators Moore (Acting Chair), Carol Brown, McKenzie and Xenophon

Witnesses

Australian Health Insurance Association

The Hon Dr Michael Armitage, Chief Executive Officer,

Medical Technology Association of Australia

Ms Anne Trimmer, Chief Executive Officer

Mr David Ross, Director, Healthcare Access

Australian Orthopaedic Association

Mr Adrian Robert Cosenza, Chief Executive Officer

Professor Stephen Ellis Graves, Director, National Joint Replacement Registry

Dr David Charles Davidson, Deputy Director, National Joint Replacement Registry

Consumers Health Forum of Australia

Ms Carol Bennett, Chief Executive Officer

Ms Karen Carey, Board Director

Johnson and Johnson Medical Pty Ltd

Mr Anthony Bishop, Area Vice President, Australia and New Zealand

Mr Nicholas Campbell, Executive Director, Corporate Affairs

Ms Robyn Chu, Director, Health Outcomes

Professor Graham Isaac, Distinguished Engineering Fellow, Hips, DePuy

Therapeutic Goods Administration

Dr Rohan Hammett, National Manager

Dr Megan Keaney, Principal Medical Adviser

Department of Innovation, Industry, Science and Research

Mr Peter Chesworth, General Manager, Pharmaceuticals, Health Industries and Enabling Technologies

Department of Health and Ageing

Mr David Learmonth, Deputy Secretary

Mr Richard Bartlett, First Assistant Secretary, Medical Benefits Division

Mr Peter Woodley, Assistant Secretary, Private Health Insurance Branch, Medical Benefits Division

Dr Brian Richards, Executive Manager, Health Technology and Medical Services Group, Medical Benefits Division

APPENDIX 3

Review of Health Technology Assessment in Australia December 2009–Recommendations

- 1. That the impact of the proposed changes to the Australian Government Health Technology Assessment (HTA) system approved by the Australian Government be evaluated within three years of the Government's response to this review.**
- 2. That the rigorous consideration of evidence be consistently applied across all Australian Government HTA processes to ensure sustainability of the Australian Government's health financing arrangements.**
- 3. That the Australian Government HTA system be guided by the vision, goal, objectives and principles articulated in the *Review of Health Technology Assessment in Australia* (HTA Review) Report.**
- 4. That DoHA establish a website for Australian Government HTA processes by July 2010 which:**
 - a) describes the roles, responsibilities and relationships between the different HTA processes;
 - b) facilitates access to all related Australian Government HTA websites to ensure that policy and guidance for all Australian Government HTA processes are easily accessible; and
 - c) regularly publishes reports on agreed performance and activity data to clearly demonstrate the performance of the system and focus attention on areas requiring performance improvement.
- 5. That the procedural fairness and consistency of Australian Government HTA processes be improved by 2011, by:**
 - a) establishing independent review mechanisms and opportunities for re-submissions in a consistent manner for Australian Government HTA processes (where they are currently not available);
 - b) updating operating procedures for administering Australian Government HTA processes, including publishing specific milestones and timeframe targets for each individual HTA process;
 - c) improving public disclosure of Australian Government HTA processes, including advisory committee membership, performance and activity data, and assessment and appraisal outcomes (including the rationale for those outcomes);
 - d) establishing and publicising specified communication points with applicants throughout each process, including providing opportunities for pre-lodgement meetings; and
 - e) adopting and implementing transparent and consistent policies and procedures for the management of conflict of interest for all external parties involved in Australian Government HTA processes.

- 6. That in order to improve the efficiency of HTA, DoHA establish a single entry point (SEP) by July 2010 to receive applications for subsidy under the Medicare Benefits Schedule (MBS), Pharmaceutical Benefits Schedule (PBS) and Prostheses List. The role of the SEP will be to:**
- a) provide a single point of contact to help applicants throughout the HTA process;
 - b) determine the most appropriate advisory committee(s) to appraise the technology;
 - c) identify the most appropriate assessment pathway for an application, including maintaining and reinforcing current processes where these are the most efficient for the technologies submitted to a particular process;
 - d) conduct an initial risk and impact assessment and determine the most appropriate methodology to be used in assessing the technology;
 - e) ensure the timely assessment and appraisal of co-dependent and hybrid technologies, or technologies being assessed concurrently for both public and private reimbursement and coordinate the provision of comprehensive advice to the Minister for Health and Ageing (the Minister);
 - f) achieve synergies through sharing and sustaining HTA expertise across the advisory committee secretariats; and
 - g) develop and report on the achievement of performance targets for HTA reimbursement.
- 7. That applicants have the option of applying to different HTA processes concurrently. Finalisation of each HTA process may be subject to the completion of a critical antecedent process (such as inclusion on the Australian Register of Therapeutic Goods (ARTG) prior to MBS or Prostheses List listing). This will require procedures to be put in place by July 2010 to allow the efficient flow of information between HTA processes (including from the TGA to other HTA agencies, subject to confidentiality constraints).**
- 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.

9. That by July 2010, MSAC strengthen and streamline its operations and improve the flexibility of its regulatory processes by:

- a) providing advice to the Minister based on a critique of an applicant's comparative clinical and economic evaluations, as an alternative to the current process and in the context of agreeing specific timeframes for assessment with the applicant;
- b) ensuring that data collection requirements supporting a recommendation for interim funding for a professional service for listing on the MBS are sufficiently rigorous and reliable to provide a sound basis for a final decision on funding;
- c) ensuring that its advice to the Minister addresses all aspects of the proposed change to the MBS, especially in regard to the proposed MBS item descriptor and fee; and
- d) streamlining current processes for accessing expert advice to improve timeliness of assessment processes and set a target of all advisory panels being established within six weeks of accepting an application.

10. That in order to reduce regulatory costs:

- a) the terms of reference for the Prostheses and Devices Committee (PDC) and its subcommittees be revised by July 2010 so that it is clear that its assessments of prostheses only consider clinical effectiveness (including comparative cost and comparative safety); and
- b) channels of communication between the TGA and PDC should be formalised to ensure that any concerns the PDC encounters regarding the intrinsic safety of prostheses are immediately referred to the TGA and dealt with appropriately.

11. That the PDC be restructured by July 2010 to ensure that its membership is balanced and:

- a) includes individuals with expertise in current clinical practice, health policy and health economics;
- b) includes representation from health consumers, health service providers, and the health insurance and health technology industries; and
- c) has an independent chair.

12. That the arrangements for the Prostheses List be changed by 2011, with appropriate consultation, to:

- a) accept applications on a continuous basis, but still make the Prostheses List every six months;
- b) establish and maintain groups of products with similar clinical effectiveness;
- c) abolish the negotiation of benefits for individual listed products, and instead establish and maintain a single (benchmark) benefit for the products included in each group, with sponsors being required to accept this benefit in order to be listed;
- d) abolish the negotiation, setting or publication of maximum benefits, to eliminate the potential for gap payments for patients who have Private Health Insurance (PHI); and

- e) permit the establishment of new product groups (or sub-groups) where a sponsor establishes clear superiority of their product compared to those in an existing group.

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.

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.

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.

16. That the Australian Health Ministers' Conference be asked to consider the need for a national approach to HTA processes, including processes required to evaluate blood and blood products.

APPENDIX 4

Review to improve the transparency of the Therapeutic Goods Administration Final Report—June 2011

Executive Summary & Recommendations

The *Therapeutic Goods Act 1989* states as its principal object 'to provide for the establishment and maintenance of a national system of controls relating to the quality, safety, efficacy and timely availability of therapeutic goods' that are used in Australia or exported from Australia. This system is achieved through the operation of the Therapeutic Goods Administration (TGA), a Division of the Department of Health and Ageing.

A perception has arisen in the community that the TGA does not provide the public with sufficient information about its activities and about the therapeutic goods that it regulates. This perception led the Parliamentary Secretary for Health and Ageing, the Hon Catherine King MP, to establish a panel of consumer, health practitioners and therapeutic goods industry representatives to review and report on the transparency of the TGA.

In the performance of its task, the Panel consulted widely with persons and organisations affected by the TGA's activities. It also took into account the requirements of the Australian Government's Declaration of Open Government which determines a whole of government context directing agencies towards enhanced transparency and a consumer focus in their activities. Coincident with this, the Panel noted that action has been taken by a number of the overseas regulators that have functions equivalent with those of the TGA to increase the transparency of their activities.

In the course of the Review it became apparent to the Panel that the TGA had done much in recent years to increase knowledge by stakeholders of the role and the functions that it performs. However, it was also apparent that the expectations of the public are not being met and there is more that the TGA can do. In this Report the Panel proposes means by which the TGA can provide greater transparency in the understanding by the public of its role and functions and can better inform stakeholders on the issues that are of concern to them.

The Panel considers that it is necessary for the TGA to recognise that it serves multiple stakeholders and that it must adapt its communication strategies accordingly. Consumers and health practitioners have as much interest in therapeutic goods as the industry that produces and markets those goods. It is important that the TGA

recognise this when formulating the communications strategy that is recommended by the Panel.

The Panel considers that the TGA should adopt a pro-active stance to the many issues relating to therapeutic goods that are of concern to the public that it serves. It should move away from the conservative approach that has characterised its actions in the past and recognise that it has a duty to collaborate with stakeholders to create a culture in which the community has confidence in the therapeutic goods the TGA regulates.

The Panel recognises that the TGA provides a service to the community by the timely registration, listing and inclusion of suitable products onto the Australian Register of Therapeutic Goods (ARTG). The TGA also has an ongoing responsibility to conduct post-marketing surveillance on these products and to inform the community about new information that changes their risk-benefit ratio. Post-marketing surveillance includes monitoring the promotion of therapeutic goods and taking timely and effective action when promotion is in breach of the Therapeutic Goods Advertising Code 2007 or when self-regulation fails.

The Panel observes that, in order to maintain confidence in the regulatory system and ensure that products beneficial to the Australian community continue to be made available by sponsors, the performance of the TGA's regulatory functions must be objective, consistent and timely. It is also essential that the TGA's independence from sponsors and fairness in decision-making be reinforced by openness in its dealings.

The Panel believes that the adoption of the following recommendations will assist both the government and the TGA by increasing the community's trust in therapeutic goods regulation and by showing that it is possible to balance legislative obligations with the need to provide more and better information to the Australian community.

Recommendations

Raise Stakeholder Involvement in the TGA

Recommendation 1

The TGA establish an Australian Therapeutic Goods Advisory Council, with membership representative of major stakeholder groups, to enable more effective stakeholder input into future directions and program implementation. The Council will have an oversight role in the implementation, ongoing monitoring, and evaluation of the recommendations of this review.

Recommendation 2

The TGA define, adopt and publish consultation principles to guide regulatory transparency and accountability.

Recommendation 3

The TGA develop and implement a comprehensive communication strategy to inform and educate. A dedicated communications team should be established within TGA to implement that strategy.

Recommendation 4

The TGA work transparently with other key providers of information to enhance the information available to the public (community and stakeholders), consistent with the principles of the quality use of medicines.

Recommendation 5

The TGA develop a plan to ensure information on the key public access portal, the TGA website, is current, accurate, relevant, timely and up to date, and meets the needs of its audiences

Recommendation 6

The TGA provide user-friendly information on the risk based framework under which it operates, including detailed explanations of how this operates for different classes of therapeutic goods. As a priority, the differences between registered and listed therapeutic goods, and their processes of evaluation, should be explained.

Recommendation 7

The TGA implement mechanisms to educate and inform the public that listed medicines are not evaluated for effectiveness by the TGA prior to market.

Recommendation 8

The TGA provide clear information on the role of its statutory advisory committees, and adopt a consistent and transparent approach to the publication of information from those committees.

Recommendation 9

The TGA improve access and quality of information on the processes for regulation of advertising of therapeutic goods, including the complaint process and the outcomes of complaints.

Recommendation 10

The TGA, in conjunction with key stakeholders, develop and publish agreed Key Performance Indicators to provide quantitative and qualitative information on the TGA's organisational effectiveness and operational efficiency. This may be achieved in conjunction with the proposed Australian Therapeutic Goods Advisory Council.

Market Authorisation Process

Recommendation 11

The TGA develop and publish a policy on the disclosure of commercially confidential information, noting significant issues for each therapeutic product type. The policy should take into account the practices followed by comparable international regulators.

Recommendation 12

The TGA explore mechanisms for providing explanations on its various regulatory processes, and adopt publication principles on the outcomes of application assessments using as an exemplar the Australian Public Assessment Reports (AusPAR).

Recommendation 13

The TGA assess and report on the feasibility of developing an on-line system for the submission and tracking of all applications for assessment, which enables the sponsor to ascertain the progress of an application.

Recommendation 14

The TGA work with stakeholders to improve labelling and packaging requirements to educate and assist consumers and health practitioners to make informed decisions about the quality use of therapeutic goods.

Post Market (Monitoring & Compliance)

Recommendation 15

The TGA conduct, and report on, a feasibility study into the development of an early post marketing risk communication scheme for therapeutic goods, with consideration of international models.

Recommendation 16

The TGA actively promote the distribution of therapeutic goods safety information, and examine mechanisms for improving the timely communication of alerts and recalls, to health practitioners and to consumers.

Recommendation 17

The TGA explore mechanisms to maintain the currency of Consumer Medicines Information (CMI) and Approved Product Information (PI).

Recommendation 18

The TGA progressively develop and implement a system to publish the outcomes of investigations and compliance actions taken.

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.

APPENDIX 5

ASR timelines

Department of Health and Ageing Answer to Question on Notice

Early 2004	TGA approves ASR Resurfacing
Early 2005	TGA approves ASR XL
Oct 2006	2006 National Joint Replacement Registry (NJRR) annual report released: Mentions ASR Resurfacing but the difference in revision rates is noted in the report as not significant
June 2007	Orthopaedic Expert Working Group (OEWG) established to review NJRR data
Aug 2007	OEWG meets for the first time – ASR NOT discussed because it had not been identified as an implant of concern at that stage
Sept 2007	J&J discuss ASR Resurfacing revision rates with TGA J&J agreed to restrict supply to surgeons who undergo further training, and to issue a Safety Notice to all implanting surgeons advising them of the revision rates and J&J intention to supply only to specially trained surgeons
Oct 2007	2007 NJRR annual report released Identifies ASR Resurfacing as an implant that is experiencing higher than expected revision rates
Oct 2007	TGA notifies other regulatory agencies TGA notifies other regulatory agencies of J&J's intended actions regarding ASR Resurfacing in the Australian market through a process called National Competent Authority Reporting (NCAR)
May 2008	J&J provides status report J&J provides update on status of actions agreed in Sept 2007. Safety Notice sent – as a result of supply being conditional on re-training, 15 surgeons had abandoned the implant, another 16 said that they would continue to use it. Overall use dropped dramatically
May 2008	TGA refers ASR Resurfacing issue to OEWG at its May meeting ASR Resurfacing, including J&J/TGA actions taken in Sept 2007 referred to OEWG for comment and/or endorsement. OEWG endorses actions taken and recommends that monitoring of the implant continue
June 2008	OEWG meets once again No change to position regarding ASR Resurfacing
Sept 2008	Internal review of TGA process begins Following concerns over procedural fairness afforded by the TGA process being used to investigate implants identified as having higher than expected revision rates by the NJRR, TGA initiates an internal review of that process

Oct 2008	2008 NJRR annual report released Re-identifies ASR Resurfacing as having high revision rates. Identifies that the ASR XL acetabular cup has higher than expected revision rates <u>ONLY</u> when used in conjunction with the Corail femoral stem component
July 2009	Internal review of TGA process ends The review found that the process is fair and appropriate and was resumed – Implants that were identified for the first time in the 2008 NJRR annual report were processed in 2009
Aug 2009	Out of Session Briefing provided to OEWG The briefing provided the OEWG a status on the process of consideration of implants identified as having high revision rates in the NJRR reports – with a view to restarting the process
Oct 2009	2009 NJRR annual report released Re-identifies ASR Resurfacing as having high revision rates. Identifies that the ASR XL acetabular has higher than expected revision regardless of which femoral stem component is used
Oct 2009	TGA and J&J have further discussions about ASR TGA indicated that in light of the information in the 2009 NJRR report, J&J would be expected to justify on-going supply of the implant. J&J indicated that ASR sales had reduced dramatically, and that there was on-going concern about the implant. This was making the implant unviable so J&J would be withdrawing the implant from the Australian Market however requests that some components be allowed to remain for partial revision purposes
Dec 2009	OEWG meeting includes discussion on ASR XL implant OEWG endorses the actions taken by J&J and the TGA also endorses the request to allow some components to remain available
Dec 2009	ASR Resurfacing and ASR XL removed from the market
Feb 2010	6 th Meeting of OEWG ASR issue had already been dealt with – no discussion on ASR
June 2010	7 th Meeting of OEWG Discussion about Metal on Metal (MoM) hip implants like the ASR. OEWG advised that there should not be a blanket condemnation of MoM implants – also advised against routine analysis of blood samples for Cobalt and Chromium levels as an indicator of early implant failure
Aug 2010	Worldwide recall of ASR implants
Oct 2010	2009 NJRR annual report released Re-identifies ASR Resurfacing and ASR XL as having high revision rates
Nov 2010	8 th Meeting of OEWG Action on ASR complete – the committee considered other implants
Mar 2011	9 th Meeting of OEWG Action on ASR complete – the committee considered other implants
May 2011	10 th Meeting of OEWG Further discussions on concerns regarding MoM implants. OEWG re-affirmed the recommendations provided at its 7 th meeting in June 2010
June 2011	11 th Meeting of OEWG Action on ASR complete – the committee considered other implants