Changes to premarket assessment requirements for medical devices

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1. Executive summary

The Medical Technology Association of Australia (MTAA) is pleased to provide comment on the Proposal Paper, *Changes to premarket assessment requirements for medical devices*. MTAA acknowledges that the current environment for regulation of medical devices has been influenced by a number of recent events including the current reforms to regulation of products in the European Union arising from high profile device failures, and the recent reports of two inquiries undertaken by Committees of the Australian Senate[1].

MTAA also notes the recent reforms in Australia which have increased the rigour of premarket review of implantable orthopaedic hips, knee and shoulder joints, and the current consideration of enhanced post-market surveillance through greater utilisation of clinical quality registries.

MTAA and its member companies are of the view that a combination of the recently-implemented reforms which have raised the level of risk classification of Class IIb orthopaedic devices, the proposed reforms to improve the identification of medical devices on the Australian Register of Therapeutic Goods (ARTG), and increased utilisation of features already available in the current regulatory system, will address many of the residual concerns sought to be addressed by the proposals outlined in the Proposal Paper. In particular the regulator, the Therapeutic Goods Administration (TGA) should make increased use of the information already provided by the sponsors of higher risk medical devices (Class III and implantable Class IIb) through the lodgement of annual reports for each of the first three years following inclusion on the Australian Register of Therapeutic Goods (ARTG).

The proposed reforms in the European Union, where many products on the Australian market are initially registered with a CE mark, may result in additional scrutiny before products are brought to the Australian market. The reforms propose increased examination of the evidence to support regulatory approval, and significantly increased vigilance of the Conformity Assessment Bodies.

[1] The Senate Community Affairs Committee Inquiry into the regulatory standards for the approval of medical devices in Australia and the Senate Community Affairs Committee Inquiry into the role of the Government and the Therapeutic Goods Administration (TGA) regarding medical devices, particularly Poly Implant Prosthese (PIP) breast implants

Any reforms need to take account of the complex nature of medical devices and the circumstances under which they are used by clinicians. It is not just the medical device itself that has relevance to an optimal patient outcome from a procedure. A patient for whom a medical device is required already has compromised health, and the effectiveness of the procedure is highly dependent on the skill and technique of the doctor, and patient compliance following the procedure.

MTAA supports transparency of decision-making by TGA, and the publication of information which substantiates the basis of the decision which has been taken. MTAA believes that transparency of decision making will lead to more consistent TGA decisions and an improvement in the quality of submissions.

MTAA supports the modest extension of conformity assessment to third party reviewers for lower risk medical devices but urges TGA to complete its 'confidence-building' to enable availability of third party assessors for higher risk devices well in advance of the full implementation of the combined regulatory agency, Australia New Zealand Therapeutic Products Agency (ANZTPA).

2. About the Medical Technology Association of Australia

MTAA represents the manufacturers, exporters and suppliers of medical technology products in Australia. MTAA represents companies which account for the majority of products listed on the Australian Register of Therapeutic Goods (ARTG) and approximately 75% of the higher risk implantable medical devices products listed on the Prostheses List and used in the Australian marketplace. The member companies cover the spectrum of the industry in Australia, from subsidiaries of major multinational medical technology companies to independent distributors and small to medium sized Australian innovator companies.

3. General comments

MTAA supports the characterisation of TGA's function as maintaining a national regulatory system relating to the quality, safety, performance and timely availability of therapeutic goods, specifically medical devices[2]. MTAA also supports the need to ensure avoidance of duplication of regulatory effort and unnecessary delays to access[3].

In reviewing the proposals for reform set out in the Proposal Paper, MTAA acknowledges the drivers for the reforms to premarket assessment which have been outlined arising out of recent Government reviews (such as the Review of Health Technology Assessment) and more recently, the recommendations from two inquiries of Committees of the Australian Senate. As the Australian and New Zealand Governments move to the establishment of a combined regulatory agency, ANZTPA, it is imperative that reforms to the regulation of medical devices are finalised to provide certainty to companies operating in both markets where many

[2] Australian Government, Department of Health and Ageing, Therapeutic Goods Administration: *Changes to premarket assessment requirements for medical devices*. Version1.0. January 2013
[3] Page 5 of the reforms paper

products are supplied on the basis of prior regulatory approval in the European Union with a CE mark.

MTAA recognises that the decentralised system in Europe has raised concerns with consistency of assessment. However the proposed reforms to the European system, which forms the basis of the Australian system, will act to improve patient safety while not unnecessarily delaying patient access to medical devices, nor impeding innovation. In particular MTAA notes the proposed reforms to monitoring and control of European Notified Bodies should ensure that only those which meet the highest standards of competence to assess safety and quality of products will be accredited. Australia should be mindful of implementing reforms prior to the EU completing its review of requirements for regulation of medical devices. Given that many products in the Australian market are also subject to review under the European system it is important to maintain alignment to ensure that Australia derives maximum benefit from the reforms to be introduced in the EU without unnecessary duplication.

The Australian market is small in a global context – approximately 2%. As a result it is essential for Australian patient access to newer life-saving and life-enhancing technologies that the Australian regulatory system should remain appropriate, accessible, and not duplicative of the efforts of equivalent overseas regulators.

The case for reform

MTAA reiterates that there should be an identifiable and demonstrated need for the proposed reforms, as opposed to a perception that 'more should be done' or the systems currently in place are inadequate.

MTAA notes that the issues which arose in the case of the two recent high profile medical device failures, the PIP breast implant and the ASR hip joint, would not have been identified even with the additional premarket scrutiny proposed. MTAA echoes the sentiments of other bodies that no amount of regulation could have prevented the PIP breast implant issue which was attributed to deliberate fraud by the manufacturer.

Recent reforms, such as the reclassification of implantable orthopaedic hip, knee and shoulder joints will increase scrutiny of those devices. MTAA also asserts that there are existing requirements within the Australian regulatory framework which are not fully utilised and could be used to more closely monitor higher risk devices in the early period in the market or made more transparent to give greater confidence in the regulatory system.

These requirements include the following:

a) Annual Report

It is a condition of inclusion in the ARTG of Class III, AIMD and implantable Class IIb devices that sponsors provide TGA with three consecutive year annual reports following inclusion.

Sponsors are required to submit the following details by product model number to TGA:

- ARTG no
- Product name
- Model no(s)
- Number supplied in Australia
- Number supplied world wide (numbers should include devices that are the same but supplied under a different name in another jurisdiction)
- Number of complaints in Australia
- Number of complaints world wide
- Number of adverse events and incident rates in Australia (Rate= No. of events/ No. Supplied x 100 = Rate%)
- Number of adverse events and incident rates world wide
- A list of the more common complaints and all of the adverse events
- Device Incident Report (DIR) number of those adverse events reported to the TGA
- Regulatory/corrective action/notification by manufacturer.

These reports act as an early warning system once a device is used in or on a patient, bringing real-world experience of the device to life.

b) TGA Statutory Advisory Committees

These are committees from which TGA can obtain independent expert advice on specific scientific and technical matters to aid the TGA's regulatory decision making and other regulatory processes. Committee members are appointed by the Minister and must have expertise in relevant clinical or scientific fields or appropriate consumer issues. While TGA gives appropriate consideration to advice from advisory committees, it is not obliged to follow it.

The advisory committees pertaining to medical devices are:

Advisory Committee on Medical Devices (ACMD) - advises and makes recommendations to the TGA regarding the entry of medical devices on the Australian Register of Therapeutic Goods.

Advisory Committee on the Safety of Medical Devices (ACSMD) - advises and makes recommendations to the TGA on the safety, risk assessment, risk management and performance of medical devices supplied in Australia.

c) Data from Australian Clinical Quality Registries

The purpose of a clinical quality registry is to improve the safety and quality of healthcare delivered to patients. The information collected from registries is used to implement quality improvements where required. The National Joint Replacement Registry (NJRR) is a clinical quality registry from which the data collected has been

used to inform surgeons, other health care professionals, governments, orthopaedic companies and the community. MTAA supports the introduction of additional clinical quality registries where there is a demonstrated need and public benefit.

d) International vigilance exchange

Through participation in Global Harmonisation Task Force (GHTF) and now International Medical Device Regulators Forum (IMDRF), the regulators of member nations (including TGA) have an obligation to exchange vigilance information on events that have led to corrective action, including recalls, being taken or where there is a serious risk to the safety of patients and other users. This system gives participating countries knowledge of problems experienced in other nations so that actions can be taken to avoid similar events.

Reforms in progress

Several regulatory reforms which address the need for greater premarket scrutiny and identification of devices included on the ARTG are already underway including:

- The up-classification of hip, knee and shoulder joints from Class IIb to Class III.
- Improved identification of medical devices on the ARTG through naming protocols for products included under a group 'family' name (the first consultation paper is on this reform is anticipated in June 2013).

Other improvement projects

MTAA recognises that the IMDRF (of which Australia is a participating member) has several work items underway to improve the regulatory model for medical devices. These work items include:

- A review of the National Competent Authority Report (NCAR) System - this work item will review current arrangements and advise on opportunities for improvement and the possible expansion of the scheme to include select premarket decisions and other post-market activities.

- Medical Device Single Audit Programme (MDSAP) - this work item is to develop a standard set of requirements for auditing organisations performing regulatory audits for a medical device manufacturer's quality management system. The consistency derived from this set of auditing requirements will encourage confidence between conformity assessment bodies with the ultimate goal of establishing a single audit programme, where the audit of one conformity assessment body will be accepted by others.

The reforms in progress, together with increased utilisation of current regulatory requirements and tools, and robust and timely post-market follow up using Australian

clinical quality registries and international vigilance systems address the major concerns underpinning the proposals for increased scrutiny.

4. Proposal A: increased scrutiny of conformity assessment as part of mandatory application audits prior to ARTG inclusion

Targeting Mandatory Audits

MTAA notes that increased premarket scrutiny is proposed for implantable or long-term surgically invasive medical devices. While MTAA agrees that the scope of coverage for premarket scrutiny of implantable devices is appropriate, MTAA raises concern about extending the requirement to all long-term surgically-invasive devices. These are understood to mean a device that is used in the human body for more than 30 days and as such would include ports for enteral feeding, shunts, and cannulas where the risk to the patient is more likely to arise from hospital-acquired infection than device-related issues. MTAA questions the justification for inclusion of these basic surgical devices. MTAA proposes that the scope be limited to Class III, AIMD, and implantable Class IIb products.

Assessment of evidence of conformity

MTAA has concerns that Class IIb implantable or surgically invasive medical devices are unable to meet the documentary requirements of a Level 2 audit as in the EU these devices do not require design examination. There is currently no mechanism under the European Medical Device Directive for design examination certificates to be issued for Class IIb devices. This reform to premarket assessment needs to be precise and detailed with respect to the documentary requirements for Class IIb devices.

MTAA questions the rationale for the introduction of the proposed Level 3 Application Audit, increasing the premarket evaluation of documentation for Class III implantable and AIMD devices rather than strengthening post market surveillance. In contrast to pharmaceuticals, the areas where medical devices cause problems are primarily in relation to sporadic manufacturing problems which are not apparent or easily detected at the market authorisation phase, and secondly, particularly in terms of implantable devices, the way they wear over time in the complex environment of the human body. As most implantable devices are designed to last for several years, the behaviour of the implant over time would be difficult to pick up in pre-clinical studies. The long term success of implanted medical devices also relies on other idiosyncratic factors such as the way they are used, how a patient is selected, the skill of the implanting surgeon, and patient compliance with caring for the device post implantation. Bearing these factors in mind, MTAA challenges the notion that an increase in premarket scrutiny, namely the additional review of the Notified Body's design examination report and site audit report, for AIMD and Class III implantable devices would improve patient outcomes with these devices.

MTAA has concerns about whether TGA will commit to timeframes for additional scrutiny, noting that currently the timeframes for abridged conformity assessment

vary considerably and are significantly longer than the evaluation time for a product undergoing Level 2 Application Audit. This results in unpredictability for a company planning to bring a new product into the Australian market in terms of forecasting, manufacturing volumes, supply chain and logistics.

MTAA proposes that TGA continue to apply the requirement for a Level 2 Application Audit to all Class III and AIMD devices and increase the annual report requirement from three to five consecutive years post inclusion on the ARTG. Proper analysis of these reports would highlight problems with high risk devices which would only become apparent in the post-market phase. TGA is already able to use existing powers to request additional information from the design dossier[4] during a Level 2 Application Audit should the standard documentation requested raise any concerns.

Impact of application audit fees and other additional costs

Member Data

Member companies of MTAA have provided cost comparisons which have enabled an analysis of the likely increase in cost, based on 2012 actual applications.
The analysis makes the following assumptions:

- The fees used are those applied as of 1 July 2012.
- The average cost of a Notified Body design examination report is approximately $10000 AUD.
- The worse case figure for Level 3 Application Audit of $15000 AUD was used.
- The kinds of devices represented by member data are those affected by the proposal:

Table 1: Kinds of devices affected by the proposal

Kinds of Device represented	Class
Medical Devices that Disinfect other Medical Devices	IIb
Implantable intra-ocular lenses and intra-ocular viscoelastic fluids or barrier contraceptives	IIb
Implantable or Surgically Invasive for long term use	IIb
Non Implantable and Non surgically invasive for long-term use	III
Implantable or long term invasive	III
Active Implantable Medical Device	AIMD

[4] Paragraph 6 page 10

Figure 1: Classification of medical technology companies represented in the member data

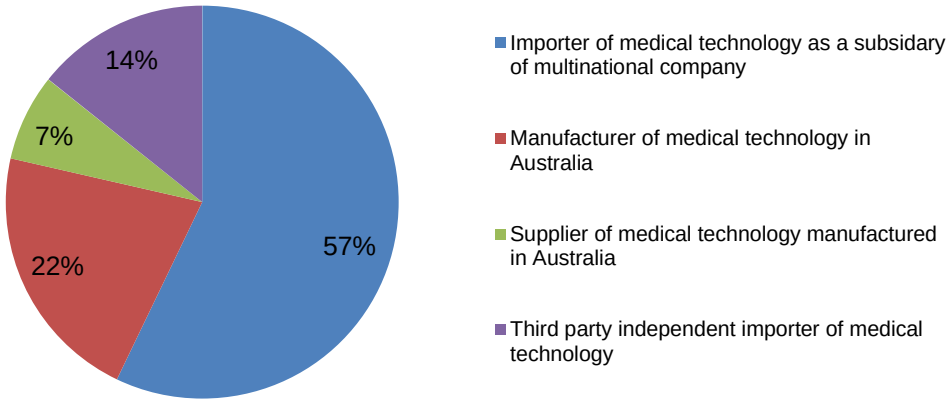
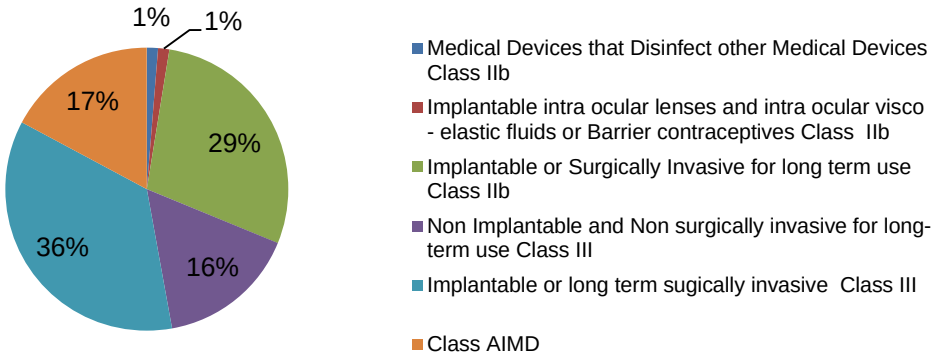


Figure 1 shows that member data collected was representative of the kinds of medical technology companies in Australia.[5]

The companies that provided cost analysis data are representative of the following therapeutic areas:

- Anesthesiology
- Cancer
- Critical care
- Diabetes
- Dialysis
- Infection control
- Musculoskeletal conditions
- Obesity
- Opthalmology
- Othopaedics
- Respiratory
- Surgical

Figure 2: Classification and kinds of devices[6] represented in the member data



[5] MTAA Database, members could select more than one category.
[6] From pages 10 and 13 of the proposal paper.

The member data provided was representative of all devices affected by the reforms to premarket assessment.

Figure 3: Current situation: Types of application audits for the kinds of devices represented.

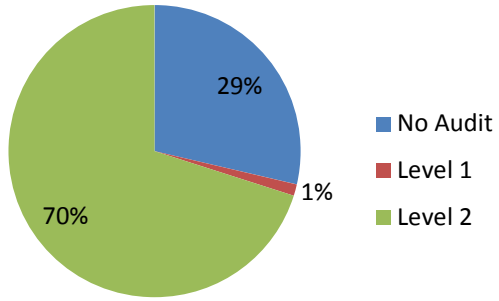


Figure 4: Proposed situation: Type of application audits for the kinds of devices represented.

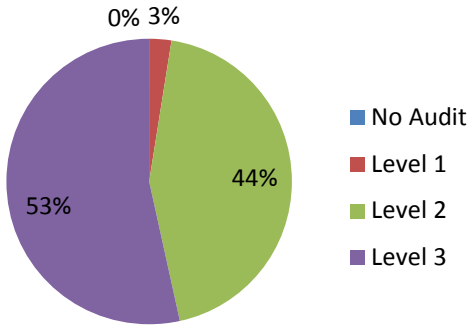
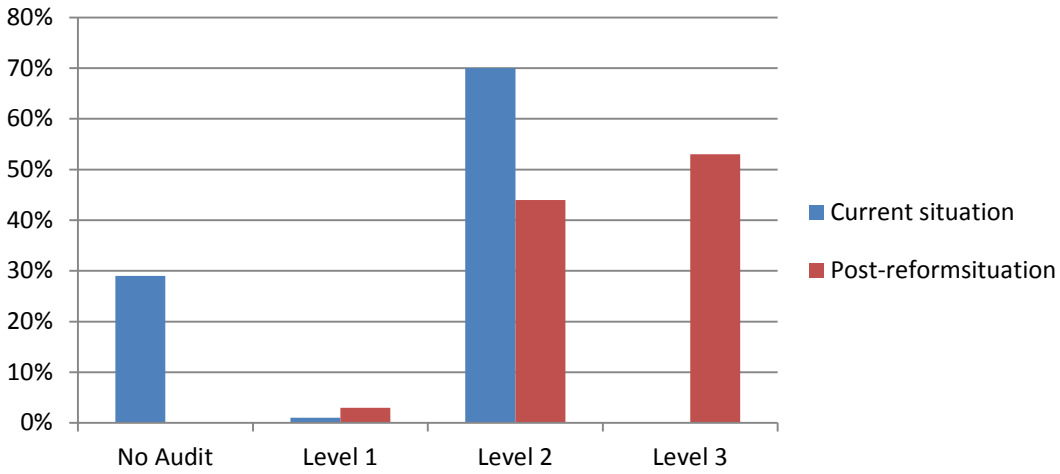


Figure 5: Application Audits pre and post reform



Figures 3, 4 and 5 show the type of application audit conducted for 2012 submissions compared to the type of application audit that would be conducted under the reforms. Should the reforms be implemented there would be a 29% increase in application audits conducted and 97% of all application audits would be Level 2 or 3.

MTAA is concerned that the medical technology sector in Australia, and the TGA itself, will struggle to find the additional resources required to submit and assess the increase in application audits given that regulatory/quality professionals make up only 4% of personnel employed in the sector.[7]

Members were asked to provide the numbers of submissions for the kinds of devices that currently undergo application audits in accordance with Regulation 5.3. The total cost of the submissions was calculated including the application fee and

[7] MTAA industry wide survey 2012

application audit fee. The calculation was repeated for the proposed application audits and costs of obtaining the technical report for the Level 3 Application Audit was added and the current situation and reformed situation compared.

Table 2: Member cost analysis

	Minimum	Maximum	Average
Difference in total cost Current situation vs. proposed situation	**$12,340**	**$694,960**	**$254,921**

	Minimum	Maximum	Average
Percentage increase in total costs	**89%**	**693%**	**$277%**

	Minimum	Maximum	Average
Percentage increase in assessment fees	**79%**	**693%**	**188%**

	Minimum	Maximum	Average
Percentage increase in fees due to proposed inclusion of Class IIb implantable or surgically invasive devices for long-term use for Level 2 Application Audit assessments	**0%**	**693%**	**567%**

	Minimum	Maximum	Average
Percentage increase in fees due to proposed Level 3 Application Audit assessment for Class III implantable or surgically invasive devices for long-term use and AIMD.	**0%**	**121%**	**88%**

	Minimum	Maximum	Average
Costs due to Design Examination reports required for Level 3 Application Audits	**$0**	**$150000**	**$46000**

Members' total submission costs were significantly affected by the proposed changes to premarket assessment with the maximum cost difference being a 693% increase (average 277%) on the current situation and the main driver being the change of Class III and AIMD devices to Level 3 audit and the $15000 assessment fee. MTAA notes that this assessment fee is comparable to the cost of an abridged conformity assessment. The maximum increase in assessment fees due to the Level 3 Application Audit requirement was 121% for Class III implantable and AIMD devices. The documentation requirements for the Level 3 Application Audit also significantly affected costs with the average calculated spend on design examination reports being $46000 (maximum $150000).

The proposed Level 2 Application Audit for Class IIb implantable or surgically invasive devices for long-term use would impose a 567% (average) increase in assessment fees for these devices.

The average increase in assessment fees considering all application audit types is 188%.

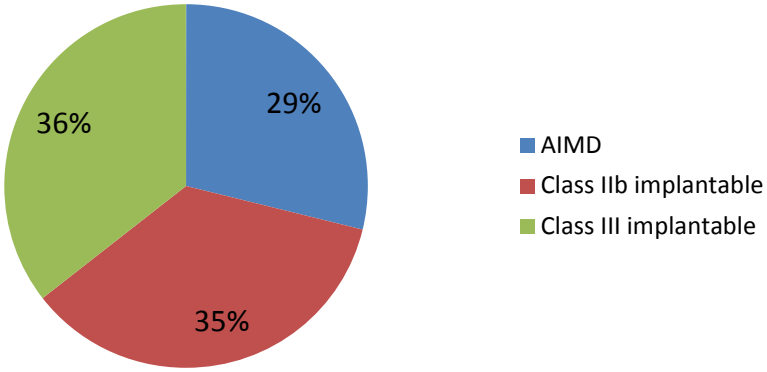
Prostheses List Data

An analysis the February 2013 Prostheses List was undertaken for devices entered on the ARTG in 2012. As the data was from the Prostheses List only the following kinds of devices are represented:

Table 3: Kinds of devices affected by the proposal on the Prosthesis List

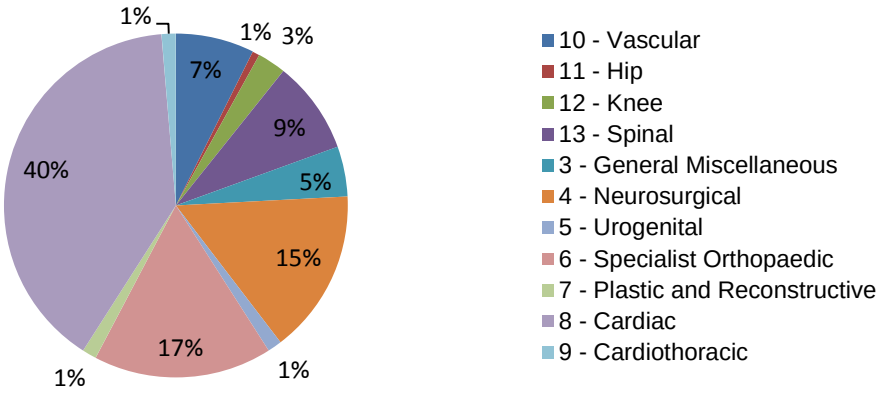
Kinds of Device represented	Class
Implantable or Surgically Invasive for long term use	IIb
Implantable or long term invasive	III
Active Implantable Medical Device	AIMD

Figure 6: Class of devices on the prostheses list included on the ARTG in 2012



This data does not capture up-classified orthopaedic joints as the reform for reclassification was implemented on 1 July 2012.

Figure 7: Prostheses List product categories entered on to the ARTG in 2012.



The percentage increase in assessment fees was calculated assuming that all devices on the February 2013 Prostheses List entered on to the ARTG in 2012 did not undergo TGA conformity assessment.

Table 3: Increase in TGA assessment fees by Prostheses List product category

Prostheses List Product Category	**% increase in assessment fees**
10 - Vascular	128%
11 - Hip	693%
12 - Knee	693%
13 - Spinal	693%
3 - General Miscellaneous	254%
4 - Neurosurgical	131%
5 - Urogenital	693%
6 - Specialist Orthopaedic	391%
7 - Plastic and Reconstructive	693%
8 - Cardiac	121%
9 - Cardiothoracic	121%
Average	419%
Max	693%
Min	121%

The maximum and minimum increases were comparable to member data however the average increase (419%) was considerably higher due to only implantable devices being considered.

Figure 8: TGA Assessment Fee increase: current situation vs post-reform situation by Prostheses List product category for devices on the February 2013 Prostheses List entered on to the ARTG in 2012.

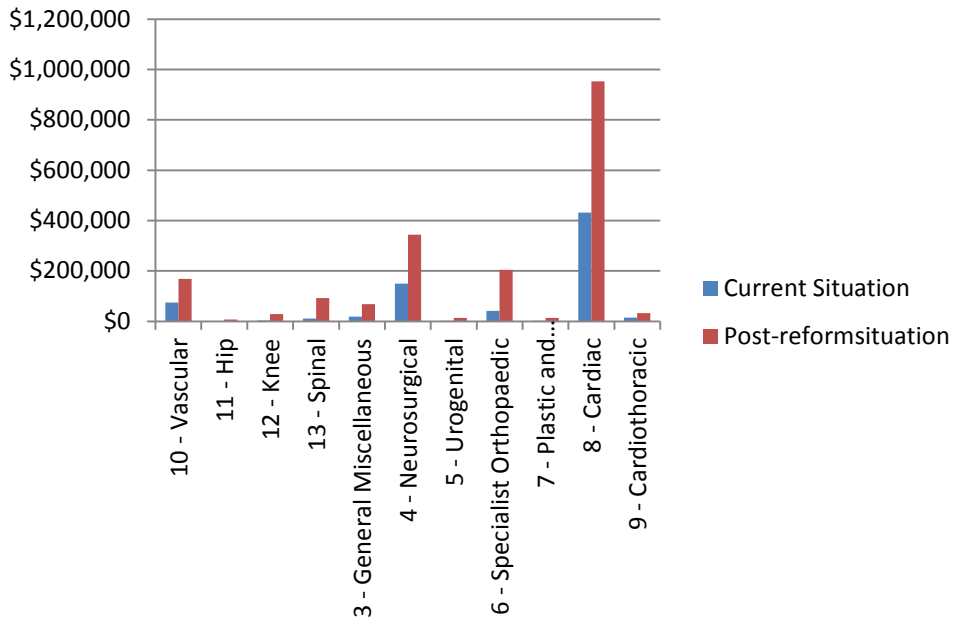


Figure 8 shows devices in the Prostheses List Cardiac product category (Class III and AIMD) are those most affected by the proposed assessment fees, with costs more than doubling due to the requirement for Level 3 Application Audit assessment.

TGA ARTG Data

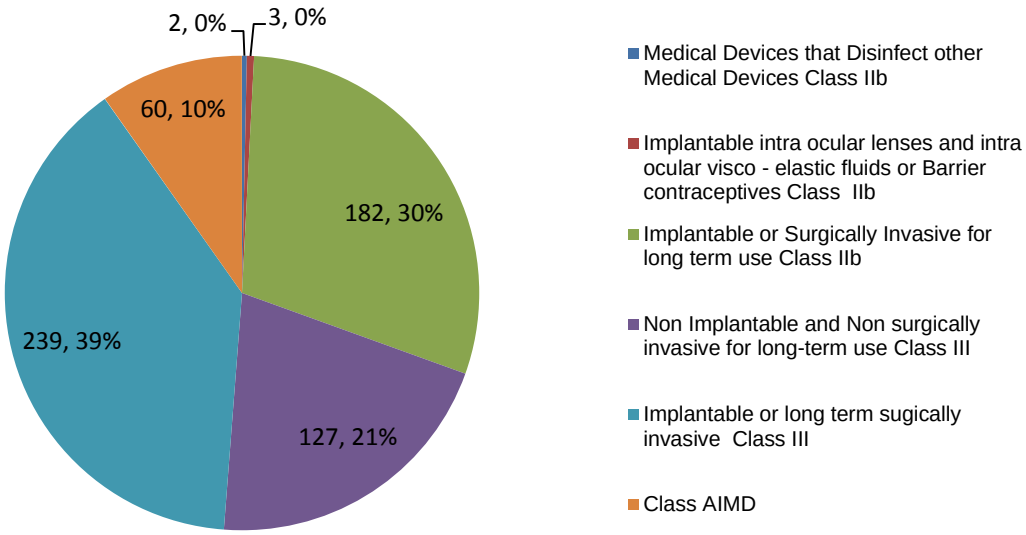
Preliminary analysis of the TGA ARTG data was conducted to ensure that the data collected from MTAA members and the Prostheses List data are indicative of the medical technology industry as a whole.

- The analysis was conducted on all ARTG medical device entries in 2012.
- There were a total of 5084 (all classes) ARTG medical device inclusions in 2012. The inclusions were sorted into the kinds of devices affected by the proposals[8] (Table 1).

Table 4: Kinds of devices affected by the proposal included on the ARTG in 2012

Kinds of Device represented	Class	Total
Medical Devices that Disinfect other Medical Devices	IIb	2
Implantable intra-ocular lenses and intra-ocular viscoelastic fluids or barrier contraceptives	IIb	3
Implantable or Surgically Invasive for long term use	IIb	182
Non Implantable and Non surgically invasive for long-term use	III	127
Implantable or long term invasive	III	239
Active Implantable Medical Device	AIMD	60

Figure 9: Classification and kinds of devices represented on the ARTG



[8] Class I and Class IIA were excluded. Class IIb and Class III implantable were determined by cross referencing the Prostheses List. Long term surgically invasive were identified by checking GMDN descriptions.

Figure 11: Current situation: Types of application audits for the kinds of devices represented.

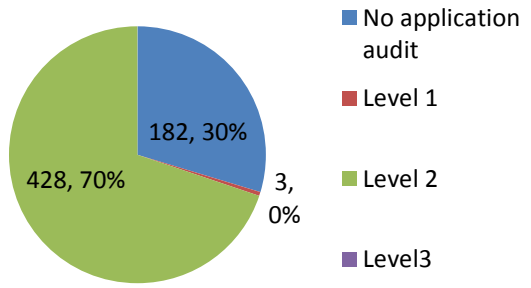


Figure12: Proposed situation: Type of application audits for the kinds of devices represented on the ARTG

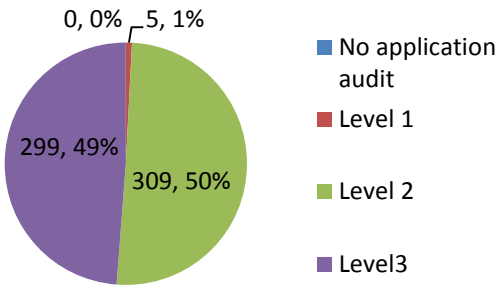


Table 5: Total cost increase for the kinds of devices affected by the proposal included on the ARTG in 2012.

	Current Situation	Post reform	Difference in cost
Difference in total cost for the kinds of devices affected by the proposal	**$3,307,170**	**$11,324,660**	**$8,017,490**

Table 6: ARTG Cost Analysis

Percentage increase in total costs	**242%**
Percentage increase in assessment fees	**114%**
Percentage increase in fees due to proposed inclusion of Class IIb implantable or surgically invasive devices for long-term use for Level 2 Application Audit assessments	**693%**
Percentage increase in fees due to proposed Level 3 Application Audit assessment for Class III implantable or surgically invasive devices for long-term use and AIMD.	**84%**

The ARTG cost analysis was comparable to the member data.

Conclusion

The requirement for additional documentation for TGA review will come at a considerable cost which appears disproportionate to the work to be undertaken and the reassurance sought for additional scrutiny. Additional cost and time is associated with obtaining and preparing the documentation required for submissions, on top of the additional TGA cost and review times associated with the proposed Level 3 Application Audits for implantable Class III and AIMD products and proposed Level 2 Application Audits for implantable Class IIb products and long term surgically invasive devices.

Other costs arising from with proposed Level 3 Application Audit are associated with obtaining Notified Body design examination reports. Not all Notified Bodies produce

design examination reports as a matter of course. These may have to be specially produced by the Notified Body for use by TGA at additional cost.

Submission cost increases resulting from the proposed reforms to premarket assessment are likely to be prohibitive for many new technologies entering the Australian market.

Devices that should be included for premarket scrutiny that have been missed

MTAA does not identify any additional medical devices that are not covered by the proposal.

Public health and safety benefits of this proposal

- MTAA agrees that this proposal delivers against the recommendation 8(c) of the HTA Review with respect to increased premarket scrutiny of Class IIb implantable devices, but questions the necessity for Class IIb long term surgically invasive devices to be included in the scope.

- MTAA questions the need for the Level 3 Application Audit proposing that Level 2 Application Audits are appropriate for Class III implantable and AIMD devices with an extension to the annual reporting requirement to five years. Additionally, MTAA challenges the notion that Level 3 Application Audit premarket scrutiny would improve patient outcomes as problems with these devices are generally seen post implantation.

- Risks - There is a level of unpredictability in the proposal in that the difference between audit levels is indicative only and at TGA's discretion. On page 10 of the Proposal Paper the range of elements which TGA might examine include quality management system (QMS) audit reports, reports about the design of the device (design and type exam reports), and component assessment reports included in the design dossier documents. Without clearly defined requirements for what would be required for a Level 3 Application Audit, the review period will be extended as companies will be left having to anticipate TGA's requirements and where they fall short, which may give rise to an increase in section 41JA requests. The increased submission cost and review times may be prohibitive to commercialisation of a device in Australia.

- Benefits - The necessity for Class IIb implantable devices to undergo Level 2 Application Audit will increase community confidence in these devices, however the documentation requirements for the Level 2 Application Audit of Class IIb implantable and long term surgically invasive devices need to be defined and not require documentation to be specifically produced for Australia at additional cost.

- Elements of the proposal that could be removed without reducing premarket rigour - MTAA is concerned that the use of Unique Product Identifiers (UPIs) the variants that results in a "family" of products being divided into multiple applications and ARTG inclusions can be seen as a fee-raising exercise rather

than a legitimate assessment of each product. Assuming that a Level 3 Application Audit is introduced (and noting that MTAA believes that concerns can be addressed as outlined above), MTAA proposes that each 'family' should be covered in one application, in alignment with how the products are assessed by the Notified Body but with each specific model covered by the application identified. The use of UPIs and variants should be replaced with identification of models of each device covered by the ARTG inclusion and this would enable physicians and consumers to search the ARTG to check if a specific model is included. The summary technical report should link to each product covered by that report without the need for an additional fee. This would still enable separate identification and registration but without duplicated cost and evaluation.

5. Proposal B: publication of TGA regulatory decisions

MTAA supports in principle the concept of greater transparency of information about approved medical devices. This information can help to inform clinicians and consumers about the products which are being used in them or on them as patients.

In considering the scope of the options outlined on page 14, MTAA comments:

- Medical devices that are automatically included in the ARTG should be excluded
- Publication should be limited to higher risk classifications such as Class III, AIMD and implantable medical devices. It is MTAA's position that clinicians have primary responsibility for properly informing patients about the medical device to be used and providing relevant information
- Publication should be after, and be independent of the time of, the decision to include the device on the ARTG.

A comparison is made with publication of information about the evaluation of a prescription medicine and the considerations that led the TGA to approve or not approve an application – Australian Public Assessment Reports for prescription medicines (AusPARS). MTAA notes that AusPARS concerning rejected medicines are only published after any appeal has been finalised.

Should an equivalent process to AusPAR be introduced for medical devices, similar considerations of commercially sensitive material and intellectual property should apply where the sponsor is provided with an opportunity to review the draft report prior to publication. A sponsor may provide alternative text for consideration by the TGA as replacement for commercially confidential material.

MTAA notes and supports the proposed approach in the EU whereby a summary of safety and clinical performance of Class III and implantable medical devices will be published on the publicly accessible European database. This is an appropriate starting point to increase the transparency of information underpinning a registration.

MTAA also supports consistent decision-making and disclosure of the basis for a decision which might create a precedent or set a standard which other applicants might follow. This is particularly of benefit where TGA publishes rulings or interpretations which can then be applied, similar to rulings by the Australian Tax Office.

MTAA believes that the transparency of the review process will encourage a higher standard of submission which will benefit both TGA and industry.

Concerns

MTAA has concerns that the publication of a rejection decision may mislead and result in an implied 'black mark' against a company, a single device or all its devices.

The misinterpretation of rejections and withdrawn applications could lead to increased public questions for both TGA and sponsors.

The information published about a rejected device could be used by a competitor company to inappropriately gain a commercial advantage.

Medicines industry's experience with AusPAR

MTAA notes that the medicines industry shared similar concerns before the introduction of AusPARs. However, none of the concerns were realised other than additional and resources required to review draft reports.

6. Proposal C: abolition of requirement for TGA conformity assessment for Australian manufacturers of lower risk medical devices

MTAA has long been an advocate for the expansion of options for conformity assessment of products manufactured in Australia. Restricting Australian-manufactured products to conformity assessment undertaken solely by TGA has impeded the development of a strong domestic medical technology industry as a number of Australian companies have moved to set up manufacturing offshore in countries where the assessment timelines and costs are more predictable and manageable.

One Australian manufacturer that would continue to be disadvantaged by proposal C is Cochlear Limited. As the only Australian manufacturer of Class AIMD devices, under proposal C its products would still be required to undergo TGA full conformity assessment. It is well recognised that timelines for this regulatory pathway are highly unpredictable, with some companies reporting assessments taking over two years to complete compared to a 90 day assessment by a European Notified Body. In Cochlear's case, this has resulted in its products being launched in the EU prior to Australia, and substantial delays in gaining regulatory approval in those markets (principally in the Asia Pacific region) that require 'country of origin' approval (and receipt of a corresponding TGA Free Sale Certificate). Conversely, cochlear implants

manufactured by foreign manufacturers have entered the Australian market prior to Cochlear's locally manufactured product, as they do not have to undergo TGA full conformity assessment.

Ideally, proposal C should be extended to all Australian manufacturers of medical devices, regardless of class of device, to enable these manufacturers to compete more fairly with foreign competitors. However, should proposal C be implemented only for lower risk medical devices, as is currently proposed, statutory TGA conformity assessment review timeframes must be reviewed and dramatically decreased (to the same level as European Notified Bodies) to ensure that Australian manufacturers of higher risk devices are not commercially disadvantaged, not only in their local Australian market but also internationally, by having to undergo mandatory TGA full conformity assessment.

Additionally and equally important, a clear regulatory evaluation pathway for changes to existing 'included' medical devices must be defined by TGA, with substantially reduced evaluation timeframes, to allow Australian manufacturers to get modified/improved medical devices to market as quickly as possible. The existing situation lumps all applications for conformity assessment into a single queue, with little regard to the ease or difficulty of assessment or the manufacturer's need for a speedy assessment/approval.

MTAA questions why TGA is willing to accept audit reports from European notified bodies for non-Australian manufacturers of higher risk medical devices but require Australian manufacturers to undergo often-lengthy TGA conformity assessment. There is an inconsistency in approach, which only negatively impacts Australian manufacturers.

MTAA notes the work underway by the IMDRF to develop protocols for a single audit under which a manufacturer will be able to select an auditor and not be bound to use its national auditor. MTAA supports this development. This may give rise to an operating environment in which there is competition between auditors which will have positive impact on cost, timeliness, and efficiency. The benefits of a single audit will be significant for Australian manufacturers in reducing the time it takes to bring a product to market and management of differing requirements from multiple regulatory authorities.

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