



Australian Government
Department of Health and Ageing
Therapeutic Goods Administration

Regulation impact statement for reclassification of hip, knee and shoulder joint implants

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TGA Health Safety
Regulation

Historical document

About the Therapeutic Goods Administration (TGA)

- The TGA is a division of the Australian Government Department of Health and Ageing, and is responsible for regulating medicines and medical devices.
- TGA administers the *Therapeutic Goods Act 1989* (the Act), applying a risk management approach designed to ensure therapeutic goods supplied in Australia meet acceptable standards of quality, safety and efficacy (performance), when necessary.
- The work of the TGA is based on applying scientific and clinical expertise to decision-making, to ensure that the benefits to consumers outweigh any risks associated with the use of medicines and medical devices.
- The TGA relies on the public, healthcare professionals and industry to report problems with medicines or medical devices. TGA investigates reports received by it to determine any necessary regulatory action.
- To report a problem with a medicine or medical device, please see the information on the TGA website.

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Contents

Introduction	6
Background	6
Current regulatory requirements for Medical Devices	6
Medical Device Classifications	7
Premarket review by the TGA before inclusion in the ARTG	8
The Medical Devices Sector in Australia	9
HTA Review	10
The Problem	11
European Response	12
HTA Review	13
Response to HTA Review Recommendation 8C	13
Senate Inquiry into the Regulatory Standards for the Approval of Medical Devices	14
Medical Device Reform announcement of September 2011	15
The desired objective	15
Options to achieve objective	16
Consideration of the Options	16
Option 1: Take no immediate action	16
Option 2: Reclassify from Class IIb to Class III either partial hip, knee and shoulder joint implants or total hip, knee and shoulder joint implants but not both	16
Option 3: Reclassify total and partial hip, knee and shoulder implants from Class IIb to Class III	18
Impact Analysis	19
Consumers	19
Medical Device Industry	20
Government Agencies	22
Potential costs and benefits	22
Application Fees Costs	23

Annual Charge Costs	23
Net Cost to Industry	24
Benefits	25
Distribution of costs and benefits	25
Identification of the data sources and assumptions used	25
Consultation	26
HTA Review	26
TGA Discussion Paper	26
Senate Inquiry	27
Further Consultation	27
Summary	27
Conclusion	28
Implementation and review	29
Appendix A: Acronyms	31
Appendix B: Glossary	33

Introduction

This Regulation Impact Statement (RIS) has been prepared by the Therapeutic Goods Administration (TGA). The purpose of this RIS is to assist Australian Government decision making on how to address concerns that the “safety and performance of some joint replacement prostheses are not adequately evaluated prior to inclusion on the Australian Register of Therapeutic Goods (ARTG) (resulting in risks to consumers and cost to payers).”¹ This concern was raised in the broader context of the Review of Health Technology Assessment in Australia (HTA Review) that reported in December 2009 and the Senate Inquiry into the regulatory standards for the approval of medical devices which reported in November 2011.

While the HTA Review more generally raised issues around the need for increased rigour in higher risk medical devices, the scope of this RIS is limited deliberately to the issues identified around hip, knee and shoulder joint implants.

In brief, this statement has been structured to provide background and context on the current medical device regulatory environment and the medical devices sector in Australia. This is followed by the identification of the problem of safety and performance of some joint replacement prostheses. The RIS then canvasses options to address the safety concerns through the reclassification of some joint replacement implants from Class IIb to Class III.

Three options to address the problem are examined in the RIS including their anticipated impact on consumers, the medical devices industry and government agencies. Consideration of costs and benefits of the various options are also discussed.

The RIS summarises the community and industry concerns in relation to the current level of regulatory assessment of hip, knee and shoulder joint implants as medical devices as raised in the consultation that was undertaken as part of the HTA Review. The RIS concludes with a recommendation (including an outline of proposed implementation) for Government consideration.

Background

Current regulatory requirements for medical devices

The TGA administers the following legislation in order to regulate medical devices:

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

¹ Australian Government, Dept of Health and Ageing, *Review of Health Technology Assessment in Australia*, December 2009, Commonwealth of Australia, p15.

The TGA regulates the quality, safety and performance of medical devices supplied in Australia, using a regulatory framework modelled on principles established by the Global Harmonization Task Force (GHTF) and is aligned with the European Union (EU) medical device framework. The framework allows inclusion of medical devices in the ARTG, that in turn allows these to be legally supplied in, or exported from Australia.

The fundamental components of the framework are:

- a set of Essential Principles (see Glossary) setting out requirements for safety and performance of a medical device;
- a classification system for medical devices based on the risk the device presents to the patient, the user and the environment;
- a set of Conformity Assessment Procedures (see Glossary), used by the manufacturer of a medical device, to demonstrate the device is in compliance with the Essential Principles of safety and performance;
- assessment of the application of those Conformity Assessment Procedures by a review organisation, such as a designated assessment body or regulatory authority, including initial and on-going surveillance audits of the manufacturer's quality management system (see Glossary); and
- inclusion as a 'kind of medical device' (see Glossary) in the ARTG.

In order for the TGA to maintain public confidence in the use of medical devices on the Australian market, the TGA may assess medical devices:

- before a device is able to be supplied to the market in Australia (premarket regulation), and/or
- while a medical device is available on the market (postmarket regulation).

Medical device classifications

The risk management approach is linked to the classification system for medical devices. Manufacturers or sponsors classify the medical device according to its intended purpose and the degree of risk involved for the patient, the user and the environment. The device classifications are determined using a set of rules contained in the Regulations that take into account the degree of invasiveness in the human body, the duration and location of use and whether the device relies on a source of energy other than the body or gravity. There are two sets of classification rules; one based on the above and the other is for In-Vitro Diagnostic devices (IVDs). The risk classification table relevant to hip, knee and shoulder joint implants is shown below, with the IVD table shown in the Glossary.

Table 1 - Medical devices (other than IVD medical devices)

CLASS	RISK	EXAMPLES
Class I	Low	Surgical retractors, tongue depressors
Class I – supplied sterile Class I – incorporating a measuring function	Low-medium	Sterile bandages, drainage bags
Class IIa		Hypodermic needles, suction unit
Class IIb	Medium-high	Lung ventilator, hip, knee and shoulder joint implants
Class III	High	Heart valves
AIMD (Active Implantable Medical Devices)		Implantable defibrillator

Premarket review by the TGA before inclusion in the ARTG

The level of regulation incrementally increases as the level of risk increases. Based on the medical device classification system (other than IVD medical devices) the levels of premarket assessment of medical devices can be summarised as follows:

Class I medical devices

Most Class I medical devices validly lodged under the TGA's electronic lodgement system will result in an automatic entry to the ARTG. There is no assessment of the application. However, applicants must certify as to a range of matters in relation to the device. The automatic entry process is monitored by a random selection process, with 10% of applications selected for review at the postmarket stage. There is also provision for targeted review, where the TGA considers there is reason for such a review.

Class I measuring, Class I sterile, Class IIa and Class IIb medical devices

Before making an application to include a Class I measuring, Class I sterile, Class IIa or IIb medical device on the ARTG, the Manufacturer's Evidence (see Glossary) must have been accepted by the TGA. The details of the device application will be compared with the details on the Manufacturer's Evidence, to ensure that the device is appropriately covered by conformity assessment certification and an administrative review of details of the application will be conducted, such as appropriate classification and intended purpose. No further assessment is conducted unless it is an application that is required to be audited under the Regulations or the application is selected for a non-mandatory application audit.

Class III and Active Implantable Medical Devices (AIMD)

Applications for Class III and AIMD devices are subject to acceptance of Manufacturer's Evidence. They will generally undergo a Level 2 application audit assessment (see Glossary).

The medical devices sector in Australia

Medical devices supplied in Australia range from bandages that are put on a scratch, to high risk products such as pacemakers that are implanted in the body. Other examples of medical devices include:

- orthopaedic joint implants, such as hip, knee and shoulder joint replacements;
- blood pressure monitors;
- urinary catheters;
- blood bags;
- condoms;
- device disinfectants, such as autoclaves and disinfectant solutions;
- lubricating eyedrops;
- medical imaging equipment, such as x-ray film, MRI machines, and imaging software;
- dental products, such as drills and fillings; and
- syringes and needles.

As at October 2010, there were only two manufacturers of major joint implants operating in Australia, with both of them having a strong export market, including to the EU.²

The Australian medical device industry is comprised of a diverse range of manufacturers and suppliers, from small family operated businesses to large multi-national companies. The Australian medical device industry:

- includes over 450 medical technology companies in Australia;
- employs over 17,500 people;
- is mainly located in NSW (54%), followed by VIC (24%), QLD (11%) and WA (7%); and
- has a total annual revenue in the order of \$7.6 billion³.

In its submission to the HTA Review, the Medical Technology Association of Australia (MTAA), the peak industry group, noted that:

² Australian Government, Dept of Health and Ageing, TGA, *Reforms in the Medical Devices Regulatory Framework – Discussion Paper*, 25 October 2010, p30 at <<http://www.tga.gov.au/newsroom/consult-devices-reforms-101130.htm>>.

³ All figures obtained from the Medical Technology Association of Australia (MTAA) website on 1 July 2011 <<http://www.mtaa.org.au/pages/page3.asp>>.

The Australian market for medical technology is approximately 2% of the global market. Because of its small size, this means that companies developing innovative technologies will always need to consider the potential return on investment in making a decision as to whether to bring a technology into Australia or invest in development of a new technology in Australia.

As at July 2011 there were approximately 36,000 entries for medical devices in the ARTG. A single entry in the ARTG may cover multiple 'kinds' of medical devices that have the same basic characteristics (see Glossary), so it is estimated that the 36,000 ARTG entries for medical devices represents a total of around 1 million distinct medical devices. Most (around 90%) of the medical devices supplied in Australia are manufactured overseas.

In the 2010-11 financial year, the TGA received approximately 6,000 new applications to include medical devices in the ARTG. Of these, 50% were for Class I medical devices (the lowest risk medical devices that undergo no TGA pre market assessment), 24% were for Class IIa, 14% were for Class IIb medical devices and 7% were for Class III medical devices.

HTA review

On 18 December 2008, the then Minister for Health and Ageing, the Hon Nicola Roxon MP, and the then Minister for Finance and Deregulation, the Hon Lindsay Tanner MP announced the HTA Review, including that it would be conducted as a Better Regulation Ministerial Partnership. The HTA Review was undertaken by the Department of Health and Ageing (DoHA) in consultation with the Department of Finance and Deregulation (DoFD). The HTA Review reported to Ministers Roxon and Tanner in December 2009.

The HTA Review report lists a key objective of the review was to address the regulatory burden on business that results from HTA processes, to ensure processes are efficient, measured and proportionate. TGA's regulation of therapeutic goods for market entry was identified as a particular focus of the HTA Review⁴. The HTA Review was required to canvass opportunities for reform within existing funding levels and consistent with Government policy objectives.

With regard to medical devices, the HTA Review report identified that "the market entry regulatory regime is crucial for ensuring the timely entry of safe technology into use by Australians" because over 90% of medical devices will never be submitted for reimbursement.⁵ While the HTA Review report acknowledged that Australia incorporates the principles of the GHTF that aims to remove unnecessary regulatory duplication, the report recommended three areas of change for medical device regulation. The three areas of change were articulated in the report as Recommendation 8 and states that the 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 ARTG and marketing in Australia;
- b. respond to the issues raised in consultations regarding third party conformity assessments by July 2010, with a view to implementing changes agreed by government by 2011;

⁴ Australian Government, Dept of Health and Ageing, *Review of Health Technology Assessment in Australia*, December 2009, Commonwealth of Australia, p5.

⁵ Australian Government, Dept of Health and Ageing, *Review of Health Technology Assessment in Australia*, December 2009, Commonwealth of Australia, p14.

- 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 in the ARTG and to provide a sound evidence basis for Commonwealth HTA processes; and
- d. develop protocols by July 2010 for sharing information with other HTA agencies through the Single Entry Point (subject to commercial-in-confidence constraints) on the outcomes of its safety assessments.”⁶

On 27 February 2010, the then Minister for Health and Ageing and the then Minister for Finance and Deregulation released the report of the HTA Review and announced the Government’s acceptance of 13 of the 16 HTA Review recommendations including acceptance of Recommendation 8.

The full report is at:

[http://www.health.gov.au/internet/main/publishing.nsf/Content/00E847C9D69395B9CA25768F007F589A/\\$File/hta-review-report.pdf](http://www.health.gov.au/internet/main/publishing.nsf/Content/00E847C9D69395B9CA25768F007F589A/$File/hta-review-report.pdf)

The problem

The community is seeking greater assurance that the safety and performance of hip, knee and shoulder joint implants has been adequately demonstrated before implantation. Joint replacement is a commonly performed surgical procedure and, in most instances, is highly successful in alleviating pain and disability. The National Joint Replacement Registry (NJRR) (see Glossary) identifies the rates of joint replacement surgery as increasing with the number of hip and knee replacement procedures having increased by 32.4% and 54.9% respectively since 2003.⁷ The NJRR anticipates that this rate of increase is likely to continue for the foreseeable future.

The success of joint replacement surgery can depend on many factors such as age, gender and diagnosis of patients, the type of prosthesis and surgical techniques involved. Another factor identified by the NJRR is the rapid rate of change in medical technology resulting in the use of new types of prostheses and surgical techniques, where for many the outcome remains uncertain.⁸

The need for greater assurance in the safety and performance of hip, knee and shoulder joint implants was identified in Europe in 2005. Concerns identified that there needed to be a focus on safety and performance of hip, knee and shoulder joint implants over other total joint replacements because of the complexity in attempting to restore function to these weight bearing joints using intricate implants.⁹ Some of the concerns identified in Europe about these joint implants included:

- complexity of the functions of the joint functions to be restored, and the consequent increased risk of failure due to the device itself;
- these joints are weight bearing and extremely sophisticated implants for which the risk of revision surgery is significantly greater than for other joints;

⁶ Australian Government, Dept of Health and Ageing, *Review of Health Technology Assessment in Australia*, December 2009, Commonwealth of Australia, p82.

⁷ Australian Orthopaedic Association, National Joint Registry. *Annual Report*, Adelaide: AOA; 2011, p5.

⁸ Australian Orthopaedic Association, National Joint Registry. *Annual Report*, Adelaide: AOA; 2011, p5.

⁹ The concerns enunciated by both the United Kingdom and France are incorporated in the opening text of the European Commission Directive 2005/50/EEC on the re-classification of hip, knee and shoulder joint replacements in the framework of Council Directive 93/42/EEC on medical devices. See <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2005:210:0041:0043:EN:PDF>

- shoulder implants are a more recent introduction, subject to similar dynamic forces and their possible replacement is, in principle, connected with serious medical problems;
- hip, knee and shoulder replacement surgery is increasingly being undertaken on younger patients with a consequently higher life expectancy. This has resulted in the need to reduce the risk associated with revision surgery by ensuring such implants function properly over the life expectancy of the patients;
- specific, long term clinical data was generally not always available before these devices were placed on the market; and
- where changes to devices were incremental and considered 'minor' by the manufacturer, there were a number of instances where device performance suffered as a result of these minor changes.¹⁰

Therefore, it is possible some devices are marketed prior to compilation of evidence to support long term performance and may subsequently be withdrawn when postmarket evidence suggests higher revision rates than for similar devices.¹¹ NJRR data has shown that there appears to be a higher than average revision rate for some orthopaedic joint replacement implants than others, which created a level of concern.

European response

In 2005, the European Commission issued Directive 2005/50/EEC amending the classification of knee, hip and shoulder joint replacement implants from Class IIb to Class III medical devices. Commission Directive 2005/50/EC states:

Hip, knee and shoulder replacements shall be reclassified as medical devices falling within Class III.

Hip, knee and shoulder replacement means an implantable component part of a total joint replacement system which is intended to provide a function similar to that of either a natural hip joint, a natural knee joint, or a natural shoulder joint.

Ancillary components (screws, wedges, plates and instruments) are excluded from this definition.¹²

¹⁰ The concerns enunciated by both the United Kingdom and France are incorporated in the opening text of the European Commission Directive 2005/50/EEC on the re-classification of hip, knee and shoulder joint replacements in the framework of Council Directive 93/42/EEC on medical devices. See <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2005:210:0041:0043:EN:PDF>

¹¹ Australian Government, Dept of Health and Ageing, TGA, *A Proposal for the Re-classification of Joint Replacement Implants – Consultation Paper, October 2009*, p3 at <http://www.tga.gov.au/pdf/consult/consult-devices-joint-replacements-091023.pdf>.

¹² Australian Government, Dept of Health and Ageing, *Reforms in the Medical Devices Regulatory Framework – Discussion Paper, 25 October 2010*, p14.

HTA review

Concerns around the safety and performance of hip, knee and shoulder joint implants surfaced as a priority issue in the HTA Review report.¹³ This is despite the fact that Recommendation 8 in general, and Recommendation 8c in particular, is couched in broad terms to encompass multiple reform issues to TGA medical device processes.

The HTA Review report stated that the performance of some medical devices was not adequately demonstrated prior to supply (resulting in premature revision and subsequent risk to the patient). Specific issues identified by the HTA Review report for consideration around the level of regulation of orthopaedic implants were:

- the long-term performance reports, which suggest the need for increased premarket review;
- the need for an enhanced capacity to monitor postmarket performance of these devices;
- the benefits in aligning Australian requirements with international standards, especially as approximately 90 per cent of devices used in Australia are imported;
- the importance of balancing timely access to innovative therapies with appropriate regulatory oversight;
- the costs of regulation and the potential for this to result in a reduction in the numbers of joint implants available on the market; and
- potential risks associated with joint implants that are unacceptable in Europe being supplied in Australia as a result of the classification change in Europe from Class IIb to Class III.¹⁴

The HTA Review report acknowledges that the TGA was consulting on a proposal to reclassify the hip, knee and shoulder joint implants to a higher level of regulatory oversight. The report goes on to note that:

If implemented, this would provide for more appropriate premarket regulation for these implants while also enhancing the TGA's postmarket controls over this important and higher risk group of medical devices¹⁵.

Response to HTA review recommendation 8C

Initially the TGA sought to develop a response to broader issues raised by Recommendation 8C and released [a discussion paper](#) in November 2010 that included the proposal to reclassify joint replacement implants as part of a suite of proposals. The discussion paper is at:

<http://www.tga.gov.au/newsroom/consult-devices-reforms-101130.htm>

The TGA invited submissions from all interested parties. In February 2011 an [overview of the 77 submissions received](#) was made available at:

¹³ Australian Government, Dept of Health and Ageing, *Review of Health Technology Assessment in Australia*, December 2009, Commonwealth of Australia, p15.

¹⁴ Australian Government, Dept of Health and Ageing, *Review of Health Technology Assessment in Australia*, December 2009, Commonwealth of Australia, p82.

¹⁵ Australian Government, Dept of Health and Ageing, *Review of Health Technology Assessment in Australia*, December 2009, Commonwealth of Australia, p15.

<http://www.tga.gov.au/newsroom/consult-devices-reforms-101130-overview.htm>

Those submissions that commented on the joint reclassification proposal were not universally positive, but the majority either supported the proposal or signalled acceptance. From industry submissions there was support for reclassification of total joint implants but there were mixed views about reclassification of partial joint implants. See Section 8 for further detail.

In June 2011, the Senate commenced an Inquiry into the Regulatory Standards for the Approval of Medical Devices (the Senate Inquiry).

Senate inquiry into the regulatory standards for the approval of medical devices

While the Senate Inquiry was in part in response to increased concerns regarding joint implant performance and safety, the terms of reference had a broader scope to review medical device regulation. The Terms of Reference for the Senate Inquiry were:

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.¹⁶

The Senate Inquiry considered the issues around the safety and performance of joint implants as part of the Senate Inquiry's review of the TGA role. The Senate Inquiry considered the TGA's proposal arising from the HTA review that there should be a reclassification of hip, knee and shoulder joint replacement implants from Class IIb to Class III.

¹⁶ The Senate, Community Affairs References Committee, *The regulatory standards for the approval of medical devices in Australia*, November 2011, Commonwealth of Australia, p1.

The Senate Inquiry reported on 22 November 2011 and the Government is still considering a formal response to the recommendations of that report. It is expected that Government will release a formal response to the Inquiry report in the first half of 2012.

Medical device reform announcement of September 2011

On 23 September 2011, the Government announced it was taking a stepped process to the development of the following reform proposals that respond to Recommendation 8c of the HTA Review. The proposals were released on the TGA website and are available at:

<http://www.tga.gov.au/newsroom/consult-devices-reforms-110923.htm>

The four proposals identified were:

- Proposal 1: Reclassification of joint replacement implants
- Proposal 2: Amendments to regulatory provisions relating to third party assessment bodies and implantable medical devices
- Proposal 3(i): Amend the way in which a kind of medical device is included in the ARTG
- Proposal 3(ii): Enhance the ability to identify devices that have been approved by the TGA for supply in Australia
- Proposal 4: Publication of device product information on the TGA website.

Since that announcement, the TGA has been working on determining the feasibility of proceeding with these proposals including the development of possible implementation strategies.

The current RIS is limited to consideration of Proposal 1 outlined above.

The desired objective

The desired objective is to address concerns that the safety and performance of some joint implants require increased scrutiny prior to inclusion in the ARTG. This objective has to be met in an environment of global harmonisation for device regulation and the reality that the Australian market for medical technology holds only a 2% share of the global market.

Options to achieve objective

Three options have been considered to address the concerns that increased scrutiny of joint implants be required prior to inclusion in the ARTG. The options involve the risk management approach outlined in Table 1 and associated text. These options are to:

1. Take no action on the single issue of joint implant reclassification immediately.
2. Reclassify either partial hip, knee and shoulder joint implants or total hip, knee and shoulder joint implants but not both.
3. Reclassify total and partial hip, knee and shoulder joint implants.

Consideration of the options

Option 1: Take no immediate action

The TGA has been developing the issue of reclassifying hip, knee and shoulder joint implants in the context of a broader package aimed at addressing the wider issue of increasing regulatory rigour for higher risk medical devices. It could be argued that the issue of reclassifying joint implants would be better timed if it were implemented as part of a more developed package of medical device reforms and therefore no immediate action should be taken on this issue.

Consultation on the broader TGA package was undertaken in December 2010. Feedback from the different groups of stakeholders was conflicting regarding the integrated package to increase regulatory rigour for high risk medical devices. On the other hand, the issue to reclassify the hip, knee and shoulder implants from Class IIb to Class III which was discussed as part of the broader TGA package in December 2010 elicited general support.

The need to move immediately on this issue was further underlined by the Senate Inquiry which reported in November 2011. See Section 8 for further detail. To delay implementation of this proposal until other reforms are in place would be seen as problematic, in addressing the concerns raised about the safety and performance of joint implants needing increased regulatory scrutiny before inclusion in the ARTG.

On this basis this option is not recommended.

Option 2: Reclassify from Class IIb to Class III either partial hip, knee and shoulder joint implants or total hip, knee and shoulder joint implants but not both

There is a threshold issue of whether it is meaningful to distinguish between total and partial joint replacements as this has an impact on providing regulatory options. The NJRR provides one means of distinguishing between total and partial joint replacements and uses the following definitions:

- A primary replacement is the initial replacement surgery undertaken on a hip, knee or shoulder joint and involves replacing either part (ie partial) or all (ie total) of the articular surface; and

- Revision surgeries are re-operations of previous hip, knee and shoulder replacements where one or more of the prosthetic components are replaced, removed or another component is added. Revisions include re-operations of primary partial, primary total or previous revision procedures.

The NJRR categorises hip replacement surgery into three broad categories of primary partial, primary total and revision hip replacement. The NJRR Annual Report 2011 analyses the cumulative total of 294,329 hip replacements reported from the start of data collection in 1999 up to and including 31 December 2010¹⁷ and categorises them in the following way:

Table 2 – Number of Hip Replacements

Hip Category	Number	Percentage
Primary Partial Hip	47835	16.3
Primary Total Hip	211114	71.7
Revision Hip	35380	12.0
TOTAL	294329	100.0

The NJRR Annual Report 2011 analyses the cumulative total of 333,764 knee replacements reported from the start of data collection in 1999 up to and including 31 December 2010¹⁸ and categorises them in the following way:

Table 3 – Number of Knee Replacements

Knee Category	Number	Percentage
Primary Partial Knee	36675	11.0
Primary Total Knee	269266	80.7
Revision Knee	27823	8.3
TOTAL	333764	100.0

The NJRR Annual Report 2011 categorises shoulder replacements in the same basic way as hip and knee replacements (i.e. primary partial, primary total and revision) numbers but percentages of shoulder replacement procedures are not available.

Attempting to consider the regulatory impacts on this basis is increasingly problematic because of advances in implant design and techniques that make it difficult to define clearly what constitutes a partial or total implant. Rapid advances in implant modularity means the categorisation of today will become less useful.

¹⁷ Australian Orthopaedic Association, National Joint Registry. *Annual Report*, Adelaide: AOA; 2011, p14.

¹⁸ Australian Orthopaedic Association, National Joint Registry. *Annual Report*, Adelaide: AOA; 2011, p99.

In part, this may explain why the classification change from Class IIb to Class III introduced into European legislation by Commission Directive 2005/50/EC appeared to be silent on whether partial hip, knee and shoulder implants were covered. The TGA understands that there is variation in different European jurisdictions as to whether Commission Directive 2005/50/EC has been interpreted to include both total and partial hip, knee and shoulder joint replacements. While the NJRR distinguishes and reports on different types of joint replacement surgery, it is considered that attempting to make these classifications the basis of regulatory options is problematic due to the trend of combining modular components in joint replacements making the distinction between partial and total implants increasingly difficult. The NJRR notes a further 330 new combinations of prosthetic components being recorded for hip replacements in 2010.¹⁹

Therefore regulation based on only total hip, knee and shoulder implants or only on partial hip, knee and shoulder implants is not further considered.

Option 3: Reclassify total and partial hip, knee and shoulder implants from Class IIb to Class III

Using the current medical device classification system discussed earlier, it is possible to increase scrutiny of joint implants before inclusion in the ARTG using the current medical device regulation framework. As stated earlier this additional scrutiny is designed to reduce the potential for high rates of revision procedures due to future product failure.

Class IIb medical devices such as hip, knee and shoulder joint replacements are included currently in the ARTG as a kind of a device and therefore, one ARTG entry can cover multiple specific devices. An examination of the design of a Class IIb medical device is not required under the Conformity Assessment Procedures (see Glossary). Only a sample of the individual devices covered by the ARTG entry may be examined prior to inclusion on the ARTG. In contrast, Class III devices are entered individually as specific devices on the ARTG, therefore each device is individually assessed. Class III devices must undergo an examination of the design of the device under the Conformity Assessment Procedures. In addition, where the conformity assessment of a Class III medical device is not conducted under Australian therapeutic goods legislation, the device application is subject to a Level 2 mandatory audit which allows examination of the international evidence prior to inclusion of the device in the ARTG. No mandatory audit is required for hip, knee and shoulder Class IIb joint implants.

The regulations do not currently require Class IIb hip, knee and shoulder joint implants to be selected for a mandatory application audit. If total and partial hip, knee and shoulder joint implants are reclassified as Class III medical devices they will be captured by Regulation 5.3 1(i) that prescribes the application be selected for auditing.

¹⁹ Australian Orthopaedic Association, National Joint Registry. *Annual Report*, Adelaide: AOA; 2011, p2.

The additional steps that a sponsor of a hip, knee and shoulder implant would be required to do for inclusion in the ARTG at the Class III level includes:

- Obtaining from the manufacturer:
 - an original or correctly notarised copy of the manufacturer's Australian Declaration of Conformity that reflects the class of the device as Class III;
 - copies of the latest and current conformity assessment (see Glossary) evidence for the medical device including evidence of an examination of the design of the device (i.e. design examination certification);
 - the risk management report; and
 - the clinical evaluation report.
- submit a Class III application via the TGA's eBusiness Services (eBS) webpage. The application fee to enter a Class III medical device is \$1,090.00²⁰ (whereas the Class IIb application fee is \$840.00); and
- Pay the level 2 application audit fee of \$5,840.00.

Unlike lower classifications, Class III devices are included in the ARTG as individual items and this will also allow better tracking of products supplied and allow for better use to be made of the NJRR.

Impact analysis

Key stakeholders affected by the reclassification of hip, knee and shoulder joint implants from Class IIb to Class III include consumers (i.e. persons who need joint implants and health care professionals who treat such people), the medical device industry (i.e. persons or organisations who sponsor or manufacture joint implants) and government agencies (i.e. the TGA as the regulator of medical devices and other parts of DoHA that are part of the Health Technology Assessment processes).

Consumers

Consumer concerns are at the centre of this policy issue. Both the HTA Review and the Senate Inquiry had a broader focus on whether there was a need for more general medical device reform and TGA sought to include the reclassification of hip, knee and shoulder joint implants in a package of measures in line with broader reform requirements.

However, from consultation through the HTA Review, the Senate Inquiry and undertaken by the TGA itself consumer concerns have underlined the need to increase scrutiny of hip, knee and shoulder joint implants as soon as possible. On this basis there is no significant benefit for consumers to implementing Option 1 as their ongoing concerns around safety and performance of joint implants would not be addressed until some unspecified time into the future.

²⁰ Application and Audit Fees shown above are the 2011-12 amounts.

Option 1 raises the risk that joint implants that are no longer acceptable in Europe may continue to be supplied in Australia. This could arise because the reclassification change in Europe from Class IIb to Class III has already been implemented. This is not an absolute risk as not all implants supplied in this possible circumstance would be inherently problematic but it is a potential risk. Such a potential risk would compound the level of concern consumers have already expressed on the public record.

For consumers, the benefits of reclassification by Option 3:

- would be a significant first step in addressing consumer concerns regarding improved regulatory assessment of these products. This will aid in reducing consumer perception of risk of adverse outcomes relating to these products;
- may lead to less than the current rate of revision surgery for hips of 12% and for knees of 8.3%.²¹ The NJRR notes that a small decrease in proportions of revision surgery has the potential to benefit a large number of consumers.²²
- provides reassurance to consumers that Australian requirements would be the same as international standards which is important because approximately 90 per cent of devices used in Australia are imported; and
- would reduce the possibility of joint implants that are no longer acceptable in Europe being supplied in Australia as a result of the classification change in Europe from Class IIb to Class III. While not all of these joints would be problematic the reclassification of joint implants would minimise uncertainty about them.

On the other hand there is potential for the reclassification through Option 3 to lead to a reduction in the numbers of joint implants available on the market which may reduce consumer choice. This may arise if sponsors or manufacturers of joint implants choose to withdraw products from the market due to: the increased scrutiny; a desire to rationalise product lines; or the desire to remove uneconomic products from the ARTG. While this may be a cost to consumer choice it is also possible that this could also lead to a reduction in the level of adverse events. Such a reduction would have a potential flow on in better consumer health outcomes and reduced costs for individuals.

Medical device industry

With the Australian market for medical technology only being a 2% share of the global market any analysis of impacts on the medical device industry must be considered in an international context. There are differences in regulation for joint implants with other regulators such as the USA, Canada and Japan. However, the most dominant international regulator and therefore most important for the Australian medical device industry, is the European Commission that completed the reclassification of hip, knee and shoulder joint implants from Class IIb to Class III in 2010.

²¹ The NJRR report does not identify an shoulder joint revision rate equivalent to the hip and knee rates identified above.

²² Australian Orthopaedic Association, National Joint Registry. *Lay Summary, 2011 Annual Report, Hip and Knee Replacement – Supplementary Report*, Adelaide: AOA; 2011, p1.

With the much bigger European medical device market having already undergone the reclassification for joint implants, the fact that Australia is yet to do so may create an additional regulatory burden (in terms of time and cost) for sponsors who currently need to undergo a Class IIb assessment specifically for the Australian market. This arises because their Class III EU assessment does not remove the requirement for sponsors to undergo a Class IIb assessment for the Australian market. Option 1 contributes to this risk for the medical device industry due to the small share that Australia has of the global medical device market.

On the other hand, implementing Option 1 may benefit some Australian medical device sponsors by allowing them to continue to supply joint implants in Australia that are no longer acceptable in Europe. The TGA does not consider this to be an acceptable impact for the community as it will not assist in the reduction of adverse outcomes and health costs.

The impacts for the medical device industry from implementing Option 3 are expected to be limited for the following reasons. Europe has already undergone this transition and a large proportion of manufacturers will already hold the required evidence, making Option 3 relatively easy for industry to implement. In fact, it may reduce the regulatory compliance cost as industry may achieve a consistent Class III assessment from a notified body for both the European and Australian market. The TGA will use European approvals as a component of its approval process.

If products are withdrawn from the market due to the increased scrutiny this may contribute to a reduction in the level of adverse events, as only those products not meeting the increased requirements would be impacted. A reduction in adverse outcomes would have a potential flow-on to reduced health and welfare costs and increase in productivity. It is anticipated sponsors will not seek to transition some products but this reflects that in any given period there is a degree of product cancellation that occurs irrespective of regulatory change.

A potential negative impact to the medical devices industry of implementing Option 3 is the effect this regulatory change may have on the provision of devices into the Australian market. Given Australia's small share of the global market, industry has identified that, if the regulation hurdles to enter the Australian market exceed those of other international/equivalent regulatory agencies, products may not be supplied into Australia. In addition, some devices that have not achieved the regulatory requirements of reclassification in the European market may be withdrawn from the Australian market. The TGA is unable to quantify these outcomes.

An issue for consideration is therefore how to retain hip, knee and shoulder component parts that may be required for future revision surgeries where they do not meet the requirements of Class III or sponsors do not wish to apply for reclassification. A number of options exist within the current TGA provisions, including a special access scheme, and the appropriate course of action will be explored with industry representatives on a case by case basis.

A further risk from implementing Option 3 may arise from companies taking the opportunity to rationalise product lines due to their normal business cycle and to increases in fees and charges and remove uneconomic products from the ARTG as a result of the proposal reforms. Given past experience, the TGA does not anticipate that this will occur at a significantly greater rate than the current level of product cancellation that occurs irrespective of any policy changes being implemented.

The proposed implementation strategy for Option 3 includes a two year transition period to mitigate the impact as much as possible. In addition, the TGA has created a Medical Device Reforms Reference Group which has participants from the medical device industry (as well as consumer representation). The Reference Group will be used by the TGA to continue to refine implementation strategies to minimise the impact as far as possible.

Government agencies

The TGA is responsible for regulating the quality, safety and performance of medical devices supplied in Australia and self-evidently will be impacted by the joint implant reclassification proposal. The TGA has been seeking to progress the joint implant reclassification proposal as one element of a broader suite of proposals to respond to Recommendation 8c of the HTA review. Option 3 will align the TGA with international standards for hip, knee and shoulder joint implants and would assist in maintaining public confidence in hip, knee and shoulder implants.

The implementation of Option 3 will generate additional costs for the TGA arising from the extra scrutiny and over the longer term there will be increase net revenue for the TGA. This is discussed in further detail at Section 8.

Impacts for other government agencies by the reclassification proposal are minimal.

Potential costs and benefits

Option 1 does not have immediate cost implications. Further consideration would be required once the entire regulatory reform package envisaged is developed.

Option 3 will not alter the current charging structure that the TGA applies to sponsors and manufacturers for the inclusion of goods where costs arise through two mechanisms during the transition period. Firstly costs arise directly to industry through a fee charged by the TGA to include products in the ARTG. Secondly annual costs arise for industry as the more ARTG entries a sponsor has, the greater the cost to the sponsor. Under both the current classification framework or upon reclassification, these costs are likely to flow through via the market to the final funder of the services whether that be the consumer directly or medical funding via Medicare or health insurance.

The fee model to be applied for Option 3 is that currently existing for Class III products.

As at 30 June 2011, there were 436 ARTG entries that will require reclassification under Option 3. As Class IIb entries can include several devices under one entry and Class III device ARTG entries correspond to only one device, the number of ARTG entries is expected to increase by around five times. Therefore in subsequent years, the increased number of entries in the ARTG and the higher level of payment for Class III in comparison to Class IIb will lead to increased costs on an ongoing basis.

In the following analysis fees and charges are quoted at the 2011-12 rates unless otherwise noted.

Application fees costs

Costs to industry for the transition of the current 436 ARTG entries from Class IIb to Class III will be at no cost arising from TGA processes if industry chooses to transition their entries in the first year (i.e. 1 July 2012 to 30 June 2013). This is because of the waiving of a Class III application fee of \$1,090.00 in the first year is designed to encourage early transition. If industry chooses to transition their entries in the second year (i.e. 1 July 2013 to 30 June 2014) then each application will attract a Class III application fee of \$1,090.00.

For new applications, the costs to industry are based on an estimate of approximately 200 new Class III applications²³. Expected Class III application costs to industry for 200 applications at \$1,090.00 per application is \$218,000.00. However this figure needs to be reduced by the cost industry would have paid for the estimated 40 Class IIb applications if the reclassification did not proceed. The costs of 40 Class IIb applications at \$840.00 each are \$33,600.00. This makes an estimated net cost to industry of \$184,400.00.

Annual charge costs

In addition there are ongoing annual charges for industry for their Class III hip, knee and shoulder implant entries in the ARTG. The annual charges are payable each financial year for medical devices on the ARTG for any part of the financial year. Class III annual charges will not be charged where relevant medical devices have been reclassified from Class IIb during the two-year transition period. Note that an application for reclassification to Class III does not automatically remove the relevant Class IIb entry from the ARTG. In this situation the Class IIb charges will continue to apply to relevant devices until the sponsor cancels those entries at which time Class III charges will commence.

The TGA estimates that from the third year of the implementation (i.e. 1 July 2014) there will be approximately 2,200 Class III hip, knee and shoulder implant entries. The annual charge for maintaining a Class III medical device in the ARTG is \$1,090.00 per entry. For 2,200 Class III entries the total yearly charge to industry is estimated to be \$2.4 million.

This figure needs to be adjusted by the cost industry would have paid for the 436 Class IIb annual charges if the reclassification did not proceed. The costs of 436 Class IIb annual charges at \$840.00 each are \$366,240.00. This makes an estimated net cost from ongoing annual charges to industry of \$2.03 million. There are over 600,000 hip and knee joint implant procedures done per year²⁴ making the cost of this change to industry in the order of less than \$3.40 for each surgery.

The cost of hip, knee and shoulder joint replacements varies depending on the type of replacement required and the number of components used in the surgery.

In Australia, private health insurers pay benefits for prostheses included on the Prostheses List (PL) for privately insured patients. The Prostheses List Advisory Committee (PLAC), makes recommendations to the Minister for Health, or their delegate about appropriate grouping and benefits for prostheses that are recommended for listing on the PL, this includes advice about joint replacements.

²³ The TGA estimates that currently for hip, knee and shoulder joint implants there are approximately 40 new applications each year as Class IIb medical devices. As each Class IIb entry may include around five devices it is anticipated that 40 Class IIb applications will equate to 200 Class III applications.

²⁴ Australian Orthopaedic Association, National Joint Replacement Registry, *Lay Summary 2011 Annual Report, Hip and Knee Replacement, Supplementary Report 2011*, October 2011, p3 at http://www.dmac.adelaide.edu.au/aoanjrr/documents/AnnualReports2011/Lay_Summary_2011.pdf.

Benefit amounts (known as a group benefit) are set by the grouping of prostheses with similar clinical effectiveness on the PL.

The Private Health Insurance Branch, DoHA has provided examples of group benefits applied for three key components of hip joint replacements including:

- the femoral (or “thigh bone”) components of a hip joint replacement group benefits range between \$1,850 to \$6,900;
- the ball component (head of the femur or “thigh bone”) group benefits range between \$800 to \$4,600; and
- the acetabular component (the cup that fits into the pelvis) group benefits range between \$750 and \$7,000.

The total cost for joint replacement surgery is dependent on the combination of different components required. This cost for implants is paid by the person receiving the joint replacement through payment of private health insurance fees (including any excess) with the insurer being required to pay the group benefit as per the PL. However, if the sponsor of the joint replacement charges more than the group benefit amount, the person receiving the joint replacement may be liable to pay out-of-pocket expenses.²⁵

Net cost to industry

The table below provides a summary of the net cost to the medical device industry from the fees and charges imposed by the TGA in the first five years following implementation. The following figures include expected indexation for 2012-13 and beyond.²⁶

Table 4 – 5 Year projection of net costs to the medical device industry arising from Option 3

Totals	2012-13	2013-14	2014-15	2015-16	2016-17
Industry Fees/Charges ²⁷	\$929,956	\$2,672,080	\$2,836,039	\$2,911,164	\$2,989,554
TGA Costs ²⁸	\$1,033,961	\$2,454,919	\$1,674,494	\$1,719,527	\$1,766,425
Net Result (Cost to Industry)	-\$104,005	\$217,161	\$1,161,545	\$1,191,637	\$1,223,129

²⁵ The issue of whether there are out-of-pocket expenses liable should be considered by doctors when selecting the appropriate joint replacement implant. In addition, the person receiving the joint replacement implant must be provided with informed financial consent to make them aware of any out-of-pocket expenses they may incur.

²⁶ Indexation applied in Table 4 at 3.6% for 2012-13, and 3% for the remaining years.

²⁷ **Industry Fee/Charges:** The amounts referred to above are the increased fees and charges that the industry will be required to pay to the TGA. These arise as a consequence:

- of the increased number of devices that will be registered; and
- the higher risk classification of those devices.

The increased number of devices occurs through the reclassification from Class IIb to Class III, which requires that the devices are included individually rather than as a type of device. The estimate used in this model is that there will be five Class III devices for every current entry as a Class IIb kind of device.

The higher risk classification also draws a greater charge, reflective of the additional work involved in reviewing an application of a higher risk device.

Note the revenues occur at two points, firstly as application fees for processing a new application, secondly as annual fees payable to maintain inclusion on the ARTG. The full impact of the revenue changes is not apparent until the start of year three (i.e. 1 July 2014) because of the waivers during the first two years (i.e. the transition period).

²⁸ **TGA Costs:** These reflect the additional costs that the TGA will incur in assessing the potential inclusion of these devices on the ARTG or in monitoring the continued inclusion of those devices. As the devices will be classified at a higher risk level there is an increased level of assessment for initial inclusion and an expectation that greater monitoring will occur while devices remain included on the ARTG.

Benefits

The benefits of the reclassification will be that a greater level of scrutiny of these higher risk devices will be applied before they enter the Australian market, with the aim of reducing the revision rate following their implantation. Including joint replacement implants in the ARTG at the Class III level will require the unique identification of the device to be entered in the Register, enabling improved tracking between the ARTG and the NJRR. Any reduction in revision requirements will reflect improved health outcomes for the recipients and in all likelihood lead to a reduction in health costs in the longer term. It may, in some cases, also increase the productive life of recipients providing a further benefit to the Australian economy.

The implementation of Option 3 may lead to less than the current rate of revision surgery for hips of 12% and for knees of 8.3%²⁹ but the TGA is unable to quantify the benefit of such an outcome. However, it can be expected that even a small decrease in the proportions of revision surgery has the potential to benefit a large number of potential recipients of hip, knee and shoulder joint implants.³⁰

Distribution of costs and benefits

The costs of requiring additional premarket scrutiny, in the first instance, will be borne by the sponsor who brings a device into the Australian market. However, that cost may flow on to the Australian consumer in the price of the device or the broader Australian health system depending on competitive forces in the market.

The additional premarket scrutiny may reduce the number of products that are less supported by evidence of performance from entering the market. This may lead to reduced rates of revision surgery or reduction in other adverse outcomes. These health benefits will flow to Australian consumers, while any associated reduction in health costs would also flow to Australian consumers and/or the Australian health system. Note that it is not anticipated the change in Australia will of itself result in a reduction in the number of products listed, as the escalation in assessment for joint implants has already occurred in Europe.

Identification of the data sources and assumptions used

The data for identification of the number of Class IIb devices currently impacted was collected from the ARTG. However, the estimated number of additional devices to be entered in the ARTG, as a product moves from being included under a group of devices for Class IIb, to the requirement to include all products uniquely as required for Class III is less certain. Analysis conducted of additions to the ARTG and the NJRR, on which specific products are recorded, indicate the ratio between ARTG entries and NJRR entry was approximately 1 to 5. The expected outcome of five Class III entries for every current Class IIb entry has been openly discussed with the industry and industry supports this ratio as an appropriate estimate.

²⁹ The NJRR report does not identify an shoulder joint revision rate equivalent to the hip and knee rates identified above.

³⁰ Australian Orthopaedic Association, National Joint Registry. *Lay Summary, 2011 Annual Report, Hip and Knee Replacement – Supplementary Report*, Adelaide: AOA; 2011, p1.

Consultation

There are three different consultation pathways involved in the development of the joint implant reclassification proposal. Consultation on this issue has been undertaken by the TGA, as part of the HTA Review and most recently as part of the Senate Inquiry.

HTA review

A significant level of consultation was built into the HTA Review with the aim of ensuring a comprehensive, publicly accessible and transparent process to take into account all stakeholder views on the appropriateness or otherwise of the current level of regulation.³¹ The regulation of hip, knee and shoulder joint implants as Class IIb was generally agreed as inadequate and that they should be more appropriately reclassified as Class III. The proposal was strongly supported by consumers and medical associations as this would increase the level of premarket regulation of these high risk devices.

All submissions available publicly can be found at:

<http://www.health.gov.au/internet/main/publishing.nsf/Content/htareview-submissions>

As part of the HTA Review DoHA contracted the Consumers' Health Forum of Australia (CHF) to ensure comprehensive consumer input to the HTA Review with a summary report available at:

<http://www.health.gov.au/internet/main/publishing.nsf/Content/htareview-reports-chf>

TGA discussion paper

In response to the invitation from the TGA to all interested parties, 77 submissions were received with an overview of these submissions available at:

<http://www.tga.gov.au/newsroom/consult-devices-reforms-101130-overview.htm>

The majority of respondents (56) had no comment. These were largely companies that would not be affected by the joint reclassification proposal.

Of the 22 respondents who did comment, 19 either supported the proposal, or signalled acceptance; several of these had comments which are discussed below. One stated that the proposal did not affect their company, but raised the issue of contractually agreed pricing which will affect their ability to pass on costs. Two did not support the proposal.

General response from sponsors and industry organisations to the reclassification proposal for joint implants was that Australia should only consider reclassification of total implants in this reform. These responses cited that the reclassification of partial implants was not in alignment with the reclassification underway in Europe, and such reclassification would introduce a higher regulatory burden in Australia than Europe.

³¹ Australian Government, Dept of Health and Ageing, *Review of Health Technology Assessment in Australia*, December 2009, Commonwealth of Australia, p30.

The Australian Health Insurance Association recommended inclusion of an expanded scope of devices, and one (QLD Health) questioned the omission of ancillary components from the proposal. Two (MTAA supported by AdvaMed) recommended a later implementation of the requirements for partial joints.

Four submissions supported a longer transition period than the two years proposed, whereas the Australian Orthopaedic Association (AOA) recommended a shorter transition period. One submission supported the "grandfathering" of existing entries, rather than re-assessment; this was not supported by the AOA. Three submissions raised the issue of ensuring the supply of revision components for older implants.

Various issues of TGA workload, time and cost to market and details around ARTG entry were also raised in individual submissions.

Of the two submissions that did not support the proposal, one argued that postmarket surveillance was an effective measure. The other proposed that reclassification be done on a product-by-product basis, with consideration being given to the reasons for revision.

Senate inquiry

In 2011 the Senate Inquiry into The Regulatory Standards for the Approval of Medical received 34 submissions: 18 from industry and industry associations and peak bodies, three from government, two from consumer groups and 11 from affected patients and consumers. Most submissions were either critical of the current level of regulation of these devices and/or agree that the increase in premarket regulation from reclassification to Class III is appropriate. All submissions available publicly can be found at:

http://www.aph.gov.au/Parliamentary_Business/Committees/Senate_Committees?url=clac_ctte/medical_devices/submissions.htm

Further consultation

The TGA has created a Medical Device Reforms Reference Group which has representation from both the medical device industry and consumers. The Reference Group will be used by the TGA to refine implementation strategies.

Summary

While there has been extensive consultation through three different pathways there is a consistency in views regarding the joint implant reclassification proposal. The reclassification proposal, while not achieving universal support, has received majority support, including from the medical device industry that will be most directly impacted by having to implement this change. There have been a small number of submissions where individual medical device industry organisations have advocated that no reclassification action is their preferred outcome.

The extensive consultation already undertaken on this issue, along with the consistency in consultation outcomes mean that further consultation on whether to reclassify joint implants from Class IIb to Class III as part of the RIS process is not intended.

Conclusion

The RIS identifies the problem as concerns around the safety and performance of hip, knee and shoulder joint implants requiring increased scrutiny before inclusion in the ARTG. These concerns have been consistently identified as a priority issue in the HTA Review report, the Senate Inquiry and through TGA consultation. The proposed regulation change is seeking to address these concerns as a first step in a broader consideration of medical device regulation reform.

The merits of the following three options have been considered:

1. Take no action on the single issue of joint implant reclassification immediately;
2. Reclassify from Class IIb to Class III either partial hip, knee and shoulder joint implants or total hip, knee and shoulder joint implants but not both; or
3. Reclassify total and partial hip, knee and shoulder joint implants.

In addition, the impact of these options on consumers, the medical device industry and government agencies have been analysed, along with the costs and benefits. Extensive consultation with industry and other stakeholders has occurred on the proposed amendments to the regulatory model.

After these considerations, Option 3 which proposes that total and partial hip, knee and shoulder joint implants be reclassified from Class IIb to Class III is recommended as the appropriate response. Class III identifies medical devices as high risk.

This option would increase the premarket regulatory rigour of these devices. The additional scrutiny is designed to reduce the potential for high rates of revision procedures (see Glossary) related to product failure in the future.

The proposed changes provide the increased scrutiny generally sought for these products, with the accompanying increase in public health and safety. However the implementation mechanism aims to minimise the cost of the transition process. While in the longer term the fees and charges will be increased for these products, these increases reflect the level of regulation considered appropriate given the invasiveness of the product.

The TGA considers that the health and safety aspects of this proposal, which will increase the premarket rigour of evidential requirements applying to hip, shoulder and knee joints, need to be balanced with the practical realities for industry to ensure that the reclassification can be implemented successfully with uninterrupted access to these important medical devices. The TGA considers that transition time of two years achieves a good balance to address public and industry concerns.

Implementation and review

The TGA proposes to implement the reclassification of hip, knee and shoulder joint implants currently included in the Class IIb to Class III of the ARTG in the following way:

- Through an amendment to the Therapeutic Goods (Medical Devices) Regulations 2002 with a two year transition period commencing from 1 July 2012. The start date of 1 July 2012 is proposed to coincide with the start of the financial year when any adjustments of fees and charges are normally implemented, for example from indexation.
- Sponsors of existing Class IIb devices will need to submit new applications to include these devices in the ARTG as Class III devices. This will include the requirement to have appropriate Class III certification, such as European Commission (EC) certification (see Glossary). The TGA will contact affected sponsors notifying them of the new requirements.
- The transition period will continue for two years from 1 July 2012, to provide sufficient time for sponsors of products to make the appropriate reclassification applications.
- To enable uninterrupted access to these devices, the TGA will put in place transitional arrangements so that affected Class IIb devices already in the ARTG will not be selected for mandatory application audits when an application is made to enter these devices in the ARTG as Class III devices. Instead the TGA will review the certification information provided by the sponsor.³²
- The TGA will waive application fees for those devices already in the ARTG that are reclassified during the first year of the transition period. Joints that are reclassified in the second year of the transition period will not receive any fee concessions.
- It is expected that TGA will, as far as possible, identify and write to those affected sponsors approximately 6 months prior to the cessation of the transition period.
- If a valid application is not received by the end of the two year transition period, the TGA will cancel all remaining affected Class IIb devices that should have been entered as Class III devices from the ARTG. The sponsor would then need to submit a new Class III application that would undergo the usual evaluation procedures.
- The reclassification will be fully operational at the cessation of the two year transition period.
- All new applications for hip, knee and shoulder joint implants as Class III devices, (i.e. for devices that are not transitioning as described above), will undergo an application audit. As with any new application for inclusion in the ARTG, these products will not be able to be supplied until such assessment has been completed by the TGA and the device is included in the ARTG.
- Review of the impact of these changes will be included in the broader post implementation review of the HTA Review that is proposed to commence in 2013.

³² Applications to include certain medical devices in the ARTG must be selected for an application audit - this includes Class III medical devices that have not been assessed under the European Commission Mutual Recognition Agreement or the European Free Trade Association Mutual Recognition Agreement.

- Review of the cost model for medical devices will be included in the development of a revised Cost Recovery Impact Statement to be developed during 2012 and to be incorporated into the setting of fees and charges from 1 July 2013.
- Specific review of the reclassification of joint implants will be considered by the Orthopaedic Expert Working Group (OEWG) following the completion of the transition period. The OEWG 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.

Historical document

Appendix A: Acronyms

AdvaMed	Advanced Medical Technology Association
AIMD	Active Implantable Medical Devices
AOA	Australian Orthopaedic Association
ARTG	Australian Register of Therapeutic Goods
CHF	Consumers' Health Forum of Australia
DoFD	Department of Finance and Deregulation
DoHA	Department of Health and Ageing
eBS	eBusiness Services
EC	European Commission
EU	European Union
GHTF	Global Harmonization Task Force
GMDN	Global Medical Device Nomenclature
HTA Review	Review of Health Technology Assessment in Australia
ISO	International Standards Organisation
IVD	In-Vitro Diagnostic device
MRI	Magnetic resonance imaging
MTAA	Medical Technology Association of Australia
NJRR	National Joint Replacement Registry
OEWG	Orthopaedic Expert Working Group
PL	Prostheses List
PLAC	Prostheses List Advisory Committee

QLD Health	Queensland Health – State Government Department of Health
QMS	Quality Management System
RIS	Regulation Impact Statement
SEP	Single Entry Point
TGA	Therapeutic Goods Administration

Historical document

Appendix B: Glossary

Adverse Event An incident in which harm resulted to a person receiving health care. Such an incident may or may not lead to revision procedures.

Australian Register of Therapeutic Goods (ARTG) The ARTG is the register of information about therapeutic goods for human use that may be imported, supplied in or exported from Australia. All medical devices, including Class I, must be included in the ARTG before supply in Australia. There are limited exceptions to this requirement specified in the legislation.

Application audit assessments The Act enables the Regulations to prescribe certain kinds of applications that are to be selected for audit. These kinds of applications must be selected for audit by the Secretary. However, the Secretary may also select for auditing any other application under section 41FH of the Act. The TGA has established two levels of application audit, Level 1 and Level 2:

Level 1: The TGA will consider:

- a. the original or correctly notarised copy of the manufacturer's Australian Declaration of Conformity;
- b. Copy of the latest and current conformity assessment evidence for the medical device; and
- c. Information about the device, including copies of the:
 - i. Label;
 - ii. Instructions for use;
 - iii. Advertising material such as brochures, web pages and advertisements.

Level 2: The TGA will consider all of the documentation considered in a Level 1 audit. In addition, the TGA will consider:

- a. the risk management report;
- b. the clinical evaluation report;
- c. efficacy and performance data for medical devices that disinfect including those that sterilise other medical devices.

Conformity assessment Conformity assessment is the name given to the processes that are used to demonstrate that a device and manufacturing process meet specified requirements. In Australia this means that the manufacturer must be able to demonstrate that both the medical device and the manufacturing processes used to make the device conform to the requirements of the therapeutic goods legislation.

Conformity assessment is the systematic and ongoing examination of evidence and procedures to ensure that a medical device complies

with the Essential Principles. It provides objective evidence of the safety, performance, benefits and risks for a specified medical device and also enables regulatory bodies to ensure that products placed on the market conform to the applicable regulatory requirements.

The Conformity Assessment Procedures allow risk based premarket assessment for devices. All manufacturers of all medical devices are required to meet manufacturing standards and all manufacturers, except those manufacturing the lowest risk devices, are audited and are required to have their systems certified. The level of assessment is commensurate with the level and nature of the risks posed by the device to the patient, ranging from manufacturer self-assessment for low risk devices through to full TGA assessment with respect to high-risk devices.

Conformity
assessment
certificate

A certificate to demonstrate that the conformity assessment procedure has been assessed.

Essential
Principles

The Essential Principles provide the measures for safety and performance and are set out in the Regulations. For a medical device to be supplied in Australia, it must be demonstrated that the relevant Essential Principles have been met.

The Essential Principles are:

General principles that apply to all devices

1. Medical devices not to compromise health and safety
2. Design and construction of medical devices to conform to safety principles
3. Medical devices to be suitable for intended purpose
4. Long term safety
5. Medical devices not to be adversely affected by transport or storage
6. Benefits of medical devices to outweigh any side effects

Principles about design and construction that apply depending on the kind of device

7. Chemical, physical and biological properties
8. Infection and microbial contamination
9. Construction and environmental properties
10. Medical devices with a measuring function
11. Protection against radiation
12. Medical devices connected to or equipped with an energy source
13. Information to be provided with medical devices.

14. Clinical evidence

Additional essential principle for IVDs only

15. Principles applying to IVD medical devices only (this includes 7 principles relating specifically to the safety and performance of IVD medical devices).

European
Commission
Certification

A certificate of compliance for conformity assessment issued by a European Notified Body to enable a device to be included in the ARTG.

In-Vitro Diagnostic
device (IVD)

A medical device is an IVD if it is a reagent, calibrator, control material, kit, specimen receptacle, software, instrument, apparatus, equipment or system, whether used alone or in combination with other diagnostic goods for in vitro use. It must be intended by the manufacturer to be used in vitro for the examination of specimens derived from the human body, solely or principally for the purpose of giving information about a physiological or pathological state, a congenital abnormality or to determine safety and compatibility with a potential recipient, or to monitor therapeutic measures. The definition of an IVD does not encompass products that are intended for general laboratory use that are not manufactured, sold or presented for use specifically as an IVD.

Kind of medical
device

A single entry in the ARTG may cover a range of products that are of the same kind rather than individual devices. At present, medical devices (with the exception of Class III and Active Implantable Devices (AIMDs) and Class 4 IVDs and Class 4 in-house IVDs) are included as a group in the ARTG under a single entry if they: have the same sponsor; have the same manufacturer; have the same medical device classification; have the same nomenclature system code (GMDN) code.

Manufacturer

A manufacturer of a medical device is the person who is responsible for the design, production, packaging and labelling of the device before it is supplied under the person's name, whether or not it is the person, or another person acting on the person's behalf, who carries out those operations. Refer to section 41BG of the Act for remainder of definition.

Manufacturer's
evidence

This is 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 in 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.

Medical device

A medical device is:

(a) any instrument, apparatus, appliance, material or other article (whether used alone or in combination, and including the software necessary for its proper application) intended, by the person under whose name it is or is to be supplied, to be used for human beings for the purpose of one or more of the following:

diagnosis, prevention, monitoring, treatment or alleviation of disease;

diagnosis, monitoring, treatment, alleviation of or compensation for an injury or disability;

investigation, replacement or modification of the anatomy or of a physiological process;

control of conception;

and that does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but that may be assisted in its function by such means; or

(aa) any instrument, apparatus, appliance, material or other article specified under subsection (2A); or

(ab) any instrument, apparatus, appliance, material or other article that is included in a class of instruments, apparatus, appliances, materials or other articles specified under subsection (2B); or

(b) an accessory to an instrument, apparatus, appliance, material or other article covered by paragraph (a), (aa) or (ab).

Refer to section 41BD of the Act for remainder of definition.

Medical device classifications

Medical devices are classified by the manufacturer according to the intended purpose of the medical device and the degree of risk involved for the patient and user. The device classifications are determined using a set of rules contained in the Regulations that take into account the degree of invasiveness in the human body, the duration and location of use and whether the device relies on a source of energy other than the body or gravity. There are two sets of classification rules; one based on the above and the other based on whether an IVD medical device.

Medical devices (other than IVD medical devices):

CLASS	RISK	EXAMPLES
<i>Class I</i>	Low risk	Surgical retractors, tongue depressors
<i>Class I – supplied sterile</i> <i>Class I – incorporating a measuring function</i>	Low-medium risk	Sterile bandages, drainage bags
<i>Class IIa</i>		Hypodermic needles, suction unit

CLASS	RISK	EXAMPLES
<i>Class IIb</i>	Medium-high risk	Lung ventilator, hip, knee and shoulder joint implants
<i>Class III</i>	High risk	Heart valves
<i>AIMD (Active Implantable Medical Devices)</i>		Implantable defibrillator

IVD medical devices:

CLASS	RISK	EXAMPLES
<i>Class 1 IVD</i>	No public health risk or low personal risk	Enzyme immunoassay analyser. Ready to use microbiological culture media.
<i>Class 2 IVD</i>	Low public health risk or moderate personal risk	Pregnancy self-testing kit. Liver function tests.
<i>Class 3 IVD</i>	Moderate public health risk or high personal risk	Test to detect the presence or exposure to a sexually transmitted agent such as <i>C. trachomatis</i> or <i>N. gonorrhoea</i> . System for self-monitoring of blood glucose.
<i>Class 4 IVD</i>	High public health risk	Assay intended for the clinical diagnosis of infection by HIV 1 & 2. Assay intended for screening blood donations for Hepatitis C virus.

National Joint Replacement Registry (NJRR)

The NJRR is managed by the Australian Orthopaedic Association (AOA)³³. Its purpose is to define, improve and maintain the quality of care of individuals receiving joint replacement surgery. The NJRR collects data following each surgical procedure that enables outcomes to be determined on the basis of patient characteristics, prosthesis type and features, method of prosthesis fixation and surgical technique used. The principal measure of outcome is revision surgery and provides an unambiguous measure of the need for further intervention. This information is then used to inform health care professionals, governments, and consumers.

³³ From the National Joint Replacement Registry website on 6 February 2012 at <http://www.dmac.adelaide.edu.au/aoanjrr/about.jsp?section=about>

Quality Management System (QMS):	The International Standards Organisation (ISO) describes a quality management system as a set of interrelated or interacting processes and interfaces, whose purpose is to achieve defined objectives, within the constraints of established policy. The system is to direct and control a group of people and facilities, with an arrangement of responsibilities, authorities and relationships. Such controls and arrangements are necessary to ensure that the outputs of the system have a set of predetermined inherent and distinguishing features that fulfil a need or expectation that is stated generally, implied or obligatory.
Revision procedures	The need to undergo further corrective surgery.
Sponsor	<p>Under Section 7 of the Act a Sponsor, in relation to therapeutic goods, means:</p> <ol style="list-style-type: none">a. a person who exports, or arranges the exportation of, the goods from Australia; orb. a person who imports, or arranges the importation of, the goods into Australia; orc. a person who, in Australia, manufactures the goods, or arranges for another person to manufacture the goods, for supply (whether in Australia or elsewhere); but does not include a person who:d. exports, imports or manufactures the goods; ore. arranges the exportation, importation or manufacture of the goods; on behalf of another person who, at the time of the exportation, importation, manufacture or arrangements, is a resident of, or is carrying on business in, Australia.

Historical document

Therapeutic Goods Administration

PO Box 100 Woden ACT 2606 Australia
Email: info@tga.gov.au Phone: 1800 020 653 Fax: 02 6232 8605
www.tga.gov.au

Reference/Publication R12/856044