Australian Government
Department of Health and Ageing
Therapeutic Goods Administration

Regulation Impact Statement

Changes to premarket assessment requirements for medical devices

10 May 2013

TGA Health Safety Regulation

About the Therapeutic Goods Administration (TGA)

- The Therapeutic Goods Administration (TGA) is part of the Australian Government Department of Health and Ageing, and is responsible for regulating medicines and medical devices.
- The 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 <www.tga.gov.au>.

Confidentiality
All submissions received will be placed on the TGA's Internet site, unless marked confidential. Any confidential material contained within your submission should be provided under a separate cover and clearly marked "IN CONFIDENCE". Reasons for a claim to confidentiality must be included in the space provided on the TGA submission coversheet. For submission made by individuals, all personal details, other than your name, will be removed from your submission before it is published on the TGA's Internet site. In addition, a list of parties making submissions will be published. If you do not wish to be identified with your submission you must specifically request this in the space provided on the submission coversheet.

Version history

Version	Description of change	Author	Effective date
V0.1	Exposure Draft	Office of Devices Authorisation	10 May 2013

Contents

Attachments 43

Consultation

The following document is an exposure draft of a Regulation Impact Statement (RIS) on proposed changes to premarket assessment requirements for medical devices.

What is a RIS?

Regulatory impact analysis is the process of examining the likely impacts of a proposed regulation and a range of alternative options which could meet the government's policy objectives. Regulatory impact analysis seeks to achieve better regulation through sound analysis, informed decision making and transparency.

RISs are central to this process, and are documents prepared by the department, agency, statutory authority or board responsible for a regulatory proposal, following consultation with affected parties. A RIS formalises and provides evidence of the key steps taken during the development of the proposal, and includes an assessment of the costs and benefits of each option (although they are not required to directly compare options).

The RIS must be presented to decision makers so that the decision is informed by a balanced assessment of the best available information.

After a decision has been made, the RIS needs to be made public. In general terms, this means that the RIS must be posted on the central online RIS register maintained by the Office of Best Practice Regulation (OBPR). Where applicable it should be published by the agency which prepared it, and tabled in parliament with the enabling legislation (attached to the explanatory material for bills or legislative instruments).

Further information on regulatory impact analysis can be found at the OBPR website, at <http://www.finance.gov.au/obpr/about/index.html>.

Consultation on this RIS

This document is being issued as an exposure draft of the RIS which will be presented to the Parliamentary Secretary for Health and Ageing, the Hon Shayne Neumann MP, who is responsible for matters relating to the Therapeutic Goods Administration.

The document is being released for comment and feedback from all parties affected by these reforms.

While the final RIS will be edited based on feedback and input received, the intention is to maximise transparency by circulating a draft which is similar to the final document which will be provided to Government. In particular, some sections, such as the analysis of costs, require industry input to be completed, and so are expected to be edited substantially before the document is finalised. Some of these expected changes are noted by editing comments, included in **<<< purple bold text >>>**.

Submissions in response to this exposure draft RIS may address any, or all, of the proposed changes to premarket assessment of implantable medical devices or other identified issues. They may be provided as:

- general comments on the proposals and the analysis outlined in the draft document, including support or opposition to proposed changes and an assessment of how the proposed change will impact on you; and/or

- specific comments on the document, such as additional or replacement text and as suggested edits to the existing text (note that specific changes to text can be provided as tracked changes where appropriate, and a rich text format (RTF) version of this document is available on request to facilitate this).

How to respond

All submissions should be accompanied by a TGA submission cover sheet. Submissions must include full personal or organisational contact details (including address, telephone number and email).

Electronic submissions are preferred and should be emailed to devicereforms@tga.gov.au. Please include **'RIS - Changes to premarket assessment of implantable medical devices**' in the subject line of the email.

Alternatively, hard copy submissions may be mailed to:

Policy and Projects Section
Office of Devices Authorisation
Therapeutic Goods Administration
PO Box 100
WODEN ACT 2606

What will happen?

Submissions will be reviewed by the TGA and the RIS amended as appropriate. When the RIS is finalised it will be provided to Government to inform decision making on this reform proposal.

When any decision is announced the RIS will be published on the TGA website, as well as OBPR's central online RIS register. Further communication with industry on implementation and transition arrangements and guidance material may also occur.

Confidentiality

All submissions will be placed on the TGA website unless marked confidential. Any confidential material contained within your submission should be provided under a separate cover and clearly marked 'IN CONFIDENCE'. Reasons for a claim to confidentiality must be included in the space provided on the TGA submission cover sheet.

For submissions made by individuals, all personal details other than your name will be removed from your submission before it is published on the TGA's website.

In addition, a list of parties making submissions will be published. If you do not wish to be identified with your submission you must specifically request this in the space provided on the submission cover sheet.

Enquiries

Questions relating to submissions should be directed to the consultation project officer, Kate Lawrence by email to devicereforms@tga.gov.au or by telephone to 02 6232 8781.

Introduction

This Regulation Impact Statement (RIS) exposure draft examines options to reform premarket assessment requirements for medical devices, and was prepared by the Therapeutic Goods Administration (TGA).

Background

A paper, *Changes to premarket assessment requirements for medical devices*, was released by the TGA on 14 January 2013,[1] with consultation closing on 15 March 2013. That paper outlined three proposed regulatory reforms for premarket assessment of higher risk medical devices:

- Proposal A: Increased scrutiny of conformity assessment as part of mandatory application audits prior to ARTG inclusion, through:
  - Targeting of mandatory audits for a wider range of high risk medical devices (but not IVDs); and
  - Increased assessment of additional evidence of conformity (but not IVDs);
- Proposal B: Publication of medical device regulatory decisions (including IVDs); and
- Proposal C: Abolition of requirement for TGA conformity assessment for Australian manufacturers of lower Class medical devices (including IVDs).

This RIS exposure draft aims to assist in Government decision making on how to progress the proposals outlined in that paper. This is based on the feedback received as part of the consultations, and aims to achieve a balanced approach to ensure public health and safety is protected through an improved targeted approach based on risk whilst minimising duplication of effort and cost.

Overview

Regulatory issues

Under the *Therapeutic Goods Act 1989* medical devices must be included in the Australian Register of Therapeutic Goods (ARTG) prior to supply in Australia (unless exempt from that requirement). An outline of the current regulatory arrangements for medical devices is included at **Attachment A: Regulation of medical devices in Australia**.

The TGA's current regulatory framework is based on the model recommended by the Global Harmonisation Task Force (GHTF) and became fully operational in Australia in October 2007. The intent of the GHTF was to achieve international alignment of regulatory

[1] <www.tga.gov.au/newsroom/consult-medical-devices-premarket-assessment-130114.htm>

requirements for medical devices to ensure, amongst other things, that devices available to the public are of acceptable quality, safety, and perform as intended.

Conformity assessment is the key mechanism for assuring that a medical device is safe and performs as intended through meeting the Essential Principles. The requirements for conformity assessment become more stringent as the risks associated with the medical device increases.

A conformity assessment certificate is issued by a conformity assessment body (where the medical device is safe, performs as intended and is of acceptable quality). Once a conformity assessment certificate is issued, an application to include the medical device on the ARTG may be made. The TGA is generally the only conformity assessment body for the purposes of administering the medical device regulatory framework in Australia.

The degree of rigour of the assessment conducted by the TGA at the point of application for ARTG inclusion depends on the risk classification of the device and the source of the conformity assessment certification (see **Attachment A: Regulation of medical devices in Australia** for details). The TGA may approve the inclusion of a device on the ARTG based solely on the application received, or may audit the application through a desk top review of information such as the labelling, instructions for use and the clinical evidence for the device. The scope of the audit will depend largely on the issues identified by the TGA as requiring further scrutiny. In most cases, high risk devices (Class III) are subject to mandatory application audits where the conformity assessment body is a European notified body.

The TGA issues conformity assessment certification under the Australian regulatory framework. European notified bodies also issue conformity assessment certification under the European regulatory framework.[2] As medical devices are assessed based on Essential Principles relating to safety and performance (rather than a prescriptive framework), and given the similarities between the Australian and European regulatory frameworks (both being based on the GHTF model), conformity assessment certificates issued by European notified bodies are generally accepted as evidence of conformity assessment sufficient for inclusion in the ARTG.

The above practice recognises that conformity assessment is an intensive and potentially expensive process and that unnecessary duplication of this work would drive up the costs of many medical devices for consumers and create disincentives to supply products in Australia's small medical devices market (around 3 per cent of the global market).

In practice, certification issued by European notified bodies is used for more than 97 per cent of applications for inclusion of medical devices (excluding IVDs[3]) in the ARTG requiring independent conformity assessment certification. Unless the application for inclusion in the ARTG is audited, European conformity assessment certification is generally accepted, relying on the accreditation of the notified bodies by European authorities.

[2] Under the Mutual Recognition Agreement (MRA) between Australia and the European Union some European notified bodies are authorised in specified circumstances to issue conformity assessment certificates under the Australian regulatory framework, and such MRA conformity assessment certificates are treated in the same manner as TGA conformity assessment certificates.
[3] Unlike Australia, Europe does not yet have the same regulatory requirements for IVDs to align with the GHTF model. However, it is proposing to implement the GHTF model as part of its recently announced reform program.

Where an application audit is undertaken, the TGA may analyse in detail the conformity assessment procedure undertaken by the European notified body. However, the TGA may only charge a fee to undertake mandatory audits. It is unable to charge a fee for audits undertaken at its discretion.

International developments

There are some significant international developments that will impact on Australia's regulatory framework and therefore need to be considered in the context of the reforms proposals outlined in this RIS. These are discussed below.

International Medical Device Regulators' Forum (IMDRF) activities and European reforms

Australia has made a commitment to support international efforts to harmonise international regulatory requirements for medical devices both through participation in the GHTF and adoption of the GHTF recommendations in setting up its current regulatory framework. Australia is continuing this commitment as a member of the IMDRF. There are a large number of projects underway that should assist in achieving a consistent regulatory approach across jurisdictions and increase confidence in assessments conducted by conformity assessment bodies. These projects are also likely to result in further refinements to the medical devices regulatory framework in the future and may reduce costs to industry over the longer term through international consistency of approach among regulators.

A set of reforms recently announced by the European Union (EU) represent a significant international development in medical device regulation. On 26 September 2012, it announced a package of reforms to provide for more stringent regulation of medical devices with the EU. These reforms were developed, prompted in part, by the failure of the ASR hip joint replacement implant and the issues with the manufacturing of the Poly Implant Prothèse (PIP) breast implants, which in Australia led to two Senate Inquiries in 2011 and 2012 respectively.

Key elements include enhanced supervision of notified bodies by European national authorities, greater postmarket vigilance, more member state market surveillance, unannounced notified body audits and increased product testing. Given the reliance by Australia on conformity assessment certification issued by European notified bodies these changes are of significant interest. It will take a number of years before the details and full scope of changes will be confirmed. A summary of the EU issues and proposed changes is included at **Attachment B: Proposed changes to European Union Medical Devices Directive.**

Mutual Recognition Agreement (MRA) with the EU and confidence building

Australia has an MRA with the EU for conformity assessment processes which allows the TGA to issue conformity assessment certificates under European legislation, and European notified bodies to issue conformity assessment certificates under Australian legislation.

Changes to the provisions of the MRA came into force on 1 January 2013 and specify that MRA certificates will no longer be accepted for Active Implantable Medical Devices (AIMD) and Class III medical devices. MRA certificates could be accepted again after confidence building has occurred to ensure that appropriate assessment of medical devices has been conducted by conformity assessment bodies (either TGA or the European notified body). Confidence building discussions under the MRA have commenced with a view to progressing these activities over 2013 and 2014.

Australian New Zealand Therapeutic Products Agency (ANZTPA)

In June 2011 the Australian and New Zealand Governments announced their agreement to proceed with the establishment of a joint scheme for regulation of therapeutic products, including medical devices. The new joint agency, ANZTPA, is expected to be operational by 2016. Given the timeframe, it is likely that any further reforms will need to be revisited as part of the shift to the joint regulatory arrangements. New Zealand's current medical device regulation is focused primarily on postmarket surveillance. This may make further increases in premarket scrutiny, including transitional arrangements, more difficult for New Zealand sponsors and manufacturers.

Problem

The current regulatory framework for medical devices in Australia has been in place since 2002. The current framework takes into account the inherent differences between medical devices and medicines. This allows a more appropriate risk-based framework able to accommodate the rapid and ongoing changes in medical device technology while reducing costs and supporting timely access.

Over time consistent concerns have arisen about certain elements of the regulatory framework. In recent years these concerns have been reflected in several reports and inquiries. A summary of the recommendations from previous report and consultations is included at **Attachment C: Previous reports and consultations**. Some of these concerns relate to:

- the need for an increased level of premarket scrutiny for higher risk implantable medical devices prior to approval;
- transparency of decision making; and
- third party conformity assessment, particularly for Australian manufacturers.

While these concerns have existed for some time (particularly the need for increased premarket scrutiny), they were brought to prominence by recent issues with the ASR hip joint replacement implants and PIP breast implants.

Increased level of premarket scrutiny

No medical device is completely safe, or immune from failure, irrespective of the level of premarket scrutiny it has undergone. It is also generally recognised that medical devices are inherently different from medicines. For instance, it is not possible to accumulate a similar body of clinical trial data at the premarket stage. This makes postmarket surveillance critically important to the effective regulation of medical devices.

Regardless of the above, where a device fails, significant difficulties can result for patients, health professionals and Government, particularly when the failure occurs with implantable medical devices. For example, difficulties can include revision surgery[4] for the

[4] 'Revision surgery' is performed to replace or compensate for a failed implant (as a hip replacement) or to correct undesirable consequences (such as scar tissue) of previous surgery. The complexity of revision surgery may increase the chance of complications.

patient, with its inherent risks, to enable removal and often replacement of the faulty device.

Given the potential impacts where implantable medical devices fail, it is critical to examine how to increase the level of rigour applied to the premarket assessment of medical devices rather than solely relying on postmarket mechanisms.

The acceptance of conformity assessment certification issued by European notified bodies as the basis for the approval of medical devices in Australia has recently emerged as another concern. Activities are currently underway to strengthen oversight and governance arrangements for European notified bodies, and reforms to notified bodies arrangements in Europe have been proposed. Options outlined in this RIS seek to balance timely access to market for medical devices (allowing continued use of EU certification) while addressing the concerns which underpin the reforms proposed in Europe (given reform of the European system is some time away).

Transparency of decision making

Unlike other leading regulators such as the United States Food and Drug Administration (FDA) and Health Canada, TGA does not currently formally publish particulars about its medical device decisions or provide any information about, or access to, its assessments. The outcome is known if and when the device appears on the ARTG. No direct information is published on:

- ***Conformity assessment:*** the approval or rejections of an application for conformity assessment;
- ***Approval for inclusion on the ARTG:*** the basis for the decision to include a medical device on the ARTG, such as whether the medical device was subject to application audit and if so what information was considered, and the conformity assessment certification (whether issued by a specific EU notified body or the TGA) used to support the application; or
- ***Rejection for inclusion on the ARTG:*** for medical device applications for inclusion on the ARTG that are rejected. There is no public record that the application was made, its rejection or the rationale for the rejection.

It became apparent during the Senate Inquiries that there is a misunderstanding of how medical devices are regulated in Australia in relation to the level of assessment TGA undertakes and that consumers and health professionals would welcome visibility of what was assessed in order to inform their decision making in relation to the use of medical devices.

The above issues emerging from the Senate Inquiry about TGA decision making are consistent with the findings of a 2010 review. This review noted the community perception that the TGA does not provide the public with sufficient information about its regulatory activities and in particular about therapeutic goods.

This review recommended that the TGA should provide explanation of its various regulatory processes, and adopt publication principles on the outcomes of application assessments. The exemplar of the Australian Public Assessment Reports (AusPAR) has been cited. An AusPAR provides information about the evaluation of a prescription medicine and the considerations that led the TGA to approve or not approve an application. More general information about particular prescription or pharmacist-only

medicines is also available for consumers (in the form of Consumer Medicine Information) and health professionals (Product Information).

This transparency theme is repeated as part of the medical device reforms proposals identified in the TGA Blueprint for Reform relating to improving the level of information published about medical devices to better inform consumers and health professionals.

Third party conformity assessment for Australian manufacturers

Medical devices made by Australian manufacturers (other than the lowest risk devices) require conformity assessment by the TGA in order to receive marketing approval. In contrast, conformity assessment can be conducted by a European notified body for the same device if it is manufactured by a company outside Australia.

This requirement can result in higher regulatory costs for Australian manufacturers as they may require a conformity assessment from the TGA if they want to supply in Australia (for one fee) and another from a European notified body if they want to supply in Europe (for a second fee). In contrast an overseas manufacturer can supply in Australia based on a European notified body certificate for the cost of only a single assessment fee.

As European notified bodies operate in a competitive environment, some industry stakeholders have indicated that there can be significant timing and cost differences in seeking conformity assessment from European notified bodies compared to the TGA. The TGA's exclusive role in issuing certificates to Australian manufacturers has been questioned for a number of years by the medical devices sector, as an unreasonable constraint on Australian manufacturers not shared by their overseas competitors.

The proposals in this paper are intended to address each of the above issues. As noted above, consultation on *Changes to premarket assessment requirements for medical devices* was undertaken between January and March 2013. A summary of the submissions made on that previous paper is included at **Attachment D: Summary of consultation on changes to premarket assessment requirements for medical devices**.

Objective

The regulatory reform proposals examined by this RIS are primarily seeking to provide greater assurance that higher risk medical devices approved do not compromise public health and safety while at the same time:

a. supporting the timely availability of medical devices to the Australian public;

b. minimising unnecessary regulatory burden and associated costs on the medical device industry (as these costs are passed on to users and funders of the health system);

c. improving the ability for TGA to target emerging risks in a timely manner; and

d. continuing Australia's commitment to promoting alignment of international medical device regulation.

Options

Three options are being considered in response to the concerns outlined above:

1. Take no immediate action to change premarket assessment requirements for medical devices;
2. Change the premarket assessment of medical devices through:
   a. increased scrutiny of conformity assessment for higher risk medical devices as part of mandatory application audits prior to ARTG inclusion;
   b. publication of information about TGA regulatory decisions (including IVDs); and
   c. abolition of the requirement for TGA conformity assessment for Australian manufacturers (excluding manufacturers of Class 4 IVDs);
3. Expand TGA mandatory conformity assessment for AIMD and Class III implantable medical devices and allow third party conformity assessment for other devices (other than Class 4 IVDs).

Option 1 - No immediate action

This option would require no change to current arrangements.

Existing arrangements are sufficient

Some respondents to the most recent consultation suggested that premarket scrutiny of medical devices has already been substantially enhanced by the reclassification of hip, knee and shoulder joint implants from 1 July 2012. It was also argued that this reclassification, balanced with pre and post market monitoring through a number of existing mechanisms within the regulatory framework was a sufficient increase in scrutiny of higher risk devices early in their market life. These include:

- Annual reporting: Sponsors are already required to provide annual reports to the TGA on high risk devices during the first three years of ARTG inclusion, thereby providing an early warning system once a device is used in or on patients;
- TGA statutory advisory committees: These committees provide independent expert advice to the TGA , with both a pre and post market focus;
- Clinical registries: There are currently some clinical registries established to assist in postmarket surveillance and the Government has recently committed to increasing the number of these to allow the safety and quality of healthcare delivered to patients to be tracked; and
- International vigilance exchange: Through the IMDRF exchanges of surveillance information provide participating countries (including Australia) with knowledge of problems being experienced in other nations, providing for timely corrective action to be undertaken.

International regulatory changes

In response to the recent consultation, some stakeholders also argued that it would be premature for Australia to undertake regulatory changes beyond those that have already occurred, until the reform activities in the EU are completed, to ensure the systems remain aligned. Additionally, it was argued that transition to the joint regulatory agency with New Zealand should be completed, as further changes to premarket requirements will make it difficult for New Zealand manufacturers to transition to the joint agency.

As a result, one option would be to delay making changes to the Australian regulatory framework until the international environment is clarified and developments in Europe are finalised and implemented (approximately 2020). After that time changes would be made to align them to and / or build on those changes for implementation in Australia and New Zealand under the ANZTPA.

Assessment of this option against the objectives

This option does not meet the key objective of the reforms – ie greater assurance that higher risk medical devices approved do not compromise public health and safety. This is because it does not enhance premarket scrutiny of higher risk devices, including certain implantable and long term surgically invasive medical devices. Nor does it focus on increasing efforts to reduce the risk of device failures occurring in the first place.

TGA has been developing options for increasing premarket scrutiny of higher risk medical devices for a number of years, dating back to consultations in December 2008. Additionally, the HTA Review in late 2009 and the two Senate inquiries in 2011 and 2012 reaffirmed the need for increased premarket scrutiny. Delaying the proposal to change premarket assessment requirements for medical devices until 2020 is not appropriate given the significance of the problems faced by patients, health professionals and Governments when higher risk implantable devices fail. Delaying dealing with these issues would be compounded by the absence of certainty of what the changes will be pursued in Europe.

Additionally, this option does not improve TGA's ability to target emerging risks appropriately as it does not facilitate a higher level of review to be undertaken where the need is identified. Finally, it also does not address the issues identified in Europe in relation to the oversight of the notified bodies and is therefore at odds with the direction being set by the European Commission.

On this basis **Option 1 is not recommended.**

Option 2 - Changes to premarket assessment of medical devices

This option proposes:

- Proposal A: Increased scrutiny of conformity assessment as part of mandatory application audits prior to ARTG inclusion, including two elements;
  - Increase the number of products targeted for mandatory audits to include some Class IIb implantable and long term surgically invasive devices;

  - Introduce a new Level 3 audit to assess additional evidence of conformity for AIMD and Class III implantable medical devices together with a fee commensurate to the additional analysis required;

- Proposal B: Publication of medical device regulatory decisions (including IVDs); and
- Proposal C: Abolition of requirement for TGA conformity assessment for Australian manufacturers of all medical devices except Class 4 IVDs.

Please note that Proposals A and C are intended to operate together as a package. However, it is possible to implement Proposal B in isolation from the other proposals in this option.

Proposal A: Increased scrutiny of conformity assessment

This proposal would expand the range of products subject to mandatory audits by the TGA for medical devices (excluding IVDs at this stage given the IVD transition is continuing).

The elements of this proposal are:

- ***Expanded range of products subject to mandatory audits***: The requirement for a mandatory audit of an application would be extended to cover specific implantable and long term surgically invasive Class IIb medical devices (in addition to applications for the kinds of devices currently referred to in Regulation 5.3).
- ***Assessment of evidence of conformity***: Using existing powers, the TGA would introduce a new 'Level 3' audit for AIMD and Class III implantable and surgically invasive medical devices, to more closely review existing conformity assessment information relating to the device. This may involve review the raw clinical data underpinning the conformity assessment report rather than the expert clinical report as occurs for the Level 2 audit, the notified body's Design Examination report, and a desk audit of the manufacturer's quality management system. This element would include introduction of a new level of application audit fee (a 'Level 3' audit, to be added to the existing 'Level 1' and 'Level 2' audits) to reflect the greater depth of analysis undertaken for those higher risk devices.

Expanded targeting of mandatory audits

It is no longer intended to capture all Class IIb implantable and long term surgically invasive medical devices as was proposed in the recent consultation document. As a result of consultation the intention is now to identify those Class IIb devices required for mandatory audit by the perceived and/or demonstrated level of risk associated with the product. This would be achieved by creating an instrument to identify these medical devices, rather than prescribing the mandatory audit requirements directly in the regulations. The advantage of this approach is that devices can be added and removed more readily to reflect emerging issues (or their resolution).

Devices could be added to or removed from this legislative instrument[5] based on an assessment of the perceived and/or demonstrated level of risk. Subject to further consultation, it is anticipated that the list would be populated with:

[5] Amendments to legislative instruments require consultation prior to being presented to Parliament for approval.

- ***Surgically invasive and/or long term implantable medical devices***: Focusing on implantable and surgically invasive Class IIb devices of particular concern as opposed to capturing all Class IIb implantable devices for mandatory audit (noting that Class III and AIMDs are already captured under existing mandatory audit arrangements);
- ***New and novel technology***: Where a new and novel technology is likely to have a significant impact on public health or where the risks have not been widely established (Class IIb and above); and/or
- ***Post market issues***: Where devices are experiencing post market issues of concern (Class IIb and above).

The changes to the list of Class IIb products to be captured is based on feedback received during the consultation process which indicated that a number of surgically invasive and/or long term implantable devices are of lower risk and do not warrant the additional level of scrutiny. The following table provides an indication of Class IIb devices to be captured for audit, and the level of audit which would normally be expected (but will not always apply). The contents of this list would be subject to further consultation with stakeholders during the implementation process.

Device	Expected Audit Level
Spinal fixation devices	Level 2 audit
Orthopaedic fixation devices	Level 1 audit
Bone screws, plates, pins and wires	Level 1 audit
Finger, wrist and ankle joint prostheses	Level 1 audit
Artificial bone matrix implants	Level 1 audit
Non-absorbable implants such as sutures, staples and anchors	Level 1 audit
Surgical mesh	Level 2 audit
Long-term invasive vascular access devices, such as implantable ports	Level 1 audit
Maxillofacial implants	Level 1 audit
Peripheral vascular stents, biliary stents etc	Level 2 audit
Shunts, such as portacaval shunts	Level 1 audit
Long term implantable devices used in bariatric surgery	Level 2 audit
Systems and procedure packs containing any of the above devices	Audit level in line with the highest audit level of the contents of the system or procedure pack

Existing mandatory audit requirements as outlined in Regulation 5.3 would also continue (with the following list also indicating the level of audit normally anticipated for these medical devices):

Device	Expected Audit Level
Barrier contraceptives (other than condoms)	Level 1 audit
Implantable contraceptive devices	Level 2 audit
Medical devices that are specifically intended by the manufacturer to be used for disinfecting another medical device	Level 1 audits for hardware devices i.e. autoclave, and Level 2 audits for disinfecting agents i.e. liquid disinfectants to disinfect other medical devices
Implantable intra-ocular lenses	Level 1 audit for posterior lenses and Level 2 audits for other lenses
Intra-ocular visco-elastic fluids	Level 2 audit
Class III and AIMD medical devices not supported by conformity assessment issued by the TGA or issued under the EU MRA	Level 3 audit for targeted devices only (AIMD, implantable and surgically invasive), Level 2 audit for other Class III medical devices

The only change to the list above arising from the consultations relates to the level of audit for medical devices intended for use to disinfect another medical device. Advice received, and subsequently confirmed within the TGA, indicates that a Level 1 audit is suitable for hardware devices but a Level 2 audit remains appropriate for liquid disinfectants.

It should be noted that Subregulation 4.1(2), which prescribes the kinds of medical devices that require a TGA conformity assessment will be retained.

Assessment of evidence of conformity and new audit fee

Proposal A would also introduce a Level 3 audit for new applications together with a new fee commensurate with the additional analysis required. As is currently the case for the existing audit program, the level of audit to be applied in relation to any particular application would be at TGA's discretion in the particular case. Discretion is necessary as the reasons for selecting particular audit levels do not relate only to the nature of the device itself, but may also reflect concerns about the particular application such as the information included with the application, the quality of the clinical evidence etc. A list of the indicative audit levels would be provided as a guide to industry in anticipating application costs and, to some extent, timeframes. An indication of those audit levels is included above.

The cost of the Level 3 audit is estimated to be $22,974. This is outlined in detail in the Costs and benefits section below.

The outcome of confidence building with the EU to be conducted in 2013 and 2014 will be another factor in deciding the mandatory audit level. For example where conformity assessment has been issued by a notified body which has satisfied confidence building requirements, the level of mandatory audit could be reduced below Level 3.

This proposal would be fundamental in TGA building and maintaining an effective and efficient confidence building system that is embedded into its business as usual. It provides a process for reviewing the work already conducted by a notified body on an ongoing basis. While it may be more resource intensive in the short-medium term, as

confidence building becomes established, the level of TGA oversight of assessments conducted by European notified bodies could reduce.

Grouping of application audits

In order to reduce costs to the medical device industry, grouping of applications for related medical devices may occur. This could reduce audit fees by 20 per cent where the following elements are the same: classification, manufacturer, level of audit, Global Medical Device Nomenclature (GMDN) code; AND where the application fee for all applications to be grouped is paid on the same day, with a letter attached to the application requesting a grouping and fee reduction.

How has this proposal changed since the January 2013 consultation?

This proposal is a progression from the changes outlined in the January 2013 consultation paper as proposal A, modifying them somewhat based on consultation outcomes. The key difference is that the scope of mandatory audits is narrowed for Class IIb implantable and surgically invasive medical devices. Additionally there is also the introduction of an instrument to replace the current regulatory provisions relating to which products are subject to mandatory audit requirements. This ensures sufficient flexibility to allow the mandatory audit program to be targeted to medical devices of concern, and for this targeting to be adjusted over time.

Proposal B - Publication of information about regulatory decisions

This proposal would involve publishing information on the regulatory decisions the TGA makes about medical devices and IVDs.

The format for publishing all medical devices decisions will assume a format similar to the AusPAR (Australian Public Assessment Reports for prescription medicines). The final format would be developed after further consultation with stakeholders, to ensure TGA provides appropriate information about decision making to the Australian public, while also considering industry confidentiality requirements. The timing of the publication of information about particular decisions will be considered carefully, to take into account the rights of unsuccessful applicants to seek internal and Administrative Appeals Tribunal review of decisions.

Consultation identified broad support for the proposal to publish medical device decisions but highlighted some stakeholder concerns, particularly publication of conformity assessment decisions or negative decisions. Concerns such as confidentiality of product information, providing advantages to competitors, and delays of product entry in the ARTG were expressed.

These concerns were also expressed during the consultation prior to the introduction of AusPARs, although the Medical Technology Association of Australia submission to the consultation noted that these issues had been anticipated but were largely not manifested in relation to publication of prescription medicine information[6].

An AusPAR is compiled by the TGA after the delegate has made a decision relating to the submission for new prescription medicines and major changes to existing prescription medicines. The draft AusPAR containing information on quality, safety, efficacy,

[6] MTAA submission, *Changes to premarket assessment requirements for medical devices*, 15 March 2013

phamacovigilence[7] and risks and benefits is forwarded to the sponsor for review of commercially confidential information.

Health Canada provides a document for medical devices covering similar information to the AusPAR but to a lesser extent. Canadian decision publications include information on the medical device, its safety and effectiveness, risk benefit assessment and the decision.[8]

This option also provides an opportunity for the TGA to progress TGA Blueprint reform Proposal 4 - publication of medical device information, through publishing information supplied with the device such as instructions for use or labelling of a product. This published information will be directed to both health professionals and consumers to improve transparency of medical device information.

How has this proposal changed since the January 2013 consultation?

This proposal is a progression from the changes outlined in the January 2013 consultation paper as Proposal B, modified somewhat based on consultation outcomes. The January 2013 paper proposed publication of the TGA's decision letter as a 'first step' towards an AusPAR equivalent, while this proposal progresses to a publication of an AusPAR equivalent document. This addresses concerns raised in consultation regarding appropriate confidentiality of commercial information and consultation prior to publication.

It is proposed to implement in stages focusing first on higher risk medical devices, given the greater inherent risks associated with those devices. Further details are contained in the 'Implementation and Review' section of this document.

Proposal C - Removing the requirement for TGA conformity assessment for Australian manufacturers except for Class 4 IVDs

This proposal abolishes the requirement for Australian manufacturers of medical devices to have TGA conformity assessment for all medical devices (except for Class 4 IVDs). The outcome would be that, except for Class 4 IVDs, an Australian manufacturer could choose to have their conformity assessment certificates issued by a European notified body rather than being limited to using the TGA. Class 4 IVDs will be excluded from this proposal until the European reforms to adopt the GHTF model for IVD regulation come into force. At this stage, the differences in regulation for Class 4 IVDs are too significant to allow TGA to accept European certification.

Proposal A above, combined with the international confidence building activities that are currently in train between Australia and the EU, provide a mechanism for the TGA to refine and better target the management of risks around a particular type of device or a notified body rather than on the location of the manufacturer. This is because devices perceived or proven to be of risk will be selected for mandatory audit under Proposal A, with the TGA being able to review the full details of the conformity assessment conducted by a European notified body under a Level 3 audit until confidence building has occurred. Thereafter, TGA would be able to reduce its level of audit to Level 1 or 2 as necessary.

Additionally, providing TGA discretion to react to a suspected or proven risk rather than a blanket approach to regulation is consistent with its risk based approach to regulation.

[7] <http://www.tga.gov.au/industry/pm-auspar.htm>
[8] <http://www.hc-sc.gc.ca/dhp-mps/prodpharma/sbd-smd/md-im/index-eng.php>

This also allows the TGA to deal with the increased workload associated with the implementation of Proposals A and B above.

How has this proposal changed since the January 2013 consultation?

This proposal has progressed from the changes outlined in the January 2013 consultation paper as Proposal C, modified somewhat based on consultation outcomes. The January 2013 proposal was limited to lower class devices (Class IIb and lower), while the current proposal expands this to cover all medical devices produced by Australian manufacturers. This proposal now includes Class III and AIMD medical devices.

During consultation, this proposal received overwhelming support from stakeholders. The majority of comments suggested extending the abolition of TGA conformity assessment for Australian manufacturers of Class III (high risk) medical devices. Additionally, the New Zealand medical device industry has expressed concern about the existing requirement for TGA conformity assessment for all Australian manufacturers being expanded to include New Zealand manufacturers under the ANZTPA arrangements, meaning that devices manufactured in New Zealand would not be able to be supplied under a joint regulatory scheme until reviewed by ANZTPA. Abolishing this requirement would address those concerns.

Assessment of this option against the objectives

This package of reforms addresses all the objectives of the RIS.

It ensures that higher risk medical devices approved do not compromise public health and safety through the greater scrutiny of a greater range of medical devices through proposal A. This is reinforced by the confidence building activities that have commenced.

Proposal C assists to balance this increased scrutiny against retaining the timely availability of medical devices to the Australian public. It achieves this by minimising unnecessary regulatory burden and associated costs and improving the ability for TGA to target emerging risks in a timely manner. Proposal A also ensures that Australia actively addresses the issues identified with European notified bodies in a timely manner, well in advance of regulatory change occurring in Europe.

Proposal B also increases public health and safety through providing consumers and health practitioners with better access to information about medical devices to allow them to make more informed health care choices and decide on the level of risk they are willing to accept. Improved transparency is also consistent with what other international regulators are publishing and therefore contributes to the international harmonisation agenda for medical device regulation.

On this basis, **Option 2 is the recommended option for reform**.

Option 3 - Expand TGA mandatory conformity assessment for AIMD and Class III implantable medical devices and allow third party conformity assessment for other devices except Class 4 IVDs

This option proposes to extend the current requirements for a TGA conformity assessment certificate to be issued to cover all AIMD and Class III implantable devices irrespective of

where they are manufactured but allows TGA to accept conformity assessment certificates from European notified bodies for all other devices other than Class 4 IVDs. The reasons for excluding Class 4 IVDs at this time are the same as those provided for excluding these devices from Proposal C in Option 2.

Regulation 4.1 currently requires the TGA to issue conformity assessment certificates for specific kinds of high risk medical devices, including those containing medicines or tissues of animal, biological or microbial origin and also for devices manufactured in Australia. This would be amended to also include all AIMD and Class III implantable medical devices, and to remove the requirement for TGA conformity assessment because a device is produced by an Australian manufacturer.

Like Proposal C of Option 2, this option would allow greater TGA scrutiny of a medical device based on the risks of the device rather than the location of the manufacturer. However, it would result in the TGA no longer accepting conformity assessment certificates from European notified bodies for those AIMD and Class III implantable medical devices where this currently occurs and undertaking the conformity assessment itself.

Industry has previously commented that requiring TGA to conduct conformity assessments for all AIMD and Class III implantable devices will significantly increase their costs, delay some products entering the Australian market (with some products being lost to the Australian market altogether) and duplicate the notified body assessment. Previous comments also raised issues about the capacity of the TGA to undertake this workload.

Assessment of this option against the objectives

This option provides greater assurance of the quality, safety and performance of higher risk medical devices as conformity assessment for AIMD and Class III medical devices provides the highest level of assessment possible. However, this option does not address the concern with certain Class IIb implantable or long term surgically invasive medical devices which, in some ways, are of greater concern given that Class III devices are already subject to the highest level of assessment whereas the level of assessment for a Class IIb medical device is not as high. Therefore, this proposal does not increase the number of products subjected to higher scrutiny by the TGA as much as option 2.

Additionally, there would be no discretion to reduce the level of assessment once confidence building has occurred and is therefore associated with ongoing costs.

On this basis, **Option 3 is not recommended**. Proposal A under option 2 provides a more balanced approach to addressing the risks of these higher risk medical devices through changes to mandatory audit arrangements.

Impact analysis

This section will provide a overview of the affected stakeholders followed by an analysis of how each stakeholder group is affected by the different proposals.

Affected stakeholders

Key stakeholders affected by the changes to premarket assessment requirements of medical devices include:

- consumers;
- health care professionals;
- the medical device industry; and
- Government, including Government agencies

Consumers

The consumer group generally includes those people who use medical devices, whether independently or as patients of or with advice from health care professionals.

Consumer concerns about the regulation of medical devices have been a key driver for the proposed regulatory changes. Consultations from the HTA review and the 2008 and 2010 medical device reforms, as well as feedback relating to the two Senate Inquiries (on medical devices and PIP breast implants) have highlighted an increased need for the TGA to address consumer concerns about medical device regulation in Australia.

Health care professionals

Health professionals include doctors, nurses and pharmacists, but also members of ancillary professions such as physiotherapists, audiologists, ophthalmologists, podiatrists etc. The institutions, such as hospitals, pharmacies and practices in which these professionals work with their patients are also relevant. Health care academics and the educational institutions in which they operate could also be included in this group.

Many medical devices are designed for use by health care professions in their clinical practices, rather than for consumer use, or may be paid for by public health providers. Many of the issues for consumers are also applicable to the healthcare professionals and other allied professionals who work towards health outcomes for consumers. These professionals have an interest in the inherent safety of medical devices, which they may facilitate use of by consumers.

Health care professionals may also have separate concerns from consumers, such as concerns about the impacts on their organisations as businesses.

Medical device industry

The medical device industry includes people or organisations that manufacture or sponsor medical devices. There are also a number of bodies which represent sectors of the industry, such as the Medical Technology Association of Australia (MTAA), AusBiotech , IVD Australia or the Australian Dental Industry Association (ADIA).

With the Australian market for medical technology only being 3 per cent 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 medical devices between other regulators such as the USA and Canada. The most dominant international regulator (and therefore most important for the Australian medical device industry) is the EU which, as noted earlier, is proposing to strengthen medical device regulation.

Government agencies

The Australian Government has a number of interests in the regulation of medical devices. In representing the interests of the Australian community they need to balance many competing issues. These range from the health and safety of the public and the confidence of the public in the health care system, to the economic interests of companies in the medical device market place. Balancing these is the purview of Government, and it is the aim of this RIS to provide Government with information on competing priorities.

There are particular impacts on the efficiency and effectiveness of Government operations in administering regulatory systems, and the impacts of regulatory changes on various Government agencies needs to be assessed. While the TGA is responsible for regulating medical devices supplied in Australia and self-evidently will be impacted by changes to the regulatory framework, other Government agencies which rely on the assurance of TGA regulatory oversight provides on the quality, safety, and performance of medical devices may also be affected. This would include other parts of the Department of Health and Ageing that are part of the Health Technology Assessment processes, and public health authorities (such as state health departments, with parallel impacts on private health providers).

Organisations which interact with TGA at an operational level may also have an interest in the changes. For example, TGA and Customs work cooperatively to enforce TGA marketing restrictions through border controls, and changes to the oversight of devices may affect the incentives to import devices.

Options outlined in this paper may also impact on broader policy areas, and so be of policy interest to other Government agencies.

Advantages and disadvantages

The following table analyses the impacts of the options on each of the key stakeholder groups in relation to the following:

- ***Public health and safety:*** Changes to the risks and benefits of using medical devices;
- ***Costs:*** Financial impacts likely to be experienced, whether direct (fees and charges, etc) or indirect (relating to implementation or compliance);
- ***Access:*** Impacts on the availability of medical devices in Australia;
- ***Timeliness:*** Impacts on the efficiency of the regulatory process; and
- ***Other:*** Such as the international impacts.

Option 1 - No immediate action (not recommended)

This would be the preferred option for a number of industry stakeholders. A number of submissions from the medical device industry argue that the more effective use of existing regulatory arrangements, particularly post market surveillance of medical device, together with changes already underway, such as the reclassification of hip, knee and shoulder joint replacement implants, the introduction of clinical registries and improved adverse event reporting, are sufficient to address the issues around implantable medical devices. Further, many manufacturers operate in an international market, so changes in other jurisdictions, such as the reforms proposed for Europe, are also affecting these stakeholders.

However, this option fails to address the fundamental concerns of other stakeholder groups on the need for increased transparency and rigour of premarket assessment, particularly around implantable medical devices.

Stakeholder	Advantages	Disadvantages
Option 1 – No immediate action		
Consumers and health care professionals	***Costs:*** No increase in regulatory costs to be passed on to consumers and/or health care professionals. ***Access and Timeliness:*** No change to incentives for supplying in Australian market, and so maintains current level of device availability and does not change market entry timelines.	***Health and safety:*** Does not address the public health and safety concerns with the existing system. ***Costs:*** Not preventing the failure of an implantable medical device can be very costly for consumers and healthcare professionals and taxpayers who ultimately fund the public healthcare system.
Medical device industry	***Health and safety:*** Industry argues that existing reforms (joint reclassification, adverse event reporting, clinical registries) are sufficient to address concerns about implantable medical devices. ***Costs and Access:*** No changes in the costs to industry (direct fees and charges, or changes to compliance costs), which means there is no change to the business viability of existing and potential products. ***Timeliness:*** No change in the time taken for regulatory assessments.	***Health and safety:*** Industry acknowledges there is community concern about transparency and rigour of assessment, and this would not be addressed. ***Cost:*** Loss of opportunity to reduce costs by removing the requirement for TGA assessment for Australian manufacturers. Not preventing the failure of an implantable medical device can be very costly for the industry through loss of confidence in the sector as a whole. ***Access:*** Loss of opportunity for faster and/or more predictable assessment timeframes.

Stakeholder	Advantages	Disadvantages
Government agencies	***Costs:*** No implementation costs. ***Access:*** No impetus for industry to withdraw existing or withhold new medical devices from the Australian market. ***Timeliness:*** No change in the time taken for regulatory assessments.	***Health and safety:*** Does not address the public health and safety concerns with the existing system. ***Cost:*** Loss of opportunity to reduce costs by removing the requirement for TGA assessment for Australian manufacturers. Not preventing the failure of an implantable medical device can be very costly for public and private health funders. ***Access:*** Loss of opportunity for faster and/or more predictable assessment timeframes.

Option 2 – Changes to premarket assessment of medical devices (recommended)

This is the recommended option on the basis it provides a balanced approach to addressing concerns about the transparency and rigour of premarket assessment of medical devices whilst minimising the additional regulatory costs to industry (and eventually to consumers). It also provides some flexibility to adjust the levels of regulatory oversight over time, based on changing risks for particular devices or notified body performance.

Stakeholder	Advantages	Disadvantages
Option 2 - Changes to premarket assessment of medical devices		
Consumers and health care professionals	***Health and safety:*** Increases the transparency and rigour of premarket assessment. ***Costs:*** There may be reduced costs for medical devices manufactured in Australia. ***Timeliness:*** Removal of requirement for TGA conformity assessment for Australian manufacturers may decrease time to market for some Australian devices.	***Health and safety:*** There may be some remaining concerns about continued use of European notified bodies, despite checks undertaken through Level 3 audits for high risk devices. ***Costs:*** Increased costs to industry may be passed on to consumers and/or health care professionals. ***Access:*** The choice of devices may be reduced as it may be unviable to continue marketing some products or as some products will not be supported by sufficient evidence. ***Timeliness:*** Increased assessment times will delay availability for some devices.

Stakeholder	Advantages	Disadvantages
Medical device industry	***Health and safety:*** Increased consumer confidence in regulatory system increases confidence in available devices. ***Costs:*** Reduced costs for Australian manufacturers from reduced duplication of conformity assessment between Australia and Europe. Mandatory audits are a less expensive option than requiring full TGA conformity assessment. ***Timeliness:*** Removal of requirement for TGA conformity assessment for Australian manufacturers may decrease time to market for some Australian devices. Mandatory audits are a faster option than requiring full TGA conformity assessment.	***Health and safety:*** Increased transparency of decisions will highlight the different levels of evidence available for different devices. ***Costs:*** Increased costs for sponsors for mandatory audits (additional audits of targeted Class IIb devices, the higher Level 3 fee for AIMD and Class III implantable devices). Costs of publication of decisions. Implementation costs for change. ***Access:*** The range of products available for marketing may be reduced, possibly reducing the profitability of the sector. ***Timeliness:*** Mandatory audits likely to increase current processing times for affected applications, extending time to reach the market.
Government agencies	***Health and safety:*** Increases the transparency and rigour of premarket assessment. ***Costs:*** Reduced costs for Australian manufacturers may encourage local medical devices industry. ***Timeliness:*** Removal of requirement for TGA conformity assessment for Australian manufacturers may decrease time to market for some Australian devices. ***Other:*** Removal of requirement for TGA conformity assessment for Australian manufacturers will assist with ANZTPA transition.	***Health and safety:*** Increased transparency of decisions will highlight the different levels of evidence available for different devices. ***Costs:*** Increased regulatory costs for devices subject to mandatory audits (additional audits of targeted Class IIb devices, the higher Level 3 fee for AIMD and Class III implantable devices). Costs of publication of decisions. Implementation costs for change. ***Access:*** The choice of devices may be reduced as it may be unviable to continue marketing some products or as some products will not be supported by sufficient evidence. ***Timeliness:*** Increased assessment will extend processing time, delaying availability of devices in the Australian market

Option 3 - Mandatory conformity assessment for AIMD and Class III implantable medical devices and allow third party conformity assessment for other devices other than Class 4 IVDs (not recommended)

Option 3 has many of the same advantages and similar disadvantages as Option 2. However, under Option 3, less higher risk devices are subjected to additional TGA scrutiny at a higher cost to industry than Option 2 (see Costs and Benefits section below). This means that the cost per public health outcome is higher and therefore less cost-effective. Furthermore, Option 3 does not provide flexibility to reduce the levels of regulatory oversight over time (and therefore costs), based on changing risks for particular devices or notified bodies.

Stakeholder	Advantages	Disadvantages
Option 3 - Expand TGA mandatory conformity assessment for AIMD and Class III implantable medical devices and allow third party conformity assessment for other devices except Class 4 IVDs		
Consumers and health care professionals	***Health and safety:*** Increases the transparency and rigour of premarket assessment. ***Timeliness:*** Removal of requirement for TGA conformity assessment for most Australian manufacturers may decrease time to market for some Australian devices.	***Health and safety:*** There may be some remaining concerns about continued use of European notified bodies for lower risk devices. ***Costs:*** increased costs to industry, which may be passed on to consumers and/or health care professionals. ***Access:*** The choice of devices may be reduced as it may be unviable to continue marketing some products or as some products will not be supported by sufficient evidence. ***Timeliness:*** Increased assessment times will delay availability for some devices.
Medical device industry	***Health and safety:*** Increased consumer confidence in regulatory system increases confidence in available devices. ***Costs:*** Reduced costs for Australian manufacturers from reduced duplication of conformity assessment between Australia and Europe. Alignment of third party conformity assessment with introduction of Australian notified bodies may decrease overall expense for international manufacturers. ***Timeliness:*** Removal of requirement for TGA conformity assessment for Australian manufacturers may decrease time	***Health and safety:*** Increased transparency of decisions will make clear the minimal evidence for some devices. ***Costs:*** Increased costs for sponsors for conformity assessment (TGA conformity assessment fees for a much broader range of higher risk devices). Costs of publication of decisions. Implementation costs for change. ***Access:*** The range of products available for marketing may be reduced, possibly reducing the profitability of the sector. ***Timeliness:*** Conformity assessment will increase current processing

Stakeholder	Advantages	Disadvantages
	to market for some Australian devices. Competitive market for conformity assessment may enable faster times to market.	times for affected applications, extending time to reach the market (more likely than for option 2).
Government agencies	***Health and safety:*** Increases the transparency and rigour of premarket assessment. ***Costs:*** Reduced costs for Australian manufacturers may encourage local medical devices industry. ***Access:*** Higher risk devices with insufficient evidence of safety and performance no longer supplied in Australia. ***Timeliness:*** Removal of requirement for TGA conformity assessment for Australian manufacturers of lower class devices may decrease time to market for some Australian devices. ***Other:*** Creation of Australian third party conformity assessment bodies may strengthen community of technical expertise. Removal of requirement for TGA conformity assessment for Australian manufacturers will assist with ANZTPA transition.	***Health and safety:*** Increased transparency of decisions will make clear the minimal evidence for some devices. ***Costs:*** Increased conformity assessment costs. Possible recruitment difficulties for technical staff to undertake TGA conformity assessment. Costs of publication of decisions. Implementation costs for change. ***Access:*** The choice of devices may be reduced as it may be unviable to continue marketing some products or as some products will not be supported by sufficient evidence. ***Timeliness:*** Increased assessment will extend processing time, delaying availability of devices in the Australian market.

Overall impact

Each of the options proposed above will have a range of positive and negative consequences for stakeholders. Option 2 provides the most balanced and cost-effective approach to improving public health outcomes in both the short term and the longer term, given that this is the only option that creates a positive feedback loop from the increased level of TGA oversight. Specifically, it is the only option that incentivises the use of notified bodies which have demonstrated their performance through confidence building, thereby increasing assurance about the safety and performance of higher risk devices.

Costs and benefits

The estimated costs and benefits associated with the options outlined in the RIS are detailed below.

Option 1 - No immediate action

As this option proposes to make no changes to the regulatory system, no additional direct regulatory costs over the status quo are anticipated. However, this option does not achieve the majority of the objectives of this RIS, particularly the primary objective of providing greater assurance that higher risk medical devices do not compromise public health and safety.

Option 2 - Changes to premarket assessment of medical devices

The TGA costs associated with each proposal contained within this option are presented below. As the TGA operates in a 100% cost-recovery basis, the additional costs associated with increased regulation are borne by the regulated industry through increases to the application fees and annual charges.

Proposal A: Increased scrutiny of conformity assessment

Proposal A increases scrutiny of conformity assessment through targeting of mandatory audits for a wider range of high risk medical devices (primarily Class IIb implantable devices) and increasing assessment of additional evidence of conformity assessment for the highest risk devices (AIMD and Class III implantable devices).

Assumptions

The following two elements of this proposal were costed:

- Mandatory audits for Class IIb implanted devices, assuming:
  - An additional 139 mandatory audits;[9]
  - An estimated 70 per cent of these audits would be Level 1 audits, while 30 per cent would be Level 2 audits;[10]
  - Existing Level 1 and Level 2 audit fees will apply (at the 2012-13 rates);

[9] A total of 697 Class IIb applications were received in 2012. These applications were analysed (using GMDN codes) to identify the number of these Class IIb applications which would be affected by mandatory audit requirements (against the list of devices outlined above at 12). This analysis indicated that 20 per cent of Class IIb applications (139) would be affected by the proposed Class IIb mandatory audit.

[10] Calculated based on the GMDN analysis of the 139 Class IIb applications received in 2012 which would be affected by mandatory audit requirements (against the indicative audit levels included in the list of devices outlined above at 12), it is estimated that 70 per cent of the Class IIb mandatory audits would be Level 1 audits, and 30 per cent would be Level 2 audits.

- All these audits are additional, as these medical devices are currently not subject to mandatory audit.

· Level 3 audits for AIMD and Class III implanted devices, assuming;
  - 261 applications requiring auditing per year;[11]
  - Level 3 audit to include:[12]
    - § desk audit of manufacturer's quality management system (20 per cent of all Level 3 audits);[13]
    - § design examination report (100 per cent of Level 3 audits);
    - § raw clinical data underpinning conformity assessment (100 per cent of Level 3 audits);
  - All of these Class III devices are already subject to mandatory audit, and a Level 2 audit would be currently expected for 100 per cent of these applications.[14]

Cost

Mandatory audits for Class IIb implanted devices: The cost of the additional audits for Class IIb implantable devices is $3,360 (2012-2013 rate) for a Level 1 audit and $6,170 (2012-2013 rate) for a Level 2 audit. Based on the 2012 applications volume date, this estimated that 20 per cent of Class IIb medical device applications will be newly subject to mandatory audit under this proposal, with approximately 70 per cent of these subject to a Level 1 audit and 30 per cent subject to a Level 2 audit. In 2012, 697 Class IIb applications were received, so if 20 per cent, or 139 applications, were audited as outlined above, this would cost the industry a total of $694,770 per annum.

Level 3 audits for AIMD and Class III implanted devices: The estimated cost of a Level 3 audit is $16,382[15] which is $10,212 more than the current Level 2 audit fee, reflecting the additional work to be undertaken for the Level 3 audit. This is a very significant increase

[11] Analysing the 468 AIMD and Class III applications received during 2012, it is estimated a total of 261 would be selected for a Level 3 audit (54 AIMD and 207 Class III applications). This is based on a sensitivity analysis which concluded that 50 per cent of Class III medical devices (those which are implantable) and 100 per cent of AIMD medical device applications will require a Level 3 audit – an average of 56% of all AIMD and Class III devices.

[12] This calculation assumes there will be no microbiology assessment for Level 3 audits. Microbiology assessments as part of application audits are typically undertaken for medical device disinfectants, which are Class IIb products and so are not affected by Level 3 audits. There were 16 Level 2 audits in 2012 which involved microbiology assessment.

[13] Analysis of the ARTG indicates that for AIMD and Class III devices, on average five separate ARTG entries are based on each quality management system certificate. Analysis by TGA's Office of Manufacturing Quality (OMQ) will be undertaken for the first Level 3 audit undertaken relating to a quality management system certificate, and not duplicated for the following four applications which will, on average, be received relying on the **same** quality management system certificate. On this basis it is assumed that only 20 per cent of Level 3 audits will, in practice, include an OMQ assessment (at a reduced cost for second and subsequent applications of $2,992). This possible reduction has **not** been factored in for the costings in this RIS.

[14] This costing calculates the **additional** cost of the Level 3 audit. The AIMD and Class III devices affected by the Level 3 audit would already be subject to a Level 2, with an associated audit fee of $6,170. The estimated full cost of a Level 3 audit is $16,382, but this costing includes only the additional $10,212, being the difference between the current cost of a Level 2 audit and the cost of a Level 3 audit under the proposed changes.

[15] The full cost of a Level 3 audit would be $22,974, but this has been reduced in this section by the cost of the publishing an AusPAR style document, which is included in Proposal B.

in costs, which would be experienced by an estimated 261 applications each year, costing the industry $4,275,609 per annum.

A Cost Recovery Impact Statement (CRIS) is currently being prepared by the TGA for medical devices. This includes assessment of actual TGA costs against the fees for these assessment tasks. While development of the CRIS is at an early stage, initial results indicate that the TGA is under-recovering against a range of premarket assessment processes including conformity assessment and audit fees. The outcomes of the CRIS however will also need to reflect business process reengineering aimed to increase the efficiency of TGA premarket assessment. While the existing fee structure is used for this costing, any changes to audit fees arising from the CRIS will flow through to these processes.

Proposal B - Publication of information about regulatory decisions

Proposal B increases transparency of TGA decision making, by publishing a summary of the decision made by the TGA in a format similar to the AusPAR.

This is likely to be quite an extensive document where the TGA decision is complex, such as when it is based on analysis of evidence through conformity assessment and application audit. Decisions for applications for inclusion on the ARTG which are not audited will not require an extensive document to be prepared, though these decisions will still be published with an explanation of the assessment process which the device underwent prior to inclusion.

Assumptions

For costing purposes, this proposal assumes:

- Publication of 2,970 decisions per annum, 945 of these are expected to be complex decisions requiring specific explanation of the decision made;[16]
- Complex decisions are estimated to take 7.5 hours to accurately document, including preparing the AusPAR style document, checking to ensure confidential information is not included, and liaison with the applicant to ensure accuracy prior to publication.
- Simple decisions are estimated to take 1.5 hours to complete, as there will be little to include in the AusPAR style document other than information included with the application.

Cost

The estimated cost of publishing decisions is $1,566,826 per annum, with 945 complex decisions at an estimated cost of $1,197 per decision, and 2,025 simple decisions at an estimated cost of $215 per decision. This results in an average cost per decision of $528.

[16] Based on 2012 data there was a total of 2,970 decisions, of which 945 would be complex decisions (200 conformity assessment decisions, and 745 audited applications). Note that all rejected conformity assessments and applications for ARTG inclusion are also assumed to be complex. All of these decisions will be captured in the above figures.

Proposal C - Removing the requirement for TGA conformity assessment for Australian manufacturers except for Class 4 IVDs

Proposal C would remove the requirement for Australian manufacturers to seek TGA conformity assessment. Australian manufacturers, like all manufacturers, would continue to be required to seek TGA conformity assessment. They would also still need to hold appropriate conformity assessment (such as certification from the European notified body) and would be subject to the mandatory audit requirements (including the new requirements outlined above) if using certification from a European notified body.

Assumptions

Due to the small numbers of Australian manufacturers, and the large variation in the type and cost of conformity assessments, costing of this proposal is subject to large variations from year to year, and so not necessarily representative.

For costing purposes, this proposal assumes:

- The TGA received 44 conformity assessment applications per annum;[17]
- There are total of 115 Australian manufacturers currently holding TGA conformity assessment certification;[18]
- Five per cent of Australian manufacturers produce AIMD or Class III devices (requiring design examination);[19]
- Two thirds of Australian manufacturers will not seek TGA conformity assessment, but rather use conformity assessment from a notified body;[20] and
- The cost of conformity assessment varies significantly depending on the nature of the assessment (from as little as $13,600 for a renewal of a Production Quality Management System Audit, to $51,200 for a new design examination). The actual fee will depend on the nature of the device and the assessment required.

Cost

If two thirds of Australian manufacturers opted not to continue with TGA conformity assessment, this may result in a reduced cost to industry (and a reduction in TGA fees) of between $448,301 and $650,662 per annum (with this variation relating to whether the applications were for changes to existing applications or applications for new devices).

Manufacturers holding quality manufacturing certification also need to undergo surveillance inspections every 12 to 18 months to maintain their certification, with an audit fee of $7,560. Given there are 115 Australian manufacturers, assuming two thirds do not seek to maintain their TGA certification, this would be a reduced cost to industry (and a reduction in TGA fees) of $390,274 per annum.

[17] This is based on 44 conformity assessment applications having been received from Australian manufacturers during 2012 (out of a total of 200 conformity assessment applications received). It is assumed that this number of representative of the expected applications volume per annum.
[18] The 115 Australian manufacturers were identified from TGA conformity assessment data.
[19] This is calculated on the basis that 6 of the 115 Australian manufacturers (5.2 per cent) currently maintain design examination certification with the TGA.
[20] The assumptions that two thirds of Australian manufacturers would opt for TGA not to undertake conformity assessment given the option is based on supposition only. No data is available to verify this figure.

In considering application and audit fees the savings to industry for this proposal (in the form of reduced revenue and workload for TGA) is estimated to range from $838,575 to $1,040,936 per annum.

<<< The assumptions that two thirds of Australian manufacturers would opt for TGA not to undertaken conformity assessment given the option is based on supposition only – any indication from industry which may assist in quantifying the actual behavioural effects which this change may enable would be appreciated. >>>

Summary

The following table summarises the costs outlined in the sections above:

Option 2 Proposal Element	Increase in TGA Costs	Reduction in TGA revenue	Net Cost to industry
Proposal A			
Mandatory Class IIb audits	$585,480		$585,480
Level 3 audits	$4,275,609		$4,275,609
Proposal B			
Publication of decisions	$1,566,826		$1,566,826
Proposal C			
Abolish TGA conformity assessment for Australian manufacturers		$1,040,936	-$1,040,936
Total	**$6,427,915**	**$1,040,936**	**$5,386,979**

Cost analysis provided by industry

<<< To be inserted following consultation, if appropriate data is received >>>

<<< This may relate to the compliance costs and expected savings to industry >>>

Option 3 - Expand TGA mandatory conformity assessment for AIMD and Class III implantable medical devices and allow third party conformity assessment for other devices except Class 4 IVDs

This Option parallels Option 2 in a number of areas.

The key difference between Option 2 and Option 3 relates to Proposal A. Rather than introducing a Level 3 audit for AIMD and Class III implantable devices, under Option 3 manufacturers would be required to seek TGA conformity assessment for these devices. Option 3 also omits the publication of decisions (as outlined in Option 2 Proposal B). If that were to be included the additional costs, as outlined above, would apply.

Mandatory TGA conformity assessment for AIMD and Class III implantable medical devices

Assumptions

For costing purposes, this proposal assumes:

- 261 applications for ARTG inclusion received by the TGA each year for AIMD and Class III implantable medical devices, which under this proposal would require TGA conformity assessment;
- Conformity assessment fees for these applications may range from $58,400 to $77,200[21] per application, depending on the conformity assessment procedure applied for, with an average cost of $67,800. These are higher than the conformity assessment fees assessed for Australian manufacturers, as it is assumed none of these manufacturers hold current TGA conformity assessment, and as Class III devices all applications will require both a design examination and quality management system certification.
- These figures do not take into account:
  - fee reductions which may apply, such as where European notified body certification exists and can be used to support an abridged assessment;
  - savings on audit fees when applying for ARTG inclusion, as Class III devices supported by TGA conformity assessment certification are not subject to mandatory audit requirement, given the rigorous assessment these devices have already undergone with the TGA;
  - the cost to manufacturers of maintaining TGA conformity assessment certification, such as fees for onsite audits, variations, etc; or
  - behavioural impacts, such as manufacturers choosing not to supply devices in Australia due to the requirement for TGA conformity assessment.

Given these assumptions, the cost to manufacturers of requiring TGA conformity assessment for AIMD and Class III implantable medical devices would amount to an estimated $17,695,800 in fees industry would pay the TGA for conducting conformity assessment procedures. This cost incurred is before any of the affected medical device applications are included in the ARTG and allowed to be sold to the Australian public.

[21] Figures based on minimum conformity assessment requirements for Class III and AIMD medical devices- Schedule 3, Part 1- Full quality management system and design examination, and Schedule 3, Part 2- Type examination, and the least expensive, Schedule 3, part 4- production quality management system audit.

Summary

The following table summarises the costs outlined above:

Option 3 Proposal Element	Increase in TGA Costs	Reduction in TGA Revenue	Net Cost to industry
Mandatory Class IIb audits	$585,480.00		$585,480
Mandatory conformity assessment for AIMD and Class III implantable	$17,695,800		$17,695,800
Abolish TGA conformity assessment for Australian manufacturers		$1,040,936	-$1,040,936
Total	**$18,281,280**	**$1,040,936**	**$17,240,344**

While the introduction of TGA conformity assessment for all Class III and AIMD implantable medical devices lowers the risk of inappropriate conformity assessment certification for these high risk devices, this approach imposes an unacceptably high financial cost to medical device industry. As this risk can be managed through the less onerous and expensive Level 3 audit approach, implementation of option 3 is not recommended.

Implementation and review

It is proposed that the proposed arrangements come into effect on 1 July 2015 for the following reasons:

- significant steps in confidence building with notified bodies in 2013 and 2014 will have been completed (noting that option 2 allows established confidence building activities to be strengthened and maintained);
- it coincides with the start of the financial year where application and application audit fees are adjusted due to indexation;
- it allows sufficient time for TGA to consult on implementation details with stakeholders and finalise transition arrangements.

The TGA proposes to implement the proposal changes to premarket assessment requirements for medical devices in the following way:

- Through an amendment to the Therapeutic Goods (Medical Devices) Regulations 2002 and the Therapeutic Goods (Charges) Regulations 1990, implemented on 1 July 2015.
- A two year transition period is proposed for the publication of information relating to TGA decisions in order to stagger this proposal as outlined below.
- It is expected that all aspects of the proposal to change premarket assessment for medical devices will be implemented by 1 July 2017.

Decision to be published	Publication Date
Successful and unsuccessful applications for inclusion in the ARTG relating to Class III, AIMD, some Class IIb implantable or long term surgically invasive medical devices and Class 4 IVDs;	1 July 2015
Successful and unsuccessful conformity assessment decisions relating to Class III, AIMD, Class IIb implantable or some long term surgically invasive medical devices and Class 4 IVDs;	1 January 2016
Successful and unsuccessful applications for inclusion in the ARTG relating to Class I Measurement, Class I sterile, Class IIa, Class IIb medical devices and Class 3 and Class 2 IVDs; and	1 July 2016
Successful and unsuccessful conformity assessment applications relating to Class I Measurement, Class I sterile, Class IIa, and Class IIb medical devices.	1 January 2017

- From 1 July 2015, it is expected that Australian manufacturers can choose whether or not to submit conformity assessment applications with the TGA for all medical devices other than Class 4 IVDs.
- From 1 July 2015, applications selected for mandatory audit will be charged a fee commensurate with the level of assessment being conducted under the audit.
- TGA will consult with stakeholders on:
  - Implementation details;
  - A communication strategy;
  - Guidance material development;
- The proposal will be continually monitored throughout the transition period and post implementation to ensure that the risk based approach to medical device regulation is consistent with international standards and emerging technology and literature.
- In order to maintain the current best regulatory practice it is proposed that the list of medical devices mandated for the application audit instrument would be reviewed on an ongoing basis, in consultation with stakeholders and amended. However, the list would be amended more frequently, where required, to address emerging issues, post market information such as recalls and current literature findings in a timely manner.
- Finally, the indexation of application and application audit fees will continue to be monitored on an annual basis to ensure that the Australian public has timely and affordable access to medical devices and that application fees reflect the level of regulatory oversight provided to the product.

Transition arrangements

Transition arrangements can be complex and therefore it is proposed that these be subject to further consultation. However, the preliminary proposal is that:

- applications for ARTG inclusion submitted prior to 1 July 2015 but for which a decision has not yet been made are not subjected to the new arrangements under proposal A and C commencing 1 July 2015;
- Information not to be published for any application submitted before 1 July 2015.

Consultation

Changes to premarket assessment requirements for medical devices - January to March 2013

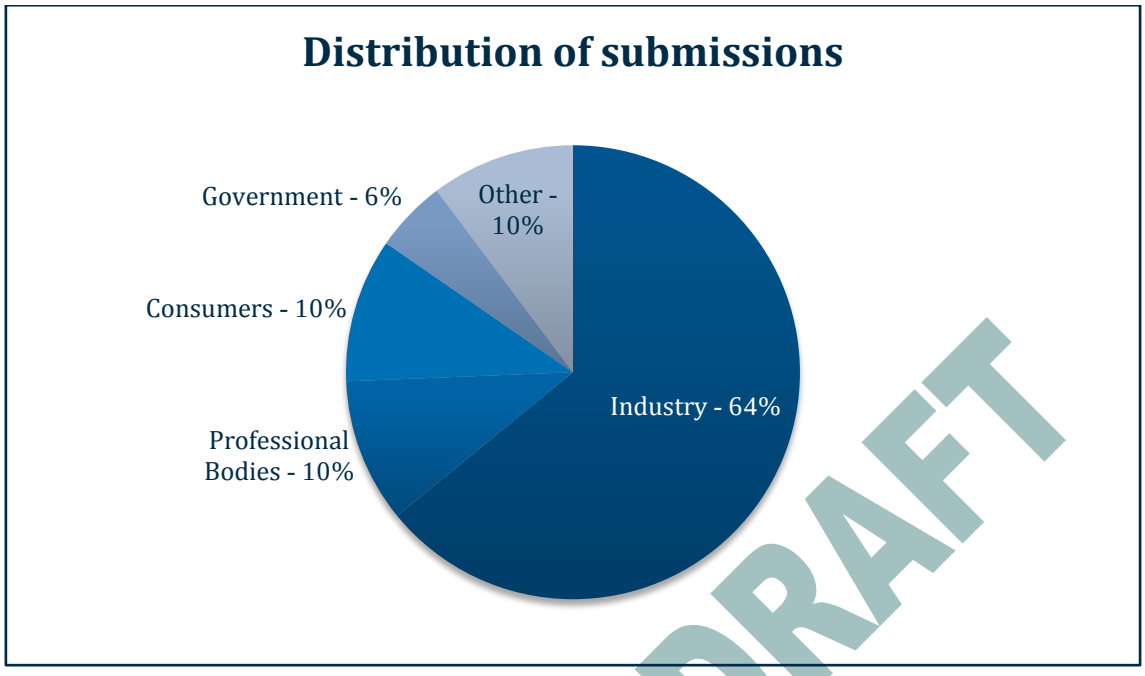
As outlined above, on 14 January 2013 the TGA released *Changes to premarket assessment requirements for medical devices: Proposal Paper*, with consultation on the paper open through to 15 March 2013.

The consultation was aimed at the TGA's currently identified externals stakeholders in order to provide a comprehensive analysis of the proposal. Consultation occurred through publication of the paper on the TGA website[22]. It was also emailed to members of the TGA's Regulatory and Technical Consultative Forum on Medical Devices (known as RegTech), and members of the medical device reforms reference group, established to provide advice to the TGA on the Blueprint medical device reforms. The Advisory Committee on Medical Devices (ACMD) meeting 15 March 2013 also discussed the consultation proposal.

The TGA received 39 submissions from a varied stakeholder group including medical device industry (including manufacturers, importers, and suppliers), consumer groups, academics, professional bodies, healthcare professionals, engineers, regulatory consultants and government organisations. The submissions received are available on the TGA website and a summary of the submissions received is included at **Attachment D: Summary of consultation on changes to premarket assessment requirements for medical devices**.

[22] <http://www.tga.gov.au/newsroom/consult-medical-devices-premarket-assessment-130114.htm>

The following graph outlines the distribution of submissions by stakeholder groups:



As expected, various stakeholders commented on the most relevant proposals according to their area of interest, expertise and cost impact. Proposal A was commented on the most, and proposal C was least commented on. While the industry sector was not overly supportive of the proposal to introduce a Level 3 mandatory audit, it was generally supportive of the proposals relating to the publication of information relating to TGA decision making. It was very supportive of the proposal to allow for third party conformity assessment for Australian manufacturers, stating the proposal should be broadened to cover all classes of medical devices, not just low-medium risk. The remaining stakeholders were very supportive of Proposals A and B but more cautious about Proposal C.

A summary of the key comments are below:

Proposal A: Mixed support. Comments included:

- Targeting of mandatory audit:
  - Not all Class IIb implantable or long term surgically invasive devices are of significant risk and therefore it was suggested TGA consider refining that list to, for example, excluding dental implants;
  - Disinfectants and sterilants should continue to undergo Level 2 audits (as the proposal suggested this drop to a Level 1 audit); and
  - Concerns were raised over the quality of EU notified bodies;
- Level 3 audit:
  - Supported by consumers, who considered this providedan appropriate balance between costs to patients if adverse events occur and sponsor profits;
  - Not generally supported by industry due to the increased cost and assessment time. (The MTAA submission suggested that in some cases this would result in a 693 per cent cost increase.)

Proposal B: Majority support- comments included:

- Trial publication of Class IIb implantable and AIMD long term implantable Class III medical devices first;
- Only publish successful applications for inclusion in ARTG;
- Should be similar to AusPAR;
- Concerns included:
  - Publication of confidential information;
  - Publication of rejected applications for conformity assessments may damage commercial interests;
  - Publication of decisions delaying ARTG inclusion;
  - Publication of rejected and withdrawn decisions damaging industry reputation.

Proposal C: Majority support- comments included

- The proposal should go further and abolish TGA conformity assessment for all devices (especially after confidence building with the EU).

Regulation Impact Statement exposure draft

<<< Description of outcomes of RIS consultation to be completed following close of submissions on exposure draft consultation >>>

A summary of the submissions made on the exposure draft of this RIS is included at **Attachment F: Summary of consultation on Regulation Impact Statement exposure draft, May 2013.**

Conclusion

This RIS has considered the merits of the following three options:

1. Taking no action to change premarket assessment requirements for medical devices;
2. Changing premarket assessment of medical devices through targeted selection of Class IIb implantable and long term surgically invasive medical devices for mandatory audit, and targeted selection of Class III and AIMD devices for Level 3 audit, staged publication of all medical device decisions and abolition of TGA conformity assessment for all medical devices (except Class 4 IVDs);
3. Changing premarket assessment of medical devices to mitigate all foreseen risks through selecting all Class IIb implantable and long term surgically invasive medical devices for mandatory audit, subjecting all implantable Class III and AIMD medical devices for full TGA conformity assessment, and abolishing TGA conformity assessment for all medical devices (except Class 4 IVDs).

In addition, the impact of these options on consumers, the medical device industry, health professionals and government agencies has been analysed, together with the costs and benefits. Extensive consultation with industry and other stakeholders has occurred on the

proposed amendments to the regulatory model and will continue to occur throughout the implementation phase.

The table below summarises how each proposed option addresses the key issues identified in the Problem section above and the objectives identified in the Objective section above:

	Option 1	Option 2	Option 3
Key issues (as outlined in the Problem section from page 11)			
Increased level of premarket scrutiny			
· AIMD and Class III implantable	û Not addressed	ü Level 3 audit ü	ü Expanded requirement for ü TGA conformity ü assessment
· Class IIb implantable	û Not addressed	ü Expanded ü mandatory ü audit requirement[23]	ü Expanded ü mandatory audit requirement[23]
Transparency of decision making	û Not addressed	ü Publication of TGA decisions	ü Publication of TGA decisions
Requirements for TGA conformity assessment for Australian manufacturers	û Not addressed	ü Abolition of requirement	ü Abolition of requirement
Objectives (as outlined in the Objective section from page 13)			
Primary objective: greater assurance that higher risk medical devices approved do not compromise public health and safety	û Not addressed	ü Level 3 audit ü and expanded ü mandatory audit requirement	ü Expanded ü requirement for ü TGA conformity assessment

[23] Note that the achievement of increased premarket scrutiny of Class IIb implantable is rated more highly for Option 2 than Option 3. This is because Option 2 provides for tighter targeting and flexibility to respond to emerging issues given the proposal to develop an instrument to identify affected medical devices. Option 3 provides for the expansion of mandatory auditing to all Class IIb implantable devices through amendment of Regulation 5.3 to capture all implantable and long term surgically invasive devices captured by classification rule 3.4.

	Option 1	Option 2	Option 3
Secondary objectives:			
(a) timely availability of medical devices	ü ü ü No changes to timeframes for availability	ü ü Audits will extend times frames for targeted devices (weeks to months)	ü TGA conformity assessment will extend times frames for targeted devices (months to years)
(b) minimising regulatory burden and costs	ü ü ü No changes to regulatory burden and no additional costs	ü ü Increases regulatory burden and significant additional costs	ü Greater increase to regulatory burden and very significant additional costs
(c) target emerging risks	û Not addressed	ü ü Instrument for additional mandatory audits allows risk management over time	û Not addressed - options proposed are static
(d) promoting alignment of international medical device regulation	û Not addressed	ü ü Minimises duplication of regulatory activity	ü Duplication of conformity assessment for AIMD and Class III implantable devices

* Note: the more ticks in a cell the greater the effect of the option on the key issue or objective. Crosses indicate not effect.

Based on the above table, and the relative cosy of the options as outlined in the Costs and benefits section above, Option 2 is recommended as the appropriate response.

<<< This conclusion section is included as a draft for consultation – it is expected it will be expanded and revised based on feedback provide through consultation >>>

Attachments

Attachment A: Regulation of medical devices in Australia

Under the *Therapeutic Goods Act 1989*, medical devices must be included on the Australian Register of Therapeutic Goods (ARTG) prior to supply in Australia unless exempt from that requirement. In order to be included on the ARTG, devices must have the necessary conformity assessment certification to ensure they are of acceptable safety and quality, and perform as intended. An application must be made to the TGA to include the device on the ARTG, supported by the appropriate conformity assessment certification. The level of assessment conducted by the TGA at the point of application for ARTG inclusion depends on the following:

- the risk classification of the device, against the following range:
  - Class I: low risk;
  - Class I - supplied sterile and/or incorporating a measuring function: low–medium risk;
  - Class IIa: low–medium risk;
  - Class IIb: medium–high risk;
  - Class III: high risk; and
  - AIMD (Active Implantable Medical Devices): high risk;
- whether the TGA or an overseas body issued the conformity assessment certificate;
- whether the certificate was issued under the provisions of trade facilitation agreements in place with European countries;[24] and
- whether there are any concerns with the application that would require the TGA to request further information for review prior to inclusion.

Conformity assessment

Conformity assessment is the systematic examination of evidence generated, and procedures undertaken, by the manufacturer to determine that a medical device is safe and performs as intended and therefore conforms to the Essential Principles.

The Essential Principles set out the requirements relating to the safety and performance characteristics of medical devices. There are six general Essential Principles that apply to all devices and a further nine Essential Principles about design and construction that apply to devices on a case-by-case basis:

General Principles that apply to all devices:

1. use of medical devices not to compromise health and safety;

[24] Agreement on Mutual Recognition in relation to Conformity Assessment, Certificates and Markings between Australia and the European Community or the European Free Trade Association, as in force from time to time.

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; and
6. benefits of medical devices to outweigh any side effects.

Principles about design and construction:

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; and
15. principles applying to IVD medical devices only.

The regulatory framework provides flexibility for manufacturers and caters for technological advances and changes in the development of new medical devices. It does not mandate the means by which a manufacturer must prove that they have met the Essential Principles.

It is the responsibility of the manufacturer to gather the evidence required to demonstrate compliance with the Essential Principles. In order to do that, manufacturers must comply with a minimum set of conformity assessment procedures defined in legislation which are based on the level of risk of the device:

- ***Class I:*** Conformity assessment for Class I (low risk) medical devices is self assessed by the manufacturer. They must apply a conformity assessment procedure and prepare an Australian Declaration of Conformity, however, it does not need to be submitted to the TGA prior to submitting a device application. Once included on the ARTG, the sponsor must provide the evidence to the TGA upon request.
- ***Class IIa and Class IIb:*** Conformity assessment for Class IIa (medium risk) and Class IIb (medium – high risk) medical devices provides for an initial and ongoing review of the manufacturer's quality management system (QMS) by a Conformity Assessment Body (CAB).
- ***Class III:*** Conformity assessment for Class III (high risk) medical devices has two elements:
  - initial and ongoing review of the manufacturer's quality management system by a CAB; and
  - a review of the design of the device by a CAB.

For review of the manufacturer's quality management system by a CAB (required for Class IIa, IIb and III medicinal devices) the manufacturer has two options:

- A full quality assurance procedure, where all clauses of the applicable QMS standard must be applied, including design and development activities; or
- A production quality assurance procedure, where all clauses of the QMS standard are applicable, but clauses relating to design and development activities can be excluded.

There are two methods of review of the design of the device required for Class III medical devices, which depend on the type of quality assurance procedure applied by the manufacturer:

- ***Design Examination:*** where the manufacturer has applied a full quality assurance procedure, the CAB conducts an examination of the design dossier (consisting of technical documentation, design files, risk analysis etc.) to assess compliance with the Essential Principles; or
- ***Type Examination:*** where the manufacturer has applied a production quality assurance procedure, the CAB conducts an examination of a representative sample of each Class III medical device. Testing can be conducted by the CAB, or the CAB can conduct tests on the device at the manufacturer's site and supervise or review the testing, or the CAB can subcontract the testing to an accredited test laboratory.

The most common conformity assessment procedure applied by manufacturers of Class III medical devices is a full quality assurance procedure including design examination. The production quality assurance procedure, including type examination, is used less often due to inherently higher costs associated with conducting tests on individual medical devices each time the design of the device is changed.

This system of review is consistent with the framework recommended by the GHTF.[25]

In Australia the TGA is the only CAB allowed to perform conformity assessments. However, certification issued by European CABs (also known as Notified Bodies) may be accepted by the TGA under the *Therapeutic Goods Act 1989* and regulations for most medical devices, except for:

- a subset of high risk devices (such as those containing tissues of animal origin or medicines); and
- medical devices made by Australian manufacturers.

In those instances, a conformity assessment certificate issued by the TGA is required which involves a conformity assessment review of the manufacturer and devices.

A TGA-issued Conformity Assessment Certificate can be used to support inclusion in the ARTG of the medical devices covered by that certificate and may also support market authorisation by other overseas regulators.

[25] GHTF was a partnership between regulatory authorities and the regulated industry and is comprised of five Founding Members: European Union, United States, Canada, Australia and Japan. The International Medical Device Regulators Forum (IMDRF) commenced from February 2011 to build on the previous work of the GHTF, and to accelerate international medical device regulatory harmonization and convergence.

Conformity assessment reviews of the technical and QMS elements involve desk-top assessments of the evidence provided. This is the internationally recognised review methodology and does not specifically provide for testing of individual medical devices before marketing approval (although such testing may be conducted during a Type Examination described above). The conformity assessment methodology allows for the safety, performance and quality of a device to be determined for all products manufactured. Testing of individual devices only provides information in relation to the particular device, or batch of devices, tested.

Review of the manufacturer's QMS

Under the full quality assurance procedures, manufacturers of Class III devices are required to implement a quality management system (QMS) that ensures appropriate control over the design, production, packaging, labelling and final inspection of the device, and implementation of an appropriate ongoing monitoring system.

In certain circumstances, following a desktop review of the manufacturer's QMS documentation, a CAB (including the TGA) may elect to undertake an on-site audit to satisfy itself that the elements required in the QMS are in place and operational. The TGA may also elect to do its own on-site audit for products with overseas certification if, following a desk top assessment, the evidence presented does not adequately cover the areas in which the TGA has an interest.

The term 'audit' (termed an inspection by other agencies) means an on-site examination of the systems, documents, processes, equipment and premises used in order to determine compliance with the requirements of the relevant manufacturing standard. A successful audit is one component of the process leading to the manufacturer of a Class III device being issued a TGA Conformity Assessment Certificate (the other component being a Design Examination).

The technical aspect of the audit is a focussed and well documented sampling exercise that includes assessment of receipt and storage of raw materials and components; verification of their compliance with specifications; control of production processes and finished product verification; and storage and release procedures. This is combined with in situ observations of the suitability of the premises and the company's routine manufacturing practices. Auditors assess the company's production systems against the relevant standards. Nontechnical factors that may influence company directions (e.g. financial position or management attitude) fall outside the scope of a conformity assessment audit.

By necessity, the actual date of an audit of an overseas manufacturing facility is arranged with the auditee; this can be months in advance of on-site attendance. The TGA cannot exercise any of its regulatory powers outside Australia. TGA officers visiting overseas manufacturing sites are invitees who have no power to remain on site without the permission of the auditee. If TGA officers were to detect serious failings of the quality system (with significant risk of producing harmful product), or observe fraud or falsification of products or data at an overseas manufacturing site, this would be reported to the regulatory authority operating in that country. Any further inspections or investigations would then rest with that authority.

During any audit (either of an Australian or overseas manufacturer), it is common to find deviations from the prescribed standards. Deviations from these standards are so called 'nonconformities' that are classified as Major or Minor according to the risk they might represent to the end-user of the devices being manufactured. Major non-conformities are those that may produce a product that is unsafe or of substandard quality. Minor non-

conformities are minor deviations from the requirements of the standard that may lead to the production of sub-optimal products if not corrected.

The discouragement, detection and prosecution for unlawful manufacturing activities must involve the regulatory authority operating in that country. The TGA can conduct a short notice or unannounced audit of an Australian manufacturer if alerted by overseas intelligence (or any other source) to potential irregularities.

Review of the design of the device

For Class III (high risk) devices, and where the manufacturer has applied a full quality assurance procedure, technical documentation relating to the design of the *specific* device (design dossier) is reviewed to demonstrate compliance with the Essential Principles.

The documentation reviewed during a design examination includes, but is not limited to, the following:

- details of the processes, systems and measures used for controlling, monitoring and verifying that at each stage of the design process, the device complies with the applicable provisions of the essential principles;
- details of the design specifications for the kind of device, including:
  - compliance with any standards that have been applied;
  - the results of the risk analysis carried out;
- a copy of the clinical evidence;
- a copy of the information provided with the device (e.g. labels, instructions for use etc); and
- unlike the QMS audit, the design examination conducted by the CAB is conducted solely as a desk top review of the documentation and does not involve an on-site audit component.

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.

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 10per cent 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).

Market authorisation (inclusion on the ARTG)

The Australian-based sponsor of a medical device is responsible for making an application for inclusion of a medical device in the ARTG, not the manufacturer of the device (although the manufacturer may be the sponsor if they are Australian-based).

In Australia, acceptable conformity assessment certification is required before an application can be made to include a medical device in the ARTG – that is, a Conformity Assessment Certificate must be from an appropriate EC Notified Body, or must have been issued by the TGA. Under the devices regulatory framework, no certification from other countries outside Europe, including the USA, can be accepted.

Medical devices can be included in the ARTG once a proper application is made, and the product has undergone the required conformity assessment certification. Some applications must be subject to an audit (which involves checking some or all aspects of the application and certification) and other applications may be selected for audit at the TGA's discretion.

The nature of the audit and the documentation required for assessment will depend on the level of risk associated with the medical device.

Standard conditions apply to all medical devices included on the ARTG. One of these is for a sponsor of a device to keep distribution records of all their medical devices which will include records of distribution centres, hospitals and export countries to which the device has been supplied. This does not extend to records of the individual users of medical devices (individual doctors or patients). For Class III (high risk) devices, these distribution records must be kept for 10 years and must be provided when requested by the TGA.

It is a requirement that the sponsor keep an up-to-date log of information about the performance of the device which includes any information of which the sponsor is aware relating to:

- any malfunction or deterioration in the characteristics or performance of the device;
- any inadequacy in the design, manufacture, labelling, instructions for use or advertising materials of the device;
- any use in accordance with, or contrary to, the use intended by the manufacturer of the kind of device that has led to any complaint or problem in relation to the device, no matter how minor;
- information that indicates that the device does not comply with the essential principles; and
- information that indicates that an overseas issued conformity assessment certificate has been restricted, suspended, revoked or is no longer in effect.

A condition that is routinely applied to Class III devices is that the sponsor must provide three consecutive annual reports to the TGA following inclusion of the device in the ARTG. The annual report must include all complaints relating to the device and problems with the use of the device that have been received by the sponsor over the year.

Irrespective of any conditions that are imposed on the inclusion of a medical device in the ARTG, it is an offence under the *Therapeutic Goods Act 1989* for a sponsor of a medical device that is included on the ARTG not to report to the TGA:

- specified information relating to a problem with the device that might lead, or might have led, to the death or to a serious deterioration in the health of a patient or a user of the device;
- any information relating to any technical or medical reason for a malfunction or deterioration of a device that has led the manufacturer to take steps to recall the device;
- information that indicates that the device of that kind does not comply with the essential principles; or
- information that indicates that an overseas-issued conformity assessment certificate has been restricted, suspended, revoked or is no longer in effect.[26]

Postmarket surveillance powers and systems for medical devices

The Australian regulatory framework for medical devices includes provision for postmarket monitoring by the TGA, including: checking evidence of conformity; conducting periodic inspections of manufacturers' quality management systems and technical documentation; and imposing specific requirements for manufacturers and sponsors to report, within specified timeframes, adverse incidents involving their medical devices. Postmarket monitoring by the TGA is carried out to ensure the ongoing regulatory compliance and safety of medical devices supplied to the Australian market.

In support of the TGA's postmarket monitoring activities, the sponsor of a medical device has ongoing responsibilities once a device has been included in the ARTG. These statutory responsibilities include that the sponsor must report to the TGA adverse incidents; overseas regulatory actions; and the results of investigations undertaken by the manufacturer. The sponsor must also maintain distribution records.

Sponsors are required to report certain individual adverse incidents involving their medical devices to the TGA within statutory timeframes that depend on the seriousness of the incident. Adverse incidents involving serious public health risks are to be reported within 48 hours. Serious adverse incidents that resulted, or may have resulted in death or serious injury are to be reported within 10 working days. Other adverse events that resulted in injury or may have resulted in injury are to be reported within 30 working days. The TGA reviews all individual adverse incident reports and undertakes its own investigation if required. Sponsors of Class III medical devices must also keep an up to date log of information about the performance of the device and provide annual reports to the TGA as described in section on market authorisation above.

Manufacturers also have ongoing obligations in respect of their devices which will vary depending on the conformity assessment procedures that apply to the particular device. The manufacturer also has specific obligations which include cooperation with the TGA in any review to determine whether conformity assessment procedures have been properly applied to the devices covered by a conformity assessment certificate. Manufacturers are also required to notify the TGA of any plan for substantial changes to the quality management systems, the product range covered by those systems or the design of the devices covered by a conformity assessment certificate. Failure to comply with these requirements may result in revocation of a Conformity Assessment Certificate by the TGA and the consequent cancellation of the devices from the ARTG.

[26] See section 41MP of the *Therapeutic Goods Act 1989*.

The manufacturer is required to have, as part of its quality management system, a procedure for gathering information on the performance and safety of the device in the postmarket phase and to ensure any information gathered continues to demonstrate compliance of the device with the Essential Principles throughout the product's life. This procedure includes the requirement for the manufacturer to maintain a system for receiving and investigating problem reports and complaints and for undertaking corrective action for a device.

Using data generated from such programs (such as safety reports, including adverse event reports, results from published literature, any further clinical investigations and formal postmarket surveillance studies), a manufacturer is required to periodically review performance, safety and the benefit-risk assessment for its device through a clinical evaluation, and update the clinical evidence accordingly. This ongoing clinical evaluation process should allow manufacturers to communicate with conformity assessment bodies and regulatory authorities any information that has an important bearing on the benefit-risk assessment of the device or that would indicate a need for labelling changes regarding contraindications, warnings, precautions or instructions for use, etc. These reviews by the manufacturer are expected to be assessed by notified bodies or those undertaking re-certification processes.

Just as with medicines, medical devices are authorised with an understanding of the expected type and frequency of side-effects. Postmarket vigilance and monitoring systems do not require expected side-effects to be reported to the regulator as these are a normal part of the use of the medical device. The TGA provides guidance as to the definition of a reportable adverse event for medical devices. This guidance (at section 22 of the Australian Regulatory Guidelines for Medical Devices[27]) states that side effects that are clearly identified in the manufacturer's Instructions for Use or labelling, or are clinically well known as being foreseeable and having a certain functional or numerical predictability when the device was used as intended, need not be reported.

The TGA's powers in relation to the keeping of records and reporting of adverse events and other safety matters are those set out in the *Therapeutic Goods Act 1989* and are limited to sponsors and manufacturers. There is mandatory reporting for sponsors and manufacturers of life-threatening or serious public health related adverse events and non-mandatory reporting for other events.

There is no requirement under the legislation or relevant guidelines to report *expected* adverse events. Since rupture of breast implants is an expected event, sponsors and manufacturers are not required nor expected to routinely report these events to the TGA.

The TGA's powers do not include the regulation of clinical practice, including surgical practice, or matters relating to doctor-patient consultations. The Medical Board of Australia is responsible for all matters relating to the regulation of medical practitioners in Australia.

Reporting of adverse events by users is voluntary. The relevant TGA guidelines make it clear that users are encouraged to report events associated with the use of a medical device to either the sponsor or to the TGA. The reporting by health professionals, patients and the public is facilitated by the availability of a Users' Medical Device Incident Report on the TGA website and information provided directly to health professionals through a range of mechanisms about how and when to report medical device adverse events.

[27] <http://www.tga.gov.au/pdf/devices-argmd-p3.pdf>

Thus, under the current regulatory framework, the capacity of the sponsor and/or manufacturer to provide comprehensive information to the TGA about adverse events and for the TGA to collect such information depends, to some extent, on relevant information being provided by those who have direct experience of those events, that is, patients and health professionals.

As a result, the adverse events reported to the TGA by healthcare professionals and consumers are limited to those that are reported voluntarily.

All adverse event reports or complaints received by the TGA are entered into a database. All reports and complaints are risk-assessed for frequency, severity and detectability by the TGA. This risk assessment is undertaken by a panel of clinicians and scientists within the TGA to determine if investigation is required. All reports are reviewed by an independent panel of experts, the Advisory committee on the Safety of Medical Devices (ACSMD),[28] which provides advice regarding whether the investigation was sufficiently thorough and whether reports should be investigated further. If MDIRC considers that there are issues that require further investigation, the TGA will reopen reports and re-investigate.

The outcomes of the TGA's investigations may result in product recovery (recalls); or hazard and safety alerts; or product modification/improvement by a manufacturer; or surveillance audits of manufacturing sites.

A safety alert is advice regarding a specific situation with respect to a medical device which, whilst performing to meet all specifications, might present an unreasonable risk of substantial harm if certain specified precautions in regard to its use are not observed. A hazard alert is specific to implantable medical devices and involves the distribution of precautionary information about an implanted device where there is no stock to be recalled and all affected devices are already implanted.

The TGA can take action[29] to suspend a device from the ARTG where, for example, the outcomes of the TGA's investigations indicate that there is a potential risk of death, serious illness or serious injury if the device continued to be included in the Register and can cancel a device from the ARTG if satisfied, for instance, that the safety or performance of the device is "unacceptable".

The TGA coordinates approximately 500 recalls of medical devices each year. The vast majority of recalls are undertaken voluntarily by the sponsor in cooperation with the TGA.

The TGA relies on the Uniform Recall Procedure for Therapeutic Goods (URPTG)[30] in the management of recalls. The URPTG is the result of an agreement between the therapeutic goods industry and Commonwealth and state/territory health authorities. Its purpose is to define the action to be taken by health authorities and sponsors when therapeutic goods are to be removed from supply or use, or subject to corrective action for reasons relating to their quality, safety, efficacy or performance.

[28] ACSMD consists of experts in consumer issues and numerous medical specialties including nuclear science and biomedical physics, oral and maxillofacial surgery, nursing, biomedical engineering, anaesthesia, orthopaedic surgery, cardio-thoracic and transplant surgery, cardiology and epidemiology and biostatistics.

[29] Under the *Therapeutic Goods Act 1989* powers to take regulatory action are conferred on the Secretary of the Department of Health and Ageing. Those powers are exercised by officers of the TGA occupying positions to which relevant regulatory powers have been delegated by the Secretary.

[30] <http://www.tga.gov.au/industry/recalls-urptg.htm>

In voluntary recalls, the TGA expects that sponsors will act in accordance with the URPTG. In mandatory recalls (that is where the powers under the *Therapeutic Goods Act 1989* are used), the TGA will usually require sponsors to comply with particular parts of the URPTG. No recall should be undertaken without consultation with the TGA and without the agreement of the TGA on the recall strategy. The text of recall letters needs to be approved by the TGA and must be despatched by the sponsor within 48 hours of receiving such approval.

In practice the TGA decides on a case by case basis whether to allow a sponsor to recall medical devices voluntarily or whether the TGA should exercise its statutory recall powers. As noted above, the vast majority of recalls are voluntary. This is for both practical and legal reasons. The TGA cannot exercise its statutory recall powers unless certain criteria are met, for instance that it appears to the TGA that the quality, safety or performance of the device is "unacceptable".[31] Moreover, any decision to mandate a recall would be subject to internal and Administrative Appeals Tribunal review if the sponsor chose to challenge the basis for the recall.

A voluntary recall at the instigation of a sponsor of a device in relation to which a potential safety issue has been identified can be implemented very quickly and effectively. The TGA would only be likely to exercise its statutory powers where it appeared that the sponsor was not prepared to initiate a recall or that a sponsor-initiated recall was not being managed appropriately and the criteria for exercising those powers were met.

Whether the recall is voluntary, or the result of the TGA exercising its statutory powers, the sponsor cannot as a matter of law be required (for obvious reasons) to recall any devices that have actually been implanted. In the case of implantable medical devices, the obligations of the sponsor are limited to recalling devices that have been supplied to hospitals and surgeons and others to whom they have been distributed.

Only in the case of a statutory recall can the TGA direct the sponsor to inform the public or particular persons about the circumstances giving rise to the recall. Because the sponsor will not normally deal directly with those implanted with the device, or have access to the relevant personal information, this power could not be used to require the sponsor to contact those with implanted devices.

The TGA has no power (even in the case of a statutory recall) to require surgeons to contact their patients with implanted devices of the kind recalled to either advise them of the recall or to ensure that all patients consult the surgeon if they have any concerns about the implanted device. However, in appropriate cases, the TGA will directly contact relevant professional societies and provide public information on the TGA website directed to those who have the implanted device, to encourage appropriate clinical review.

The TGA has no regulatory authority to conduct or commission clinical research involving individual patients to investigate the impact on health outcomes from the use of a device included on the ARTG. The TGA may conduct its own tests, generally in accordance with accepted international standards, on a particular device in order to evaluate any specific concerns about the manufacturing quality or performance of the device itself.

[31] This would be grounds for cancelling the device from the ARTG.

Attachment B: Proposed changes to European Union Medical Devices Directive

On 26 September 2012, the European Union (EU) Commission released a package of proposed reforms of medical device and in vitro diagnostic (IVD) medical device regulation in Europe.

The EU is proposing updated regulations on medical devices to ensure these products are safe, and can be freely and fairly traded throughout the EU. This involves consolidating the three existing directives on medical devices, Active Implantable Medical Devices (AIMD) and IVDs, into two new directives with three overall objectives:

- to ensure a high level of protection of human health and safety;
- to ensure the smooth functioning of the internal market; and
- to provide a regulatory framework which is supportive for innovation and the competitiveness of the European medical device industry.

Underpinning these broad objectives are a series of specific objectives:

- ***Uniform control of notified bodies:*** ensuring the legal requirements concerning the premarket evaluation applied and implemented effectively in all member states in a consistent and efficient way, with
  - notified bodies designated only for the assessment of devices or technologies which correspond to their proven expertise and competence, and
  - the position of notified bodies vis-à-vis manufacturers is strengthened with all notified bodies following the same high standards and criteria when they assess the conformity of medical devices;
- ***Enhanced legal clarity and coordination in the field of postmarket safety:*** ensuring complete information regarding safety issues and enhancing coordination of competent authorities regarding incidents and non-compliant products. The aim is to avoid duplication of work and inconsistent reactions to the same problem in different Member States.
- ***Cross sectoral solution of "borderline" cases:*** the relevant legislations need to be clearly delimited from each other. Moreover, experts from different regulatory fields may need to discuss the question together. The aim is to set up a mechanism involving other relevant regulatory authorities (pharmaceuticals, biocides, food, cosmetics etc.) which would allow for the EU-wide determination as to which legislation is applicable to a given product or type of product.
- ***Enhanced transparency regarding medical devices on the EU market, including their traceability:*** enhance transparency by developing modern IT tools building on the Eudamed databank, allowing better tracking and tracing of certain devices in the interest of patient safety. Better traceability would help to contact users of devices when these devices need to be modified or taken off the market and to identify counterfeit devices.
- ***Enhanced involvement of external scientific and clinical expertise:*** provide for access at EU level to scientific and clinical expert advice to support decision-making,

taking into account "real use" experience with devices and the needs of patients and users.

- ***Clear obligations and responsibilities of economic operators, including in the fields of diagnostic services and internet sales:*** provide a clear and simple description of the obligations and responsibilities of the relevant economic operators (manufacturers, authorised representatives, importers, distributors) to make it easier for them to comply with the requirements and for competent authorities to enforce them, so ensuring that only safe products are placed on the EU market or put into service. Clarification should be provided that devices used in the framework of commercial diagnostic services provided to the EU market fall within the scope of the legislation on medical devices. Addressing the issue of internet sales will enhance the safety of devices offered via the internet and contribute to the fight against counterfeit products.

- ***Governance - efficient and effective management of the regulatory system:*** well structured and result-oriented coordination between the national competent authorities and the Commission to ensure a high level of patient safety and the good functioning of the internal market, sharing of resources and avoid duplication of action. Tasks to be fulfilled at EU level include organisation of expert group meetings, document management, development and maintenance of IT tools, pooling of experts, and a central contact point for authorities and stakeholders, in particular manufacturers.

These reforms were prompted by a number of concerns.

- ***Oversight of notified bodies:*** The primary task of notified bodies is to carry out an assessment of the manufacturer's quality management system and/or the design of a device before those medical devices which require a third party certification are placed on the market. Currently there are 78 notified bodies are designated by 24 EU member states.

  Currently there are reportedly variations in the:

  – designation and monitoring of the notified bodies by member states, such as the level of oversight authorities provide to ensure notified bodies are designated only for the assessment of devices or technologies which correspond to their proven expertise and competence; and
  – quality and depth of the conformity assessment performed by notified bodies, in particular in relation to the assessment of the manufacturers' clinical evaluation or the use of their existing powers such as unannounced factory inspections or product checks.

  These differences can lead to varying levels of protection of patients' and users' safety which, from a public health perspective, is an issue of concern. In addition, it distorts competition between manufacturers of similar products.

  Changes included in the reforms to address this include:

  – Member states to more closely monitor activities of notified bodies, based on the following criteria for clinical evaluation and clinical investigations:
    § clinical evaluation needs to demonstrate safety and performance of the device;
    § Process for conducting clinical investigations is further developed- with introduction of the “sponsor” term which applies to the manufacturer, his

authorised representative or another organisation conducting clinical investigations for the manufacturer;

- § Every clinical investigation must be registered in a publically accessible system which the Commission will establish;
- § Before clinical investigations commence, sponsors must submit an application to confirm there are no health and safety, or ethical aspects would oppose it, allowing health and safety aspects of a device to be assessed by member states.

– Notified bodies (for both newly designated and regular interval monitoring of existing) will subject to joint assessments with experts from other member states and the EU Commission.
– Notified bodies to carry out unannounced factory inspections of manufacturers and conduct physical and laboratory tests on devices.
– Notified body personnel involved in assessment of medical devices will be required to rotate at intervals to ensure a balance between knowledge and experience to carry out thorough device assessments and for continuous objectivity and neutrality in relation to the manufacturer subject to those assessments.
– Manufacturers must have a "qualified person" responsible for regulatory compliance.
– The notified body audit of manufacturers quality management system, technical documentation check and examination of the design dossier have been streamlined and tightened by specifying rules according to which notified bodies perform assessments (i.e. documentation to be submitted, scope of the audit, unannounced factory inspections, sample checks). This ensures a level playing field and avoids notified bodies being overly lenient.

· ***Postmarket safety (vigilance and market surveillance):*** Member states collect and analyse information about serious incidents occurring with devices and restrict or ban the marketing of a device when it may compromise the health and safety of a patient, user or third person or when the CE marking has been illegally affixed to a product.

Member states assess incidents and inform each other about measures taken or contemplated in order to minimise the recurrence of such incidents, however the number of reports exchanged vary significantly between Member States. The criteria for reporting are applied diffidently in different member states, and there are no consolidated statistics regarding the total number of incidents reported.

The national competent authorities also appear to react in different ways to the same problems, so that while some member may ban or restrict a device, it may freely circulate in other member states. This puts into question a harmonised level of protection of patients and users in the EU and also creates obstacles to the internal market.

Changes included in the reforms to address this include:

– Introduction of an EU portal where manufacturers must report serious incidents and corrective actions taken to reduce the risk of reoccurrence. The incidents and corrective actions are then automatically forwarded to the national authorities concerned.
– Where same or similar incidents have occurred, or where corrective action has to be taken in more than one member state, a coordinating authority will take the

direction of coordinating the analysis of the case to reduce work and expertise sharing to avoid procedure duplication.

- Reinforce rights and obligations of the national competent authorities to ensure effective coordination of their market surveillance activities and to clarify applicable procedures.

- ***Regulatory status of products:*** The demarcation between the medical devices directives and the other regulatory frameworks applicable to e.g. medicinal products, biocides, food or cosmetics is not always clear. In the case of food and medical devices, the respective legislations are even overlapping. Since a decision on the regulatory status of a product falls within the competence of member states, divergent interpretations in respect to "borderline" cases lead to the application of different legal regimes in the various member states and lengthy discussions between authorities. "Borderline" cases also exist between medical devices and IVD which need to be decided since the existing directives for these devices are mutually exclusive.

  Borderline and classification problems can be circulated among the member states through the so-called 'Helsinki procedure' to reach consensus amongst the competent authorities. However controversial cases can remain unresolved, and consensus statements are not legally binding and competent authorities or national courts may decide at any moment not to follow them.

  The application of different regulatory regimes to the same product compromises both the protection of patient safety and the internal market, reducing the legal certainty and prompts criticism from stakeholders. The lack of uniform qualification (or classification) of a product across the EU creates a fragmentation of the internal market (as a manufacturer must follow different legal regimes in order to sell the same product in different Member States) and may put patient safety at risk.

  Changes included in the reforms to address this include:

  - Extension of the proposed Directive to:
    - Products manufactured using non viable human tissues or cells, or their derivatives that have undergone substantial manipulation, unless covered by Regulation (EC) No 1394/2007 on advanced therapy medicinal products.
    - Certain implantable or other invasive products without a medical purpose and that are similar to medical devices in terms of characteristics and risk profile (e.g. non corrective contact lenses, implants for aesthetic purpose).
    - Extension of the definitions section of the Regulations, aligning definitions in the field of medical devices with established EU and international practice such as the new legislative framework for the marketing of products and guidance documents produced by the Global Harmonization Task Force (GHTF) for medical devices
  - Products not covered by the proposed Directive include:
    - Products that contain or consist of viable biological substances (e.g. living microorganisms).
    - Food covered by Regulation (EC) No 178/2002 (e.g. certain slimming products).
  - For borderline medicine/medical device products, if the product is defined as a medical device, it was be classified by the highest risk class for medical devices.

- The Commission may set up a group of experts from various sectors (such as medical devices, IVD's, medicinal products, human tissues and cells, cosmetics and biocides) to determine regulatory status of borderline products.
- Sponsors to submit evidence such as EU declaration of conformity or certificate issued by an EU notified body that the medicine/medical device boundary product device complies with the general safety and performance requirements of the future regulations on medical devices.
- Regulation EC No 1223/2009 to be amended to empower the Commission to determine whether or not a product falls within the definition of a cosmetic product.
- Regulation 528/2012 to be amended concerning making available on the market and use of biocidal products.
- Food regulation (EC) No 178/2002 to be amended to exclude medical devices from its scope
- The proposed regulations will facilitate the adoption of EU wide decisions on borderline cases where the regulatory status of product needs to be clarified

· **Lack of transparency:** No exact data exist as regards the number, the types and the approval status of medical devices on the European market. The European associations representing the medical technology industry give an estimate of around 500,000 different medical devices available whilst the number of IVD is estimated to be around 40,000 by the European IVD manufacturers association.

From a public health point of view authorities need to have at their disposal consistent information about medical devices on the market. Many interested parties, in particular patients, healthcare professionals, Health Technology Assessment (HTA) bodies, insurers and third countries, consider the regulatory pathway of medical devices opaque and lacking in transparency since there is no access to key data regarding the characteristics, the clinical data and the conformity assessment path of certain medical devices, in particular implantable or other high risk devices.

The scope of the European databank for medical devices (Eudamed) is limited and not accessible to the public (patients, healthcare professionals etc.). It requires the uploading of information by the competent authorities, which are in turn required to set up their own systems for collecting the data to be entered into Eudamed.

Manufacturer of medium or higher risk devices, or their authorised representative, may also be required to notify the competent authorities of various member states when the device is sold in those countries, placing a considerable administrative burden on manufacturers and authorised representatives when they want to market a product in different member states.

Changes included in the reforms to address this include:

- Introduction of an EU portal where manufacturers must report serious incidents and corrective actions taken to reduce the risk of reoccurrence. The incidents and corrective actions are then automatically forwarded to the national authorities concerned.
- Where same or similar incidents have occurred, or where corrective action has to be taken in more than one member state, a coordinating authority will take the direction of coordinating the analysis of the case to reduce work and expertise sharing to avoid procedure duplication.

- Reinforce rights and obligations of the national competent authorities to ensure effective coordination of their market surveillance activities and to clarify applicable procedures.
- All manufacturers/authorised representatives and importers must register themselves and the device they place on the EU market in a centralised database.
- Manufacturers of high-risk devices to make publically available a summary on safety and performance with key elements of the supporting clinical data.
- Further development of the European databank on medical devices (Eudamed) which will contain integrated electronic systems on a European UDI, on registration of devices, relevant economic operators and certificates issued by Notified Bodies, on clinical investigations, on vigilance and on market surveillance. A large part of the Eudamed database will become publically available in accordance with the provisions regarding each electronic system.
- The centralised database will provide high level transparency, converge national registration requirements and lessen administrative burden on manufacturers.

· ***Lack of harmonised traceability:*** Traceability of medical devices is currently not regulated by the medical devices directives. This has prompted some member states to impose traceability requirements on economic operators (manufacturers, importers, distributors, hospitals) at national or sometimes even at regional level through a Unique Device Identification (UDI) mechanism.

Traceability contributes to enhance patient safety in cases where restrictive measures have to be taken on specific devices, such as a recall of products already placed on the market. It can also contribute to the fight against counterfeiting.

The national systems, however, are not compatible with each other and do not allow traceability across borders which would be necessary for an EU-wide high level of patient safety. Moreover, products or their packaging need to be adapted to the different sets of rules. In addition, the UDI mechanisms are often linked to databases so that manufacturers have to enter data in different national (or even regional) databases as already described in the preceding section, thus increasing their administrative burden and hampering the internal market.

Changes included in the reforms to address this include:

- Clear conditions are set for enterprises involved in relabelling/repackaging for parallel traded medical devices.
- Patients who are implanted with a device should be given essential information on the implanted device allowing it to be identified, and containing any warnings or precautions that need to be taken; for example indication as to whether or not it is compatible with certain diagnostic devices or with scanners used for security control.
- Economic operators must be able to identify who supplied them and to whom they have supplied medical devices.
- Manufacturer's fit their device with a Unique Device Identifier (UDI) which allows traceability. The UDI system will be gradually implemented and proportionate to the risk class of the device.
- All manufacturers/authorised representatives and importers must register themselves and the device they place on the EU market in a centralised database.
- Manufacturers of high-risk devices to make publically available a summary on safety and performance with key elements of the supporting clinical data.

- Further development of the European databank on medical devices (Eudamed) which will contain integrated electronic systems on a European UDI, on registration of devices, relevant economic operators and certificates issued by Notified Bodies, on clinical investigations, on vigilance and on market surveillance. A large part of the Eudamed database will become publically available in accordance with the provisions regarding each electronic system.
- The centralised database will provide high level transparency, converge national registration requirements and lessen administrative burden on manufacturers.

· ***Access to external expertise:*** The medical devices directives currently do not make provision for a structured involvement of external experts (e.g. healthcare professionals, academics) in the regulatory process. Notified bodies usually seek expert advice in the context of conformity assessment procedures but at EU level the dialogue on regulatory or safety issues usually takes place between regulatory authorities and manufacturers except in cases when a scientific opinion is sought from the Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR) on specific issues.

  Regulators, medical societies and manufacturers have expressed the need to better involve scientific and clinical experts in the dialogue and make their advice available in the regulatory decision-making process to keep pace with the innovation of products.

  Changes included in the reforms to address this include:

  - The central role in achieving harmonised interpretation and practice will be assigned to an expert committee (the Medical Device Coordination Group or MDCG) made up of members appointed by member states due to their role and experience in the field of medical devices and chaired by the commission. The MDCG and its subgroups will allow a forum for discussions with stakeholders. The commission will provide technical, scientific and logistical support to the MDCG.
  - The introduction of MDCG creates the legal basis that for specific hazards or technologies, EU reference laboratories, may in the future be designated by the Commission.
  - Notified Bodies can notify the MDCG of new conformity assessment applications for high risk devices. The MDCG can request the Notified Body provide a preliminary assessment if on valid health grounds which the committee can comment on within 60 days. This allows authorities to have e second look at individual assessments before devices are placed on the market. Its use should be the exception rather than the rule and follow clear, transparent criteria.
  - The Commission may set up a group of experts from various sectors (such as medical devices, IVD's, medicinal products, human tissues and cells, cosmetics and biocides) to determine regulatory status of borderline products.

· ***Unclear and insufficient obligations and responsibilities of economic operators, including in the fields of diagnostic services and internet sales:*** The obligations of manufacturers and/or authorised representatives are clearly articulated in the current directives but often need to be deduced from requirements mentioned within the annexes, and the way these requirement are administered can vary between member states.

  Where authorised representatives act instead of a non-EU manufacturer with regard to the manufacturer's obligations under the directives, no minimum requirements

currently exist and need to be established. As importers and distributors (including parallel traders and those selling over the internet) are currently not covered this leads to different levels of protection of patient safety and to obstacles to the internal market.

Furthermore, uncertainties exist as to the application of the directives where (mainly) diagnostic devices, in particular IVD, are used to provide test results at a distance, either to a healthcare professional or directly to a consumer, without the diagnostic device itself being placed on the market or put into service in the EU. The problem also exists with regard to diagnosis made on the basis of medical imaging devices. There are increasing concerns regarding the validity and the reliability of the results provided at a distance and their understanding by lay users.

Changes included in the reforms to address this include:

- All manufacturers/authorised representatives and importers must register themselves and the device they place on the EU market in a centralised database.
- Concerns also exist around sales of medical devices over the internet, particularly counterfeit products. Even though devices bought over the internet within the EU or Economic operators must be able to identify who supplied them and to whom they have supplied medical devices.
- Manufacturer's fit their device with a Unique Device Identifier (UDI) which allows traceability. The UDI system will be gradually implemented and proportionate to the risk class of the device.
- Further development of the European databank on medical devices (Eudamed) which will contain integrated electronic systems on a European UDI, on registration of devices, relevant economic operators and certificates issued by Notified Bodies, on clinical investigations, on vigilance and on market surveillance. A large part of the Eudamed database will become publically available in accordance with the provisions regarding each electronic system.

· ***Management of the regulatory system:*** The management of the regulatory system at EU level has shown weaknesses which have been reported by various interested parties, i.e. healthcare professionals, patients, insurers, manufacturers and the media. It is considered as not sufficiently efficient and effective. There is no legal basis in the medical devices directives to ensure an overview of the situation at EU level and appropriate coordination between the member states. This is particularly an issue for identification of devices placed on the market, designation and monitoring of notified bodies, assessment of products, and vigilance and of market surveillance. In addition, there is no legal basis to ensure a gathering of expertise at EU level.

This leads to a lack of uniform application of the rules and of common reactions in the European market, compromising both patient safety and the good functioning of the internal market. Efforts to achieve a certain degree of harmonised implementation have been made, such as informal working groups, however in the absence of any reference in the directives to the management of the system at EU level, the informal working groups produce guidance documents which serve a good purpose but cannot address fundamental issues.

There is also no appropriate structure to ensure the sustainability and the efficiency of these activities, with the Commission having less than seven full time equivalent staff working on issues related to medical devices. There is a lack of:

- administrative, technical and scientific support to the cooperation between member states;

- solid IT tools to manage the system; and
- consolidated scientific and clinical expertise.

A number of the changes outlined above also address this issues, such as introduction of cooperative monitoring between member states, and common tools such as the Eudamed and UDI requirements for devices.

Transition arrangements for the proposed changes include:

- The changes are proposed to occur 3 years after its entry to allow manufacturers, notified bodies, and member states time to adapt to the proposals.
- The 3 year period also allows for IT and organisational arrangements to be put into place.
- Designation of notified bodies needs to occur shortly after entry into force of the Regulations to allow sufficient designated notified bodies to avoid medical device shortages in the market.
- Transitional provisions are foreseen for the registration of medical devices, relevant economic operators and certificates issued by Notified Bodies to allow for smooth transition from registration requirements at national level to central registration at EU level.

Attachment C: Previous reports and consultations

Over the past few years there have been a number of reviews and inquiries relevant to premarket assessment of medical devices. These include:

- *Review of Health Technology Assessment in Australia report* (the HTA Review);
- TGA consultations on medical device reforms (2010 and previous);
- *Review to improve the transparency of the Therapeutic Goods Administration* (the Transparency Review);
- *TGA reforms: A blueprint for the TGA's future* (the TGA Blueprint);
- Senate Community Affairs Reference Committee inquiry report on *The regulatory standards for the approval of medical devices in Australia* (Medical Devices Inquiry), and the Government response to this report (tabled 13 September 2012); and
- Senate Community Affairs Reference Committee inquiry report on *The role of the Therapeutic Goods Administration regarding medical devices, particularly Poly Implant Prosthese (PIP) breast implants* (PIP Inquiry).

HTA review

The HTA Review report in December 2009 noted the TGA is responsible for protecting Australian consumers from health technologies which cause harm, by ensuring that goods on the ARTG are 'free from unacceptable risk'. The report recommended that the TGA, in the context of international harmonisation:

8(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;

8(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 Commonwealth HTA processes.

The HTA Review also made a number of recommendations about the post market surveillance of medical devices:

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 postmarket 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 postmarket 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.

Further information on the HTA Review, including a copy of the report, is available at the Department of Health and Ageing website at <www.health.gov.au/internet/main/publishing.nsf/Content/hta-review>.

TGA medical device consultation

A discussion paper on options to increase regulatory assessment of higher risk medical devices was released in October 2010, with consultations undertaken in November and December 2010, and included options to:

- cease requiring Australian manufacturers to seek TGA conformity assessment (Proposal 2A);
- requiring TGA conformity assessment for all high risk devices (Proposal 2B); and
- allowing conformity assessment by third party assessment bodies (Proposal 2C).

The response to this consultation was not entirely supportive of the proposals as outlined.

The 2010 consultation built upon earlier discussion papers released by the TGA in late 2008 and early 2009 in respect of the reclassification of joint replacement implants and the use of third party conformity assessment bodies for medical devices manufactured in Australia.

Further information on the 2010 TGA consultation, including the consultation paper and submissions received in response, is available at the TGA website at <www.tga.gov.au/newsroom/consult-devices-reforms-101130.htm>. Information on the previous consultations is also available on the TGA website.

Transparency review

On 20 July 2011 the *Report of the Review to improve the transparency of the Therapeutic Goods Administration* was released. The review had been commissioned in response to the perception 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. The panel of consumer, health practitioners and therapeutic goods industry representatives consulted widely with persons and organisations affected by the TGA's activities.

The report outlined 21 recommendations for changes for increasing the community's trust in therapeutic goods regulation, balancing legislative obligations with the need to provide more and better information to the Australian community. The recommendations included:

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).

The Government's response to the Transparency Review recommendations is contained in the TGA Blueprint. Further information on the Transparency Review, including a copy of the report, is available at the TGA website at <http://www.tga.gov.au/newsroom/review-tga-transparency-1101.htm>.

TGA Blueprint

On 23 September 2011 the TGA announced that, based on previous consultations, a number of reform proposals on medical devices would proceed to consultation with key stakeholders:

- Proposal 1: Reclassification of joint replacement implants;
  - To be implemented from 1 July 2012 with a two year transition period;
- Proposal 2: Amendments to regulatory provisions relating to third party assessment bodies and implantable medical devices;
  - Subject to further consultation on amended versions of Proposals 2A, 2B and 2C;
- Proposal 3 (i): Amend the way in which a kind of medical device is included in the ARTG (product name);
  - Options to be explored in consultation with stakeholders;
- Proposal 4: Publication of device product information on the TGA website (product information)
  - Options to be explored in consultation with stakeholders.

The TGA Blueprint also included in-principle agreement with consultation to be undertaken with stakeholders to further develop options in relation to Recommendation 12 of the Transparency Review.

In December 2011 these activities were incorporated into *TGA reforms: A blueprint for the TGA's future*. This document draws together a broad range of reform activity from across the TGA operations, and is available at <www.tga.gov.au/about/tga-reforms-blueprint.htm>, together with the related implementation plan which was released in July 2012, which is available at <www.tga.gov.au/about/tga-reforms-blueprint-implementation.htm>.

Senate medical devices inquiry

On 16 June 2011 the Senate Community Affairs References Committee commenced an *Inquiry into the regulatory standards for the approval of medical devices in Australia*. The committee tabled its report on 22 November 2011, and included a number of recommendations relevant to and supportive of greater regulatory rigour in the premarket assessment of higher risk medical devices. As outlined below, in its 13 September 2012 response to this report the Government largely agreed to these recommendations.

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.

Government response: Agreed.

Recommendation 3

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

Government response: Agreed to consult further with affected stakeholders.

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 premarket assessment and postmarket surveillance of higher risk medical devices, for the ultimate benefit of patients.

Government response: Agreed with the intent, to improve the quality of medical devices available in the Australian market place, by continuing to refine requirements for premarket assessment and postmarket surveillance.

Recommendation 5

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.

Government response: Agreed.

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. These recommendations address the need for improved postmarket surveillance by increasing the rate of reporting of adverse events, including by health service providers and consumers; facilitating the expansion and use of postmarket surveillance data to inform safety, effectiveness and reimbursement decisions; and establishing further clinical registers for high risk implantable devices and procedures.

Government response: Agreed in principle.

Further information on the Inquiry, including transcripts of public hearings, submissions made to the committee, the Committee's report and the Government's response, are available at the Medical Devices Inquiry website at <http://www.aph.gov.au/Parliamentary_Business/Committees/Senate_Committees?url=clac_ctte/completed_inquiries/2010-13/medical_devices/index.htm>.

Senate PIP inquiry

On 8 February 2012 the Senate Community Affairs References Committee also commenced an inquiry into *The role of the Government and the TGA regarding the approval and monitoring of medical devices listed on the ARTG, including issues around Poly Implant Prothese (PIP) breast implants*. While recommendations of this inquiry focused more on the administration of the existing regulatory framework and postmarket monitoring of medical devices, a number of recommendations were proposed for action:

Recommendation 9

> The committee recommends that, in light of the PIP breast implant recall, the Department of Health and Ageing establish an opt-out Breast Implant Registry as a priority. The design of such a registry should be based on the National Joint Replacement Registry.

Recommendation 11

> The committee recommends that the Department of Health and Ageing implement recommendations 13, 14 and 15 of the HTA Review recommendations as soon as possible. The committee notes this recommendation was also made in its 2011 report on regulation of medical devices (recommendation 7).

The Government has not yet responded to the PIP report.

Further information on the Inquiry, including transcripts of public hearings, submissions made to the committee and the Committee's report, are available at the PIP Inquiry website at:
<http://www.aph.gov.au/Parliamentary_Business/Committees/Senate_Committees?url=clac_ctte/completed_inquiries/2010-13/implants_2012/index.htm>.

Attachment D: Summary of consultation on changes to premarket assessment requirements for medical devices

The following summaries submissions made in response to the consultation paper *Changes to premarket assessment requirements for medical devices.* The paper was released on 14 January 2013, and was open for comment until 15 March 2013

Stakeholder	Stakeholder comments	TGA Comments
Proposal A: Increased scrutiny of conformity assessment as part of mandatory application audits prior to ARTG inclusion		
Support		
AMS Laboratories Pty Ltd	· Disinfectants separated into high level (sterilants and enter body orifice), intermediate level and low level. · Sterilants and high level disinfectants= level 2 audit, intermediate and low level disinfectants= level 1 audit. This is not expected to be a burden as few new applications will be received for these products.	In response to consultation feedback the proposal to reduce audits of disinfectants from a Level 2 to a Level 1 audit has been modified. Level 2 audits will be maintained for liquid disinfectants, with Level 1 audits for hardware such as autoclaves. This allows for a microbiological assessment of liquid disinfectants.
AusBiotech	· List of targeted devices in paper is appropriate and should be continually reviewed. · Concerned of level 1 audit for MRA applications when could direct resources to post market audits. Audits of MRA certificates to be removed once confidence building occurred. · TGA publish formal plan of confidence building activities · Concerns of backlog potential with level 3 audit. · Costing needs review to truly reflect work put into audits. · Clear timeframes for audits and penalties to the TGA if not compliant.	Under the proposed arrangements MRA certificates, which are issued to Australian regulatory requirements, will continue to be treated as TGA certificates are (ie no mandatory audit). Under the amended MRA notified bodies are unable to issue MRA certificates for Class III devices until confidence building is undertaken. Existing MRA certificates continue to be valid until their expiration date. After expiration manufacturers may use notified body certification for these devices but it will be subject to audit until such confidence building occurs. See <http://www.tga.gov.au/about/international-eu-mra-amendments.htm> for more details.

Stakeholder	Stakeholder comments	TGA Comments
Australian Dental Association Inc	· Reconsider audit level costs to reflect actual costs involved not per class of device and include upper cost limits for all device classes.	Audit fees relate to the actual costs incurred by TGA. The audit level to apply for a given application is at TGA discretion, however indicative audit levels are indicated in the RIS, and will be reflected in guidance.
Australian Dental Industry Association	· Audit costs should be determined by actual costs involved and certain classes of device may have different audit cost depending on assessment involved. · Look at IRIS reports for devices before determining if certain devices should be subjected to mandatory audit. · Dental implants should not be subjected to Level 2 audit. · Indirect cost to industry could be 4-7xcurrent application fees. · Level 1 audits for MRA certified products is not in line with ERA agreement. · Increases regulatory burden and healthcare costs therefore cannot proceed as is.	Audit fees relate to the actual costs incurred by TGA. The audit level to apply for a given application is at TGA discretion, however indicative audit levels are indicated in the RIS, and will be reflected in guidance. Option 2 allows for identification of Class IIb implantable devices subject to mandatory audit, providing the flexibility to exclude dental implants if this is appropriate. Actual implants to be included for mandatory audit will be subject to further consultation during implementation. It is not proposed to make devices supported by MRA certificates subject to mandatory audit.
Australian Medical Association	· Proposal provides balance between access to medical device technology and patient safety. · Increased costs to patients possible monitor impact by Private Health Insurance Administration Council.	
Australian Orthopaedic Association	· All joint replacements should be Class III · New devices for mandatory audit are appropriate · No elements of this proposal can be removed without reducing regulatory rigour · Support Level 3 audit · No comment on Level 3 audit fee	Hip, knee and shoulder joint replacement implants were reclassified as Class III from 1 July 2012. Reclassifying other joint replacement implants in advance of parallel moves in other jurisdictions (particularly Europe) would create significant issues for conformity assessment certification, and may result in numerous products no longer being supplied in Australia.

Stakeholder	Stakeholder comments	TGA Comments
Bruce Arnold & A/P Wendy Bonython	· Endorse amendments to Regulation 5.3 including mandatory audits for surgically invasive and long term/implantable devices and adopting foresight to anticipate future device problems. · Endorse Level 3 audit and audit fee (outweighed by the priority of consumer safety) and use of raw data from notified bodies. · Concerns over quality of EU notified body assessments. Suggested manufacturers provide TGA information where a product not registered overseas or a problem with the device identified by the regulator. · Evaluate claims made by manufacturers to ensure safety.	Level 3 audits seek to manage risks for conformity assessments by European notified body for high risk products. Confidence building of notified bodies also being pursued under the MRA.
Cancer Voices Australia	· Supports increased rigour in premarket assessment of medical devices	
Consumers Health Forum of Australia	· Welcome expanded list of devices and Level 3 audit. · Concerns over role of EU notified bodies in conformity assessment. · Concerns over ANZTPA to ensure it strengthen regulation in Australia. · Highlights strengthening of post market surveillance.	Level 3 audits seek to manage risks for conformity assessments by European notified body for high risk products. Confidence building of notified bodies also being pursued under the MRA.
GE Healthcare Australia Pty Ltd	· All new devices mentioned for mandatory audit are appropriate. · Level 3 audit may not be the best way to scrutinise Class III devices as length processing times and costs may discourage suppliers and prevent access to medical devices. · Focus resources into post market	It is anticipated that undertaking a Level 3 audit (as proposed in Option 2) will be significantly faster than undertaking a conformity assessment (as proposed in Option 3).

Stakeholder	Stakeholder comments	TGA Comments
GS1 Australia	· Use EU System as much as possible to reduce costs. · Use National Product Catalogue to ensure consistency of product information. · Use bar coding in product packaging	The proposal to introduce Level 3 audits (as an alternative to requiring TGA conformity assessment) aims to reduce duplication (and costs) between Europe and Australia while also providing additional assurance. Confidence building of notified bodies also being pursued under the MRA will also support this.
IVD Australia	· Clarification that Regulation 5.3(j) and IVD transition period will be unchanged post July 2014. · Level 3 audit may result in more companies seeking TGA conformity assessment and therefore increase assessment times. · Prefer not to use the words 'raw data'. · Level 3 audit possibly necessary for Class 4 IVDs.	The IVD transition period and Regulation 5.3(j) are not proposed to change as part of this proposal but may occur as part of other regulation updates in the future. Such changes would be subject to consultation. Level 3 audits not proposed to apply to IVDs at this stage – this may be revisited following the IVD transition, and any change would be subject to consultation.
Friends of Science in Medicine	· Supports proposals for high risk devices, concerned low risk devices will be ignored and adversely affect consumers (especially if not efficacious). · Improved post market surveillance required. · Highlights the need for devices to be evaluated for efficacy to prevent misleading consumers. · Prevent devices cancelled from ARTG to be re-included.	

Stakeholder	Stakeholder comments	TGA Comments
Johnson & Johnson Medical Pty Ltd	· Wish to collaborate on devices selected for mandatory audit as concerns over time costs and increased regulatory burden. · Introduce mandatory application audit timeframes and allocate sufficient resources to deal with extra work. · What is TGA's value in reviewing notified body assessment reports considering EU notified body problems · Level 3 audit resources should be redeployed after EU notified bodies reformed. · Once MRA confidence building completed should abolish Level 3 audits. · Improve post market surveillance. · Descriptive list of audit levels required for each medical device mandated for audit. · Clarification of the 'raw data' required by TGA, Level 2 audit requirements i.e. DE certificates removed for Class IIb devices, grouping of Class IIb applications under one submission ID, continuation of Class IIb as a kind of device (without notifying TGA). · Concerns that Class IIb implantable/long term devices evaluated through a Class III audit pathway. · Support level 1 audit for disinfectants. · Audit fees needs further discussion to ensure fairness and fees according to amount of assessment undertaken.	Further consultation on Class IIb devices to be targeted for mandatory audit will occur during implementation phase. It is anticipated that regular consultation would be required over time to manage the list, to ensure it keeps pace with emerging issues (both adding devices to and removing devices from the list). Confidence building in EU notified bodies to be conducted in to be conducted in 2013 and 2014 (prior to 1 July 2015 implementation date for Level 3 audit process). TGA would review the raw clinical data underpinning the conformity assessment report rather than the expert clinical report as occurs for the Level 2 audit, and also the Design Examination report which is currently only reviewed as part of the conformity assessment process. Class IIb devices would generally not be subject to a Level 3 audit, which would be of limited utility given Class IIb devices are not required to hold design or type certification. In response to consultation feedback the proposal to reduce audits of disinfectants from a Level 2 to a Level 1 audit has been modified. Level 2 audits will be maintained for liquid disinfectants, with Level 1 audits for hardware such as autoclaves. This allows for a microbiological assessment of liquid disinfectants.

Stakeholder	Stakeholder comments	TGA Comments
Medical Technology Association of Australia	· Class III, AIMD and Class IIb implantable should be subjected to mandatory audit as Class IIb long term invasive does not pose a significant risk. · Concerns over Level 3 audit increasing premarket assessment when could increase post market assessment. · Maintain Level 2 audit (with additional documentation such as design dossier reports requested when required) for Class III and AIMD and increase post market reports to 5 years. · Concerned of timeframes for Level 3 audit considering conformity assessment backlog. · Clear guidelines on what device is subjected to a specific audit level. · Level 2 documentation requirements do not fit Class IIb medical devices. · Provided detailed data on costing increases if TGA incorporates a Level 3 audit.	Introduction of instrument to identify Class IIb devices for mandatory audit allows consideration of risks of different devices, and flexibility to target emerging risks over time. Clear guidance on expected audit levels will be provided, although TGA will retain the discretion to vary this in individual cases, as devices are audited not only based on the nature of the device itself, but may also reflect concerns about the particular application such as the information included with the application, the quality of the clinical evidence etc.
National E-Health Transition Authority	· These reforms provide opportunities to incorporate other healthcare reforms and change mandatory requirements to ARTG listings.	
NSW Department of Health	· Supportive, especially of implantable devices. · Concerns that reduction in assessment for disinfectant devices will compromise patient safety.	In response to consultation feedback the proposal to reduce audits of disinfectants from a Level 2 to a Level 1 audit has been modified. Level 2 audits will be maintained for liquid disinfectants, with Level 1 audits for hardware such as autoclaves. This allows for a microbiological assessment of liquid disinfectants.

Stakeholder	Stakeholder comments	TGA Comments
Professor Guy Ludbrook	· List of new devices subjected to audit seems appropriate. · Level 3 audit provides greater scrutiny in information provided in applications and in raw data. · Consider types of devices and risk before subjecting to Level 3 audit. · Clarification of whether sub-classifications align with different risk levels and audit type?	The introduction of the instrument to identify additional Class IIb devices for mandatory audit aims to allow for assessment of varying risk levels and audit types within the Class IIb (medium – high risk) devices.
Robert Lugton	· Every Class III implantable medical device should be subjected to Level 3 audit confirming the manufacturer has a minimum of two years of pre market trials. $15,000 for level 3 audit is not appropriate (implied more money necessary).	The proposed changes under Option 2 seeks to balance the need for additional premarket scrutiny of Class III devices against the expense of such changes.
Stellar Consulting	· Clarification required as to the purpose of the level 1 audit for MRA certificates as removes incentive for MRA certificates. · Clarification of the statement "conformity assessment certificates from European notified bodies would continue to be accepted for devices not on this list". Does this mean that certificates from EU notified bodies would not be accepted for devices on the list, requiring instead a TGA conformity assessment certificate? · Contact lens care products, instrument grade disinfectants and sterilants should be subjected to level 2 audit to allow for assessment of safety and performance data and prevent disease transmission. Changing classification of these devices will not assess efficacy (which is the reason they are Class IIb in Australia compared to Class IIa in EU). · Review Barrier contraceptives (both male and female	Under the proposed arrangements MRA certificates, which are issued to Australian regulatory requirements, will continue to be treated as TGA certificates are (ie no mandatory audit). Under the amended MRA notified bodies are unable to issue MRA certificates for Class III devices until confidence building is undertaken. Existing MRA certificates continue to be valid until their expiration date. After expiration manufacturers may use notified body certification for these devices but it will be subject to audit until such confidence building occurs. See <http://www.tga.gov.au/about/international-eu-mra-amendments.htm> for more details. In response to consultation feedback the proposal to reduce audits of disinfectants from a Level 2 to a Level 1 audit has been modified. Level 2 audits will be maintained for liquid disinfectants, with Level 1 audits for hardware such as autoclaves. This allows for a microbiological assessment of

Stakeholder	Stakeholder comments	TGA Comments
	condoms) in Regulation 5.3 or review the wording of Regulation 5.3 and consider the compliance of the products with the standards. Currently condoms are excluded from the MRA but included in the ARTG with EC certification and no audit assessment (inconsistent with EU)	liquid disinfectants. Those devices currently identified under Regulation 5.3 for mandatory audit will be reviewed in consultation with stakeholders as part of implementation for Option 2.
Stryker South Pacific	· No mandatory audit for Class IIb surgically invasive for long term use devices. · Class 3 audits may be unnecessary as Class 2 gives consistent oversight. · Concerns over cost and delay in product approval associated with Class 3 audits. Possibly group products (similar to Class III mandatory audit)	Introduction of instrument to identify Class IIb devices for mandatory audit allows consideration of risks of different devices, and flexibility to target emerging risks over time. Option to group audits for Class III products will be available under Option 2.
William A Cook Australia Pty Ltd	· Ambiguity of level of scrutiny of level 3 audits · Pre market process should be identical between EU and Australian manufacturers.	
Name withheld at submitters request	· New devices listed for mandatory audit appropriate. · Reclassify Class IIb implantable/long term use devices as “medium high” risk devices.	
Not support		
Global Orthopaedic Technology	· Current way to regulate medical devices provides sufficient scrutiny. · Proposal penalises sponsors choosing Notified Bodies over TGA assessment. · Increases costs and lack of product choice for surgeons and patients.	

Stakeholder	Stakeholder comments	TGA Comments
Integra Neurosciences Pty Ltd	· Premarket assessment will not ameliorate 100per cent of the risk- efforts should therefore be focused towards post market (through annual reports). · Suggested to wait for EU changes to occur. · Not specifying additional documentation required for a Level 3 audit may cause backlog of applications.	Acknowledge that premarket assessment of medical devices must be complimented by post market surveillance measures. Additional scrutiny is targeted to implantable devices due to the particular difficulties these pose when postmarket issues arise.
Medical Technology Association of New Zealand	· Increased costs for applications, put resources into post market, NCAR, MDSAP, & UDI. · Question whether the TGA has technical expertise to assess high risk devices. · Increased regulatory burden without increased rigour. · Concerns that Australian is adopting reforms ahead of ANZTPA and New Zealand will have to accept these reforms.	
N Stenning & Co Pty Ltd	· Improved post market surveillance more effective than premarket. · Concerns on EU MRA amendments- increase application costs and delay new product introductions to market. Therefore, reinstate EU MRA certificate acceptance. · Clarification of the statement "greater assurance in the quality, safety and performance of medical devices" required.	No notified bodies have confidence building agreements in place with the TGA. Under the amended MRA notified bodies are unable to issue MRA certificates for Class III devices until confidence building is undertaken. Existing MRA certificates continue to be valid until their expiration date. After expiration manufacturers may use notified body certification for these devices but it will be subject to audit until such confidence building occurs. See <http://www.tga.gov.au/about/international-eu-mra-amendments.htm> for more details.
ResMed Ltd	· Current level of scrutiny is appropriate	
Name withheld at submitters request	· Increased regulatory burden and cost to patients. · Dental implants should be mandated for audit only if safety or performance issues identified.	

Stakeholder	Stakeholder comments	TGA Comments
Name withheld at submitters request	· Increased regulatory burden and cost to patients. · Dental implants should be mandated for audit only if safety or performance issues identified.	Option 2 allows for identification of Class IIb implantable devices subject to mandatory audit, providing the flexibility to exclude dental implants if this is appropriate. Actual implants to be included for mandatory audit will be subject to further consultation during implementation.
Name withheld at submitters request	· Level 1 audit not appropriate for devices outlined in consultation paper and no higher audit level required either. · Don't support Level 2 audit for Class IIb implantable or long term surgically invasive medical devices as they have been used safely with no post market events. · Product groups with reported safety problems should have a mandatory audit under Regulation 5.3. · Don't support Level 3 audit as increases cost to production. · Increased premarket scrutiny won't improve public safety as adverse events occur years after implantation. · Don't increase regulatory burden til EU reforms are in place.	The reasons for selecting particular audit levels do not relate only to the nature of the device itself, but may also reflect concerns about the particular application such as the information included with the application, the quality of the clinical evidence etc. Acknowledge that premarket assessment of medical devices must be complimented by post market surveillance measures. Additional scrutiny is targeted to implantable devices due to the particular difficulties these pose when postmarket issues arise. Proposed implementation of Option 2 would be from 1 July 2015, which would mean EU reforms should be more advanced, and confidence building in notified bodies progressed.

Stakeholder	Stakeholder comments	TGA Comments
Name withheld at submitters request	· No benefits identified to adding Level 1 audit to MRA certificates. · No benefit identified in Level 3 application audits · Increased costs and time associated with application assessments. · Duplication of EU assessments · Difficult to obtain design exam certificates for Class IIb devices · Post market mechanisms should be utilised instead to improve patient safety such as review of mandatory annual reports for Class IIb implantable and Class III and AIMD devices. · Clarify: a) Why is a level 1 audit required for conformity assessment certificates issued by Notified Bodies which the TGA has confidence in? b) Why include long term surgically invasive, what evidence is of a need to include this group? c) How does the new level 3 application audit for AIMD and Class III, increase the rigour of assessment?	Under the proposed arrangements MRA certificates, which are issued to Australian regulatory requirements, will continue to be treated as TGA certificates are (ie no mandatory audit). Under the amended MRA notified bodies are unable to issue MRA certificates for Class III devices until confidence building is undertaken. Existing MRA certificates continue to be valid until their expiration date. After expiration manufacturers may use notified body certification for these devices but it will be subject to audit until such confidence building occurs. See http://www.tga.gov.au/about/international-eu-mra-amendments.htm for more details. Acknowledge that premarket assessment of medical devices must be complimented by post market surveillance measures. Additional scrutiny is targeted to implantable devices due to the particular difficulties these pose when postmarket issues arise. The reasons for selecting particular audit levels do not relate only to the nature of the device itself, but may also reflect concerns about the particular application such as the information included with the application, the quality of the clinical evidence etc. Introduction of instrument to identify Class IIb devices for mandatory audit allows consideration of risks of different devices (including surgically invasive), and flexibility to target emerging risks over time.
Name withheld at submitters request	· Disinfectants and sterilants should be subjected to Level 2 audit to prevent performance compromise. · Instigate biannual or triannual audits.	In response to consultation feedback the proposal to reduce audits of disinfectants from a Level 2 to a Level 1 audit has been modified. Level 2 audits will be maintained for liquid disinfectants, with Level 1 audits for hardware such as autoclaves. This allows for a microbiological assessment of liquid disinfectants.

Stakeholder	Stakeholder comments	TGA Comments
No comment		
Accord Australasia Ltd		
Name withheld at submitters request		

Stakeholder	Stakeholder comments	TGA Comments
Proposal B: Publication of TGA regulatory decisions		
Support		
Accord Australasia Ltd	· Publication of successful applications of high risk devices only. · Don't publish unsuccessful decisions and 'interesting' devices difficult to define.	The format for publishing medical device decisions to assume a format similar to the AusPAR, with the final format to be developed after further consultation with stakeholders, to ensure TGA provides appropriate information about decision making to the Australian public, while also considering industry confidentiality requirements. Publication of negative decisions is an important element to ensure transparency of the regulatory process. Phased implementation proposed.
AusBiotech	· Information to be clear, concerns over publishing withdrawn and rejected decisions.	
Australian Dental Industry Association	· Only publish applications for inclusion including the degree of assessment undertaken. · Publication of conformity assessment decisions may provide competitors with advantages · Do not publish rejected decisions. · Do not publish confidential information. · Definition of "more interesting" devices difficult to define.	
Australian Medical Association	· Provides balance between timely access to technology and patient safety.	
Australian Orthopaedic Association	· Increased transparency is beneficial · All information for orthopaedic prosthesis except commercial sensitive information should be disclosed	
Bruce Arnold & A/P Wendy Bonython	· Publication of successful and unsuccessful decisions including level of scrutiny undertaken. · Information should be published timely and ongoing (i.e. not every 6 months). · Intellectual property responsibilities lie with manufacturers and not TGA.	

Stakeholder	Stakeholder comments	TGA Comments
Cancer Voices Australia	· All models or variation of a device included in the ARTG are to be clearly identified. · ARTG number should be printed on the information that accompanies the device. · Product information should be published on the TGA website to enable consumers to make informed decisions about safety and efficacy.	
Consumers Health Forum of Australia	· Supports publication of both conformity assessment and device application decisions (both successful and unsuccessful). · Supports publicising decisions on Class III and implantable medical devices- but ideally all devices publicised. · Medical Device regulatory decisions to be published.	
GE Healthcare Australia Pty Ltd	· Publication does not delay inclusion. · In confidence information is not published and information discussed with manufacturers at the start. · Information is regularly updated. · Initially only successful applications for inclusion in ARTG.	

Stakeholder	Stakeholder comments	TGA Comments
IVD Australia	· Concerns of publicising unsuccessful applications and all conformity assessment decisions. · Limited to Class 3, Class 4 IVD's and Class III and AIMD medical devices. · Concerns that publication will hold up IVD inclusion. · Publication of "interesting" devices would be difficult to set criteria and may indicate that "interesting devices" only are subjected to review. · Want reports on number of conformity assessment applications and successful, unsuccessful and withdrawn ARTG applications, reasons for rejection and assessment time per class to aid industry understanding. · Do not publish auto included device decisions.	
Johnson & Johnson Medical Pty Ltd	· Do not include automatically approved inclusions. · Publish successful decisions on Class IIb implantable, Class III and AIMD for applications to include in the ARTG. · Do not publish unsuccessful decisions. · Publish the degree to which a medical device has been assessed.	
Medical Technology Association of Australia	· Should exclude publication of Class I auto inclusion decisions. · Publication should be quick and limited to Class IIb implantable, Class III and AIMD devices. · Sponsor should be able to review material prior to publication. · Publication of unsuccessful applications should be publicised after appeal rights exhausted but concerns were raised over competitor advantages, reputational	

Stakeholder	Stakeholder comments	TGA Comments
	damage to companies if published and misinterpretation of rejected and withdrawn applications. These concerns were not however realised in the medicine context after introduction of AusPAR. · Also publicise precedents or standards after they have been set by particular applications. · All comments related to applications for inclusion only.	
Medical Technology Association of New Zealand	· Further consult about what kinds of devices to be published. · Concerns over confidentiality of published information.	
NSW Department of Health	· Important to consider how information will be accessed by the public · Transparency may clearly identify devices not included in the ARTG and used via SAS	
Professor Guy Ludbrook	· Publishing successful and unsuccessful decisions of high risk devices such as those subjected to mandatory audit or Class IIb where clinical evidence has been assessed. · Confidentiality concerns raised. · Ensure consultation with advisory groups.	
ResMed Ltd	· Information needs to be accurate, not disclose confidential information and not burden manufacturers. · Suggested not to publish rejected decisions and start with publication of high risk devices.	
Stryker South Pacific	· Follow AusPAR process with review and appeal rights.	

Stakeholder	Stakeholder comments	TGA Comments
William A Cook Australia Pty Ltd	· Consult company before releasing information. Follow similar guidelines to the FDA.	
Global Orthopaedic Technology	· Information not currently released on public ARTG summary as it is commercial in confidence. · Rejections could be used by competitors as a marketing tool. · Information may be accidently released when not meant to. · All relevant information already included in public ARTG summary.	
Integra Neurosciences Pty Ltd	· No health and safety benefit of publicising unsuccessful decisions.	
Name withheld at submitters request	· Successful Class III, AIMD and Class IIb implantable application decisions publicised only. · Do not include automatic entries, "interesting products", unsuccessful decisions, and conformity assessment decisions.	
Name withheld at submitters request	· Approval decisions for application for inclusion only. No benefit to public if rejections are published. · Concerns that publication will delay ARTG inclusion. · Clarification required if this is similar to AusPAR.	
Name withheld at submitters request	· Class III, AIMD, and Class IIb implantable to be publicised, if rejected- only information on safety and efficacy to be published for rejected applications. · If publish low risk decisions- only successful applications.	

Stakeholder	Stakeholder comments	TGA Comments
Name withheld at submitters request	· Class III, AIMD, and Class IIb implantable to be publicised, if rejected- only information on safety and efficacy to be published for rejected applications. · If publish low risk decisions- only successful applications.	
Name withheld at submitters request	· Publication of successful applications for inclusion decisions for Class III, AIMD and Class IIb implantable only. · Do not publish conformity assessment decisions or unsuccessful decisions. · Publication of variant types and functional description reinstated on ARTG certificates.	
Name withheld at submitters request	· Trial Class III, AIMD and Class IIb implantable first. · Do not publicise withdrawals due to numerous reasons for withdrawing applications.	
Not support		
No comment		

Stakeholder	Stakeholder comments	TGA Comments
Proposal C: Abolition of requirement for TGA conformity assessment for Australian manufacturers of lower risk medical device		
Support		
Accord Australasia Ltd	· Prefer abolish TGA conformity assessment for all devices	Option 2 Proposal C now proposed the abolition of the requirement for TGA conformity assessment for all Australian manufacturers
AusBiotech	· Should be for all Australian manufacturers	Option 2 Proposal C now proposed the abolition of the requirement for TGA conformity assessment for all Australian manufacturers
Australian Dental Industry Association	· This proposal should be progressed independently of Proposal A. · Also include Class IIb surgically invasive for implantable/long term use	The link between Proposal A and Proposal C is necessary. Proposal A provides assurance in the conformity assessment of higher risk devices. This, together with MRA confidence building to be undertaken during 2014 and 2015, provides greater premarket scrutiny of higher risk devices (whether manufactured in Australian or overseas) which enables this change for Australian manufacturers.
Australian Medical Association	· Provides balance between timely access to technology and patient safety	
Australian Orthopaedic Association	· Risks of abolishing conformity assessment for low risk devices may pose a risk. Cost/benefit and impact analysis needs to be conducted. Health funding is a finite resource · Believes that the proposal is reasonable	Low risk medical devices are devices where use of the device constitutes low risk to the public – Class I medical devices are defined as 'low risk', and conformity assessment for these devices is already certified by the manufacturer. Proposal A and Proposal C are linked. Proposal A provides assurance in the conformity assessment of higher risk devices. This, together with MRA confidence building to be undertaken during 2014 and 2015, provides greater premarket scrutiny of higher risk devices (whether manufactured in Australian or overseas) which enables this change for Australian manufacturers.

Stakeholder	Stakeholder comments	TGA Comments
Cancer Voices Australia	· Clarification of the statement 'low risk' · Supports 3rd party assessment of low risk devices with certified 3rd parties.	Low risk medical devices are devices where use of the device constitutes low risk to the public – Class I medical devices are defined as 'low risk'.
Consumers Health Forum of Australia	· Concerns raised of quality of EU notified bodies and assessment processes. · Only implement if proposal A is implemented · If Proposal C is implemented, even more important to publish regulatory decisions for all devices. · Review risk classifications if proposal implemented- if not can place consumers at risk.	Proposal A and Proposal C are linked. Proposal A provides assurance in the conformity assessment of higher risk devices. This, together with MRA confidence building to be undertaken during 2014 and 2015, provides greater premarket scrutiny of higher risk devices (whether manufactured in Australian or overseas) which enables this change for Australian manufacturers.
GE Healthcare Australia Pty Ltd	· Enables resources to be focused into high risk devices.	
IVD Australia	· Abolish TGA conformity assessment for Class 1-3 IVD's and possibly even Class 4 IVD's. · Concerns abolishing TGA requirement will result in more Level 3 audits.	Proposal to apply to IVD manufacturers – although not manufacturers of Class 4 IVDs at this time (this may be revisited at the end of the IVD transition period). Manufacturers relying on EU certification are subject to greater when applying for inclusion on the ARTG than those holding TGA or MRA conformity assessment certification, and this may include audit requirements. All manufacturers continue to have the option to seek TGA conformity assessment, and this is a business decision they need to make in the context of their operational requirements.
Johnson & Johnson Medical	· Support and wish for expansion to cover all medical devices.	Option 2 Proposal C now proposed the abolition of the requirement for TGA conformity assessment for all Australian manufacturers

Stakeholder	Stakeholder comments	TGA Comments
Medical Technology Association of Australia	· Support abolition of TGA conformity assessment for low risk devices but confidence building should be completed before ANZTPA so quality of high risk devices also assured.	Proposal A and Proposal C are linked. Proposal A provides assurance in the conformity assessment of higher risk devices. This, together with MRA confidence building to be undertaken during 2014 and 2015, provides greater premarket scrutiny of higher risk devices (whether manufactured in Australian or overseas) which enables this change for Australian manufacturers.
Medical Technology Association of New Zealand	· Abolish TGA conformity assessment for all classes of medical devices to prevent disadvantage to Australian companies.	Option 2 Proposal C now proposed the abolition of the requirement for TGA conformity assessment for all Australian manufacturers
Professor Guy Ludbrook	· Success of the proposal depends on quality of overseas conformity assessment	For this reason Proposal A and Proposal C are linked. Proposal A provides assurance in the conformity assessment of higher risk devices. This, together with MRA confidence building to be undertaken during 2014 and 2015, provides greater premarket scrutiny of higher risk devices (whether manufactured in Australian or overseas) which enables this change for Australian manufacturers.
ResMed Ltd	· Clarification required whether this will prevent manufactures obtaining quality system certification from the TGA- thus impacting supply in Southeast Asia and South American countries. · Supportive of these changes for all classes of device.	All types of conformity assessment certificates will still be offered by the TGA.
Stryker South Pacific	· Supports- Make use of Notified Bodies ASAP	
William A Cook Australia Pty Ltd	· Should extend to Class III, AIMD and Class IIb implantable devices as well and then undergo a Level 3 application audit.	Option 2 Proposal C now proposed the abolition of the requirement for TGA conformity assessment for all Australian manufacturers. Manufacturers relying on EU certification are subject to greater when applying for inclusion on the ARTG than those holding TGA or MRA conformity assessment certification, and this may include audit requirements.

Stakeholder	Stakeholder comments	TGA Comments
Name withheld at submitters request	· Supports proposal as is	
Name withheld at submitters request	· Proceed even if Proposal A not implemented. No TGA conformity assessment for devices other than Class III, AIMD and Class 4 IVDs, implantable medical devices and/or surgically invasive devices intended for long term use.	Proposal A and Proposal C are linked. Proposal A provides assurance in the conformity assessment of higher risk devices. This, together with MRA confidence building to be undertaken during 2014 and 2015, provides greater premarket scrutiny of higher risk devices (whether manufactured in Australian or overseas) which enables this change for Australian manufacturers.
Name withheld at submitters request	· Aim towards abolishing conformity assessment for high risk devices as well. · Support proposal as is · Accept 3rd party conformity assessment certificates from TGA designated agencies for all Class III/AIMD medical devices.	Option 2 Proposal C now proposed the abolition of the requirement for TGA conformity assessment for all Australian manufacturers
Name withheld at submitters request	· Aim towards abolishing conformity assessment for high risk devices as well. · Acknowledge IMDRF work and develop single audit to recognise 3rd party assessments.	Option 2 Proposal C now proposed the abolition of the requirement for TGA conformity assessment for all Australian manufacturers
Name withheld at submitters request	· All Australian manufactured devices to use EU reports.	Option 2 Proposal C now proposed the abolition of the requirement for TGA conformity assessment for all Australian manufacturers

Stakeholder	Stakeholder comments	TGA Comments
Name withheld at submitters request	· The proposal should encompass any device that has undergone EU conformity assessment certification. · TGA needs to end confidence building and designate notified bodies that meet audit criteria and align with international regulators.	Option 2 Proposal C now proposed the abolition of the requirement for TGA conformity assessment for all Australian manufacturers Proposal A and Proposal C are linked. Proposal A provides assurance in the conformity assessment of higher risk devices. This, together with MRA confidence building to be undertaken during 2014 and 2015, provides greater premarket scrutiny of higher risk devices (whether manufactured in Australian or overseas) which enables this change for Australian manufacturers.
Not support		
Global Orthopaedic Technology	· Increased costs and prevention of Australian consumer's access to products	Proposal A and Proposal C are linked. Proposal A provides assurance in the conformity assessment of higher risk devices. This, together with MRA confidence building to be undertaken during 2014 and 2015, provides greater premarket scrutiny of higher risk devices (whether manufactured in Australian or overseas) which enables this change for Australian manufacturers.
NSW Department of Health	· Implied not support- what other mechanisms in place to ensure device safety standards. · Suggested simplification of processes rather than abolition	
Bruce Arnold & Dr Wendy Bonython	· Concerns over EU notified bodies. · Level of scrutiny seems to be discretional	
No comment		

Other issues: IVD Australia recommends the term 'raw data' not to be used as it implies individual data points.

Comments outside of the scope of proposal 2- Cancer Voices Australia: (1) Support the idea of all models and variations of a device be registered to ensure safety of use and to remove confusion as to what exactly is registered and what is not. (Proposal 3 – Product name); (2) Strongly support more product information being required to be published on the TGA website. (Proposal 4)

Attachment E: Previous and current reform proposals

The following table maps the reform proposals in the 2010 and 2013 consultation processes, illustrating how these proposed reforms have developed over this period.

October 2010 Consultation Paper	TGA Blueprint Implementation Plan July 2012*	January 2013 Consultation Paper	May 2013 RIS Exposure Draft	Notes
Proposal 1 Reclassification of joint replacement implants	Agreed			Done – joint replacement implants were reclassified from 1 July 2012.
Proposal 2A Use of third party assessment bodies for all Australian medical device manufacturers	The TGA will further develop these proposals in consultation with stakeholders and provide advice to Government.	Proposal C – Abolition of requirement for TGA conformity assessment for Australian manufacturers of lower risk medical devices (limited application to Class IIb and lower)	Option 2 - Proposal C - Abolition of requirement for TGA conformity assessment for Australian manufacturers (applies to all classes of devices, as originally proposed in 2010 proposal)	
Proposal 2B Increasing pre market scrutiny for implantable medical devices	The TGA will further develop these proposals in consultation with stakeholders and provide advice to Government.			
(i) Class III and AIMD implantable devices require a TGA conformity assessment certificate to be issued		Proposal A – introduction of Level 3 audit to assess evidence of conformity (including new fee)	Option 2 – Proposal A - new Level 3 audit to assess evidence of conformity (including new fee)	The initial proposal for TGA conformity assessment for all Class III implantable and AIMD medical devices has been replaced with the Level 3 audit proposal
(ii) Expanding the Class IIb implantable devices to be selected for mandatory auditing		Proposal A – expanded targeting of mandatory audits to all Class IIb implantable and long term surgically invasive medical devices.	Option 2 – Proposal A - expanded targeting of mandatory audits for targeted devices (new regulatory instrument proposed)	Though not identical, this option is a direct progression from the 2010 proposal to select Class IIb implantable devices for mandatory audit

October 2010 Consultation Paper	TGA Blueprint Implementation Plan July 2012*	January 2013 Consultation Paper	May 2013 RIS Exposure Draft	Notes
Proposal 2C Recognition of third party assessment bodies	The TGA will further develop these proposals in consultation with stakeholders and provide advice to Government.			
(i) Confidence building for EU notified bodies designated under the MRA				This option has been overtaken by the update of the MRA and confidence building is being progressed in that context
(ii) Recognising Australian third party assessment bodies				This option has been overtaken by the proposed EU notified reforms. Immediate issues are addressed by the Option 2, Proposal A- mandatory audit requirements.
Proposal 3 Amending the way in which a medical device is included in the ARTG and enhancing identification of approved devices				
(i) Amend the way in which a kind of device is included on the ARTG (product name)	The TGA will work with stakeholders to develop a proposal to provide device product names with a planned implementation from 1 July 2013			This proposal is being pursued as the separate TGA 'product name' project and will be considered separately to this consultation process.

October 2010 Consultation Paper	TGA Blueprint Implementation Plan July 2012*	January 2013 Consultation Paper	May 2013 RIS Exposure Draft	Notes
(ii) Enhance the ability to identify devices that have been approved by the TGA for supply in Australia (including ARTG number on product labels, etc)	Not agreed. Proposal not supported as other reforms will achieve this objective			Following the 2010 consultation it was agreed that this proposal would not progress.
Proposal 4 Publication of device product information on the TGA website	The TGA will work with stakeholders to develop a proposal to provide product information for medical devices with implementation planned from 1 July 2014	Proposal B – Publication of TGA regulatory decisions	Option 2 – Proposal B - Publication of TGA regulatory decisions	This option is addressed through Proposal B under Option 2 and will be progressed as described in the RIS exposure draft

* At the time the TGA Blueprint was released in December 2011, the response for Proposals 2A, B and C was only noted, pending the outcome of the Senate Community Affairs Referenced Committee inquiry into "The regulatory standards for the approval of medical devices in Australia". The response for Proposal 2A, B and C at that time was: *Noted. Linked to further recommendation in Senate Community Affairs Referenced Committee inquiry into "The regulatory standards for the approval of medical devices in Australia".* By the time the Blueprint Implementation Plan the way forward on these issues had been clarified, and so this is included in the table above.

Attachment F: Summary of consultation on Regulation Impact Statement exposure draft, May 2013

<<To be completed following close of submissions on exposure draft consultation>>

Attachment G: Glossary and acronyms

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.
AusPAR	An AusPAR provides information about the evaluation of a prescription medicine and the considerations that led the TGA to approve or not approve an application. Before a prescription medicine can be made available in Australia, the company legally responsible for supplying the product must lodge a submission with the TGA. The TGA then evaluates the safety, quality and effectiveness of the product to determine if the benefits to people taking the medicine outweigh the risks.
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: · 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. ***Level 2:*** The TGA will consider all of the documentation considered in a Level 1 audit. In addition, the TGA will consider: · the risk management report; · the clinical evaluation report; · efficacy and performance data for medical devices that disinfect including those that sterilise other medical devices. ***Level 3:*** This RIS proposed introduction of a Level 3 audit, which would consider most of the documentation considered in a Level 1 and Level 2 audits. In addition the would consider: · raw clinical data underpinning the conformity assessment report (in addition to the expert clinical report as occurs for the Level 2 audit); and

- the Design Examination report; and
- a desk audit of the manufacturer's quality management system.

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 Body	Conformity assessment body means an organisation that conducts conformity assessment activities and includes test facilities and certification bodies. This may include: · First-party conformity assessment is where assessment and/or testing are undertaken by the responsible party (e.g. the manufacturer, supplier, or importer); · Second-party conformity assessment is assessment and/or testing are undertaken by a person or organization that has a user interest in an object (e.g. the procurer, purchaser or user); · Third party conformity assessment is where assessment and/or testing are undertaken by an independent organisation. Third parties such as testing laboratories are qualified as independent in that they do not possess an interest in the person or organisation that provides the medical device being assessed and do not have any user interests in that object.
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 Declaration of Conformity	A certificate of compliance for conformity assessment issued by a European Notified Body. With this Declaration of Conformity, the manufacturer can label the product with the CE Mark, which is required for distribution and sale in the EU. The EU Declaration of Conformity can also be used to support an application for inclusion of a medical device in the ARTG.
European Competent Authority	A competent authority designates notified bodies to conduct conformity assessment procedures specified in the various directives – in the European Union these are the regulators in the Member States, such as the Medicines & Healthcare products Regulatory Agency (MHRA) on the UK.
European Notified Body	A notified body, in the European Union, is an organisation that has been accredited by a Member State to assess whether a product meets certain preordained standards. Assessment can include inspection and examination of a product, its design and manufacture. For medical devices, a Notified Body may designate that a medical device conforms to the EU Medical Devices Directive, which defines the standards for medical devices.
In-Vitro Diagnostic	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

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

IVD medical devices:

Class	Risk	Examples
Class 1 IVD	No public health risk or low personal risk	Enzyme immunoassay analyser. Ready to use microbiological culture media.
Class 2 IVD	Low public health risk or moderate personal risk	Pregnancy self-testing kit. Liver function tests.
Class 3 IVD	Moderate public health risk or high personal risk	Test to detect the presence or exposure to a sexually transmitted agent such as C. trachomatis or N. gonorrhoea. System for self-monitoring of blood glucose.
Class 4 IVD	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)[32]. 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.

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.

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

Revision procedures	The need to undergo further corrective surgery.
Sponsor	Under Section 7 of the Act a Sponsor, in relation to therapeutic goods, means: (a) a person who exports, or arranges the exportation of, the goods from Australia; or (b) a person who imports, or arranges the importation of, the goods into Australia; or (c) 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; or (e) 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.

Acronyms

AIMD	Active Implantable Medical Devices
AOA	Australian Orthopaedic Association
ARTG	Australian Register of Therapeutic Goods
ASR	A series of DePuy hip replacement products
CAB	Conformity Assessment Body
CHF	Consumers' Health Forum of Australia
CRIS	Cost Recovery Impact Statement
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
IMDRF	International Medical Device Regulators Forum

ISO	International Standards Organisation
IVD	In-Vitro Diagnostic device
MTAA	Medical Technology Association of Australia
NJRR	National Joint Replacement Registry
OBPR	Office of Best Practice Regulation (Department of Finance and Deregulation)
PIP	Poly Implant Prothèse (French breast implant manufacturer)
QMS	Quality Management System
RIS	Regulation Impact Statement
TGA	Therapeutic Goods Administration

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 #