White Paper:

Improvements to the Australian Regulatory System for Medical Devices

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Medical Technology
ASSOCIATION OF AUSTRALIA

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1. Executive summary

This paper outlines some of the regulatory challenges experienced by Australian businesses involved in the supply of medical technology, and proposes an improved system that significantly reduces the regulatory burdens on industry, without compromising the quality or safety of medical devices supplied in Australia.

The current Australian regulatory system involves significant red tape for businesses, particularly in relation to the time and cost of bringing medical devices to market. This may contribute to companies deciding not to bring the latest medical technology into Australia, and thereby depriving Australian patients access to the clinical benefits of the most modern technology available in other developed economies.

A number of opportunities for improvement exist, including the Therapeutic Goods Administration (TGA):

- taking on the role of a designating authority of third-party conformity assessment bodies
- ceasing to conduct duplicative pre-market assessments already conducted in other similar regulatory jurisdictions
- improving internal systems to remove unnecessary steps in the pre-market application process
- increasing resources devoted to post-market monitoring and compliance activities
- licensing suppliers of medical devices requiring them to adhere to industry codes of practice.

The expected results of implementing these improvements would include:

- more timely access to the latest medical technology for Australian patients
- a decrease in pre-market regulatory costs for Australian businesses
- more predictable and timely regulatory processes for Australian businesses
- maintaining an equivalent level of quality, safety and performance to that of medical devices already on the market
- earlier detection of device failures and increased ability of TGA to react quickly, thereby reducing the number of Australians adversely affected by potentially unsafe devices
- greater confidence in the supplier's ability to support devices throughout the product lifecycle.

The suggested improvements would remove red tape and duplication in the current regulatory system while improving patient safety, and allow TGA to operate more efficiently and effectively.

2. About the Medical Technology Association of Australia

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 included in the Australian Register of Therapeutic Goods (ARTG), and approximately 75% of implantable medical devices listed on the Prostheses List used in the Australian marketplace. MTAA member companies cover the full 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. Aim of the paper

This paper aims to:

1. Describe the current Australian regulatory system for medical devices and how it compares to that of other developed economies.

2. Identify elements of the current system that:
   - result in unnecessary red tape for Australian businesses, and
   - delay or prevent access to modern medical technology for Australian patients.

3. Propose options for improving the regulatory system to:
   - reduce or eliminate red tape for Australian businesses,
   - increase Australian patients access to the benefits of the latest medical technology, and
   - strengthen the post-market monitoring and compliance regime,

   without compromising the quality, safety or performance of medical devices supplied in Australia.

4. The current Australian regulatory system for medical devices

Australia was a founding member of the Global Harmonization Taskforce (GHTF), which was a voluntary group of representatives from national medical device regulatory authorities and the regulated industry. At its inception GHTF was comprised of representatives from five founding members (Australia, Canada, European Union, Japan and United States), each of which actively regulated medical devices using their own unique regulatory framework.

The purpose of GHTF was to encourage convergence in regulatory practices related to ensuring the safety, effectiveness/performance and quality of medical devices, promoting technological innovation and facilitating international trade, and the primary way in which this was accomplished was via the publication and dissemination of harmonised guidance documents on basic regulatory practices, which could be adopted/implemented by member national regulatory authorities.

In late 2011 GHTF was replaced by the International Medical Devices Regulators Forum (IMDRF), which Australia (TGA) was also a founding member. IMDRF aims to accelerate the international medical device regulatory harmonisation and convergence started by GHTF.

The GHTF model was fundamentally based on the European regulatory system adopted in the early 1990s, and included the following key elements:

- Pre-market evaluation:
  - Definitions of key terms, including ‘medical device’ and ‘manufacturer’
  - Rules-based risk classification system
  - Conformity assessment procedures to be followed by manufacturers, including the requirement to implement a Quality Management System (QMS) and post-market surveillance system
  - Standards and Essential Principles to demonstrate the safety & performance of medical devices, including requirements for labelling
- Post-market surveillance & vigilance
- QMS & auditing
- Clinical safety & performance

The Australian regulatory system (adopted in 2002) is based on this GHTF regulatory model and is therefore also closely aligned with the European Union (EU) regulatory system for medical devices. Adoption of this system in Australia provided more opportunities in the global market for Australian manufacturers.

The requirement for medical devices to meet the Essential Principles for safety and performance was legislated in 2002 in the *Therapeutic Goods (Medical Devices) Regulations 2002*. The regulations are administered by the Therapeutic Goods Administration (TGA). These regulations prescribe a risk-based system for the assessment of conformity to the Essential Principles. The greater the risk carried by the product (in terms of how invasive within the human body it is, the duration of use and the risk it poses to people), the more stringent the conformity assessment procedure that needs to be applied by the manufacturer.

The regulatory system effectively requires manufacturers of medical devices to apply internationally harmonised standards to the design and manufacture of their product to demonstrate compliance with the Essential Principles. This includes compliance with the international QMS standard (ISO13485), which requires manufacturers of medical devices to establish and maintain the high quality of design, manufacturing and post-market monitoring necessary for medical technology, is a pre-requisite for all but the lowest risk (Class I) medical devices.

Assessment and certification of a manufacturer's QMS occurs before manufacturers can supply their products. Continued adherence to the QMS requirements is also assessed through regular surveillance inspections. This continuous monitoring and surveillance ensures that medical devices are manufactured to their specification and continue to perform as intended.

Devices manufactured by Australian manufacturers, and a sub-set of high risk devices (such as those containing medicines or materials of animal origin), must obtain conformity assessment certification from the TGA prior to supply in Australia. For all other kinds of devices (including high risk implantable devices such as pacemakers and artificial hearts) the TGA will accept European CE certification issued by an EU Notified Body (NB).

Once conformity assessment certification has been obtained, the manufacturer signs a 'Declaration of Conformity' declaring that they have applied the relevant conformity assessment procedures, and that the devices comply with the Australian Essential Principles for safety and performance.

The Australian 'sponsor' is the entity responsible for the importation and supply of the device in Australia, and they can use the certification as evidence to enter the device in the Australian Register of Therapeutic Goods (ARTG). It is a requirement for the sponsor to include the device in the ARTG before it can be supplied in Australia (with some exceptions, such as custom-made devices).

For higher risk devices (Class III and some Class IIb) that have undergone conformity assessment by an EU Notified Body, TGA will conduct a further 'application audit' of the documentation supporting the conformity assessment certification before including the device in the ARTG.

Figure 1 below shows the current main supply pathways for medical devices in Australia. This does not show all the possible pathways for supply, as there are many exceptions and options in the legislation available to sponsors, such as Clinical Trial and Special Access schemes, which are not represented.

The TGA processing times and proportion (%) of devices subject to each time frame are approximations only. Due to the lack of equivalent published data from TGA, these figures have been estimated based on a combination of previously reported figures from TGA, the proportion of different device classifications included in the ARTG, and indicative feedback from MTAA members.

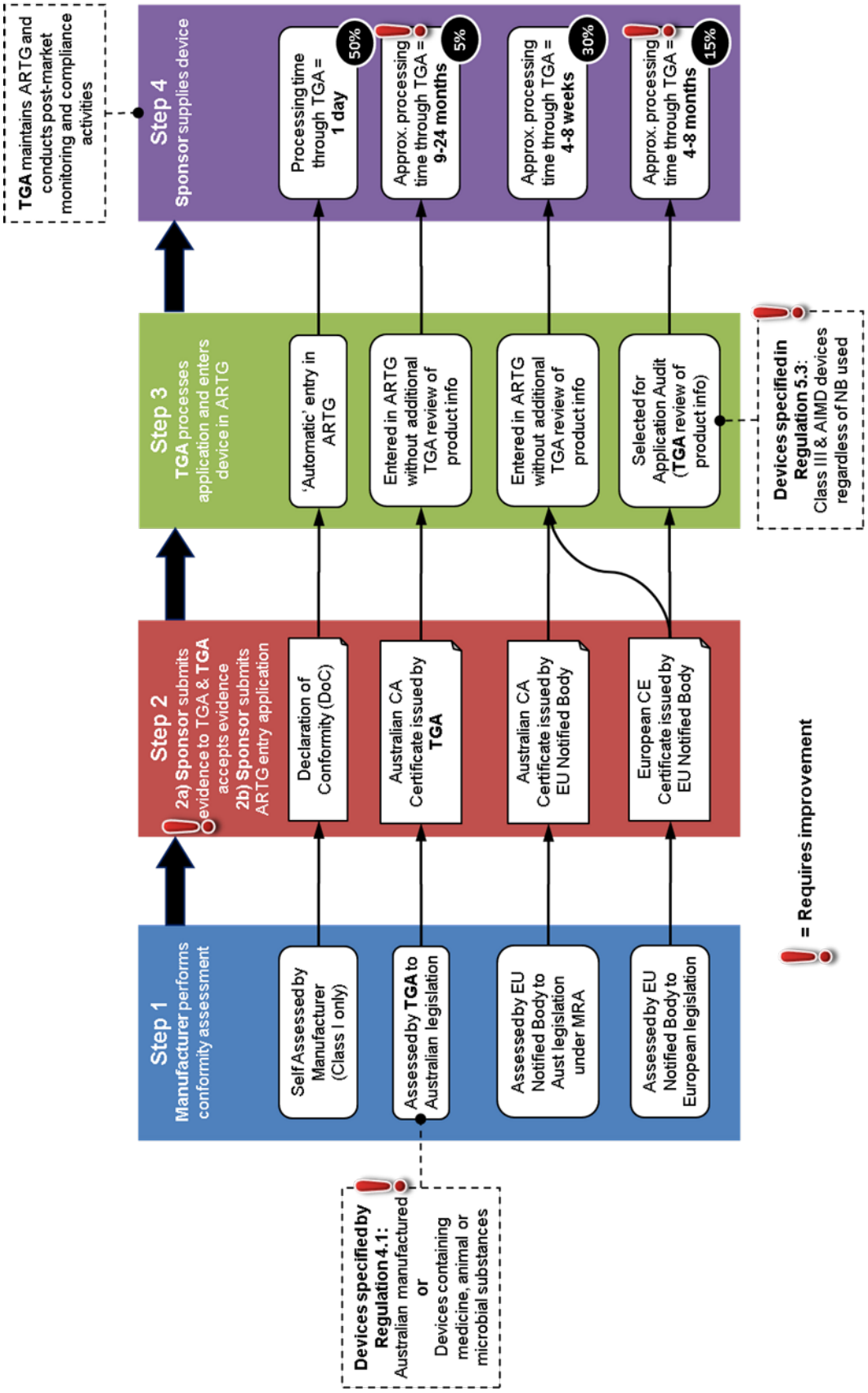

Figure 1 - Current Regulatory Supply Pathway for Medical Devices in Australia

Link between the Australian and European regulatory systems

The Australian and European systems are similar in that a manufacturer must apply a conformity assessment procedure (including an audited QMS) to demonstrate that a device meets the requirement of the 'Essential Principles' of safety and performance. In the EU these are known as the 'Essential Requirements'. Risk-based classification of medical devices in Australia and EU are generally the same, as are the different conformity assessment procedures applicable to each classification of device.

The differences in regulations include specific requirements of the two regions local laws; other differences are minor enough that European conformity assessment certification can be used by Australian sponsors to include devices in the ARTG.

Most medical device manufacturers will gain EU certification to commercialise the device in Europe prior to including the device in the ARTG and supplying the product in Australia. This is in large part due to:

- the relatively large market size of Europe (approximately 30% of the global market) compared to Australia (around 2% of the global market)
- the time to gain CE certification from an EU Notified Body (approximately 3-4 months) compared to the time it takes to gain TGA conformity assessment certification (usually between 9-24 months)
- the cost of obtaining EU CE certification compared to the cost of obtaining TGA conformity assessment certification.

EU Notified Bodies and Competent Authorities

In the EU conformity assessment of medical devices is undertaken by Notified Bodies (NB). These bodies are impartial, independent third-party commercial organisations specifically designated to monitor and review conformity assessment procedures applied by medical device manufacturers. Each member state of the EU has a Competent Authority (e.g. in the United Kingdom the Competent Authority is the Medicines and Healthcare Products Regulatory Agency (MHRA)), which is responsible for implementing the European laws ('Directives') nationally, and designating Notified Bodies (e.g. in the UK BSI and SGS are Notified Bodies) within their respective nation.

The member state Competent Authority will assess a resident Notified Body's organisational structure, operational policies and procedures, and particularly the skills and competence of personnel involved in activities related to medical device assessments.

If a Notified Body meets the criteria, the Competent Authority recommends that it is listed on the *Official Journal of the European Commission* (OJ). Notification stipulates the specific directive areas in which the Notified Body has been approved (e.g. medical devices or consumer electronics). It is not uncommon for a notification to also list specific product groups, which the Notified Body is approved to assess (e.g. active medical devices or implantable medical devices). The designating Competent

Authority is responsible for periodically assessing the resident Notified Bodies to ensure continued compliance with the standards for assessment.

Competent Authorities are also responsible for post-market monitoring of medical devices. Under the EU Directives a manufacturer of medical devices supplied in the EU must report adverse events involving medical devices to the Competent Authority of the nation where the event occurred. It is the Competent Authority's responsibility to investigate, monitor and trend adverse events so they can initiate recalls or provide advice to the health system of other Competent Authorities and regulators around the world.

TGA operates in a similar fashion, in that it performs the function of a Notified Body for pre-market device and manufacturer assessments, but also has the post-market monitoring and vigilance responsibilities of a Competent Authority.

5. Issues with the current Australian regulatory system

Although closely aligned with the regulatory requirements in Europe, there remain a number of aspects of the current Australian regulatory system, which result in Australian medical technology companies experiencing unnecessary and burdensome costs to their business, and ultimately affect the ability of Australian patients to access the latest medical technology.

These issues can be broadly categorised as follows:

- unnecessary duplication of effort by TGA
- high TGA costs and lengthy and unpredictable processing times
- unique Australian-only requirements (such as the ARTG).

Duplication of effort

The TGA process for including medical devices in the ARTG has often been criticised as being repetitive of the assessment undertaken by EU Notified Bodies. The necessity in the regulations for TGA to conduct mandatory application audits of documentation supporting some higher risk devices is repetitive of the assessment undertaken to gain European CE mark certification. The audit of documentation supporting higher classification devices is intended to give TGA confidence that the work undertaken by European Notified Body is sufficient for the EU Certification to be accepted as evidence to support compliance with Australian regulations.

However, this TGA review process is conducted on a product-by-product basis, even though the same CE certification may be used by the same manufacturer for their entire range of devices. One could argue that if TGA was willing to accept the certification issued by a particular Notified Body for a particular device and manufacturer, there should be no need to conduct another review of similar devices from the same manufacturer, as the certification issued by that Notified Body has already been found to be acceptable.

TGA has recently advocated that an increase in pre-market assessment is required to gain confidence in the EU Notified Bodies' ability to undertake conformity assessments. But there has been no proposal to reduce the level of pre-market assessment conducted by TGA once that confidence building activity has been undertaken.

For devices required to obtain TGA conformity assessment certification, such as those made by Australian manufacturers and those containing medicines or materials of animal origin, there is also a duplication of effort by TGA in addition to the assessment already conducted by the EU Notified Body during the CE marking process.

Once again, this would appear to be an unnecessary duplication of effort as the quality, safety and performance requirements are effectively identical to those in Europe.

There has also been no review of the TGA's ability to conduct conformity assessments by an independent third-party (such as required of a Notified Body by their EU Competent Authority). Therefore there is no evidence to suggest that an assessment conducted by TGA is any more comprehensive or reliable than that conducted by any EU Notified Body.

MTAA suggests that in conducting its own conformity assessment review the TGA does not necessarily add any additional value to the review already performed by EU Notified Bodies. Therefore TGA is no more likely to identify actual problems with the quality, safety or performance of medical devices before being supplied in Australia.

One example of this is the silicone breast implants produced by French manufacturer Poly Implant Prosthese (PIP). The issues surrounding the failure of the PIP breast implants are well known and were the subject of a Senate Community Affairs Committee inquiry in 2012. The Department of Health's own submission to the inquiry indicated that:

> *In April 2003, Medical Vision Australia submitted an application to the TGA for a Conformity Assessment Certificate to be issued to PIP for high and standard profile silicone gel pre-filled breast implants for use in breast augmentation and reconstruction.*
>
> *The TGA conformity assessment review was conducted over an 18 month period (May 2003 to October 2004) and included the following elements:*
> 1. *Review of the manufacturer's QMS, which included an onsite audit of the manufacturing facility in France.*
> 2. *An examination of the design of the PIP implants, including detailed assessments of the following aspects:*
>   - *a microbiological review relating to packaging, shelf life and sterilisation validation activities;*
>   - *a biocompatibility and biological safety review, including a review of the cytotoxicity, genotoxicity and reproductive toxicity of the various materials used in the implants;*
>   - *a review of materials engineering (mechanical and chemical performance) and manufacturing processes, including physical strength of the shell, and detailed information on the description of polymerisation, curing and catalytic conditions of every step of manufacture of the shells, patches, glue and filling gel for the products;*
>   - *an assessment of clinical evidence.*
>
> *On 18 October 2004 the TGA issued a Conformity Assessment Certificate to PIP for the manufacture of nine models of silicone gel-filled implants. In accordance with standard TGA (and international) practice, the TGA Conformity Assessment Certificate was valid for five years so would expire on 18 October 2009.*

This clearly demonstrates that even when TGA conducts its own rigorous conformity assessment review of high risk devices and their manufacturers, this does not prevent potentially unsafe product from being supplied in Australia, and does not result in a different outcome compared to the equivalent assessment conducted by a suitably qualified and experienced EU Notified Body.

TGA costs and processing times

The TGA's costs for conducting pre-market assessments of medical devices and their manufacturers are considered to be some of the highest regulatory costs in the world. This is exaggerated further when taking into account the relatively small market size of Australia (less than 2% globally).

Similarly, the TGA's processing times for pre-market assessments are often considerably longer than those in other comparable regulatory jurisdictions such as Europe and Canada.

Unlike other regulators in developed countries under the current regulatory system the TGA's activities are fully cost recovered from industry. Although conformity assessments conducted by TGA are relatively expensive compared to an EU Notified Body, the additional cost does not translate to greater efficiencies in the TGA or better outcomes for patients. A conformity assessment conducted by TGA can take two years or more, compared to a standard 90-day assessment, or 45-day expedited assessment, by an EU Notified Body.

It is clear to industry that yearly increases in TGA fees and charges have not been invested in process improvements that are required to make the regulatory system more predictable and efficient.

Most conformity assessments conducted by TGA are undertaken for devices containing medicinal substances or materials of animal origin. Once TGA certification has been gained, any changes to those devices must also be assessed by TGA. These submissions for assessment of changes can take over 18 months to review. During this time, the overseas manufacturer, which has had the change assessed and approved by FDA (notification) and the EU Notified body (one month), may have to stock pile the superceded version of the device for supply in Australia until TGA has completed its review. Due to the unpredictability of TGA review time frames the stored products may expire resulting in users having to switch to using a different device, which poses usage risks, until the TGA review process is complete.

TGA's timelines for conducting conformity assessments are highly unpredictable, with some companies reporting assessments taking over two years to complete, compared to a standard 90-day assessment by a European Notified Body. In the case of an Australian manufacturer of high risk devices this has resulted in its products being launched in the EU prior to Australia and substantial delays in gaining regulatory approval in other markets that require 'country of origin' approval (principally in the Asia-Pacific region).

Unlike many pharmaceuticals the product life-cycle for medical devices is relatively short. Many medical devices typically have a commercial life of around 18-24 months before an improved product becomes available and replaces it on the market. The pace at which this continual development and improvement process occurs means that some devices are never supplied in Australia because the time taken for the TGA assessment process exceeds the life of the product itself.

As Australia only represents a relatively small fraction of the global medical device market, it may not be commercially viable for manufacturers to continue producing old versions of medical devices solely for supply in Australia. Australian patients may miss out on access to the latest medical technology already available in other developed economies (such as the EU and US) due to delays in the market approval process through TGA.

Many of these latest developments in medical technology (such as miniaturisation for minimally invasive surgery) are designed to reduce operating times and length of hospital stays, as well as improve recovery time and clinical outcomes for patients. Lack of timely access to technology is resulting in unnecessary cost pressure on an already stretched health system. Australian patients may be denied or experience delayed access to potentially life-saving technology.

Unique Australian requirements

It is a requirement in Australia that all devices are included in the ARTG prior to supply. This is an additional requirement to the regulatory system in Europe, where no central database of devices exists.

The ARTG is used as a resource by medical device manufacturers, sponsors, healthcare providers, government, patients and consumers to establish if a device has regulatory clearance to be supplied in Australia.

The ARTG provides the legislative basis for TGA to take action if a device no longer meets the requirements of the 'Essential Principles' or the sponsor of the device has not kept up their regulatory obligations.

Devices are included in the ARTG by device 'kind' (as defined in the *Therapeutic Goods Act 1989*). Most device entries cover a range of similar products rather than an individual model number. With the exception of high risk devices, which are individually included in the ARTG by product name or Unique Product Identifier(UPI).

For example if a consumer wants to check if their coronary stent is included in the ARTG, they would be able to enter the device model name in the ARTG search function and view an entry for the product (if it is still being supplied). This does not work for lower risk devices that are entered in the ARTG by device 'kind', as one entry in the ARTG may cover several different models of the same kind of device. For example a urinary bag supplied by a sponsor may have a single entry in the ARTG that covers a range of different models of urinary bag.

The ARTG has been criticised for not displaying that a specific device has been approved for supply in Australia and that the TGA does not know all of the devices that are available for supply in Australia based on the information held in the ARTG.

Sponsors of medical devices have also commented that the ARTG does not meet their needs by not naming models of products for lower risk classification devices. Some healthcare providers have not accepted evidence of product approval by TGA, even though the sponsor has an ARTG inclusion covering that kind of device.

Sponsors submitting an application for higher risk devices have also had to submit several applications to enter a ‘device family’ in the ARTG. For example, an orthopaedic hip implant may have been assessed by an EU Notified Body as a system of devices. This means that one part of the implant cannot work without the other parts of the system. Because of the mandatory use of Global Medical Device Nomenclature (GMDN) codes used to describe a ‘kind’ of device, a hip system has to be included in the ARTG by its component parts. Unless the reader is very familiar with the system, they may not be able to see that the entire system has been approved for supply by TGA. This also adds duplication to the review process. TGA assessors may have to review multiple sets of the same technical documentation to describe a single hip system.

The current structure of the ARTG does not appear to serve the purposes of the regulator, sponsor, consumer or healthcare provider. Sponsors of medical devices pay an annual charge to maintain each entry in the ARTG, and additional costs if they need to apply for a change to those ARTG entries. This in itself imposes an unnecessarily duplicative cost on the sponsor.

For example, a company who is the sponsor of over 1,000 ARTG entries for medical devices from one manufacturer is required to pay a fee of $400 per entry simply to have the manufacturer’s name changed and updated in the ARTG. Due to the way the ARTG has been designed and the cost recovery arrangements of the TGA this amounts to over $400,000 for what should be a simple administrative task.

6. Opportunities for improvement to the Australian regulatory system

There are a number of ways to improve the current pre-market regulatory system for medical devices, without reducing the quality, safety or performance of devices supplied in Australia, and at the same time improving post-market monitoring and compliance of devices already on the market.

The opportunities for improvement can be briefly summarised as:

1. Changing the focus of TGA's involvement in pre-market assessment by:
    a. moving away from conducting conformity assessment reviews and taking on the role of a designating authority of third-party conformity assessment bodies
    b. ceasing to conduct duplicative pre-market assessments of medical devices already approved for supply by other similar regulatory bodies
    c. increasing oversight of other assessment bodies through existing international collaborations such as confidence building under the Mutual Recognition Agreement (MRA) with the EU, and the IMDRF Medical Devices Single Audit Program (MDSAP)
    d. improving internal systems to remove unnecessary and duplicative steps in the pre-market application process, and improving the functionality of IT systems and ARTG.
2. Increasing TGA resources devoted to post-market monitoring and compliance activities by moving resources previously involved in pre-market activities of limited value, and using them to conduct more valuable and efficient post-market activities.

The expected results of implementing these changes would include, but is not limited to, the following:

- quicker access to the latest medical technology for Australian patients
- a decrease in pre-market regulatory costs for Australian businesses
- more predictable processes and time frames for Australian businesses
- maintaining an equivalent level of quality, safety and performance to that of medical devices already on the market
- earlier detection of device failures and increased ability of TGA to react quickly, thereby reducing the number of Australians adversely affected by potentially unsafe devices

An overview of the proposed improved regulatory system is shown in Figure 2. This does not show all the possible pathways for supply, as there are many options available to sponsors, such as Clinical Trial and Special Access schemes which are not represented. TGA processing times and proportion (%) of devices subject to each time frame are estimates only based on a combination of previously reported target times from TGA, and the proportion of different device classifications included in the ARTG.

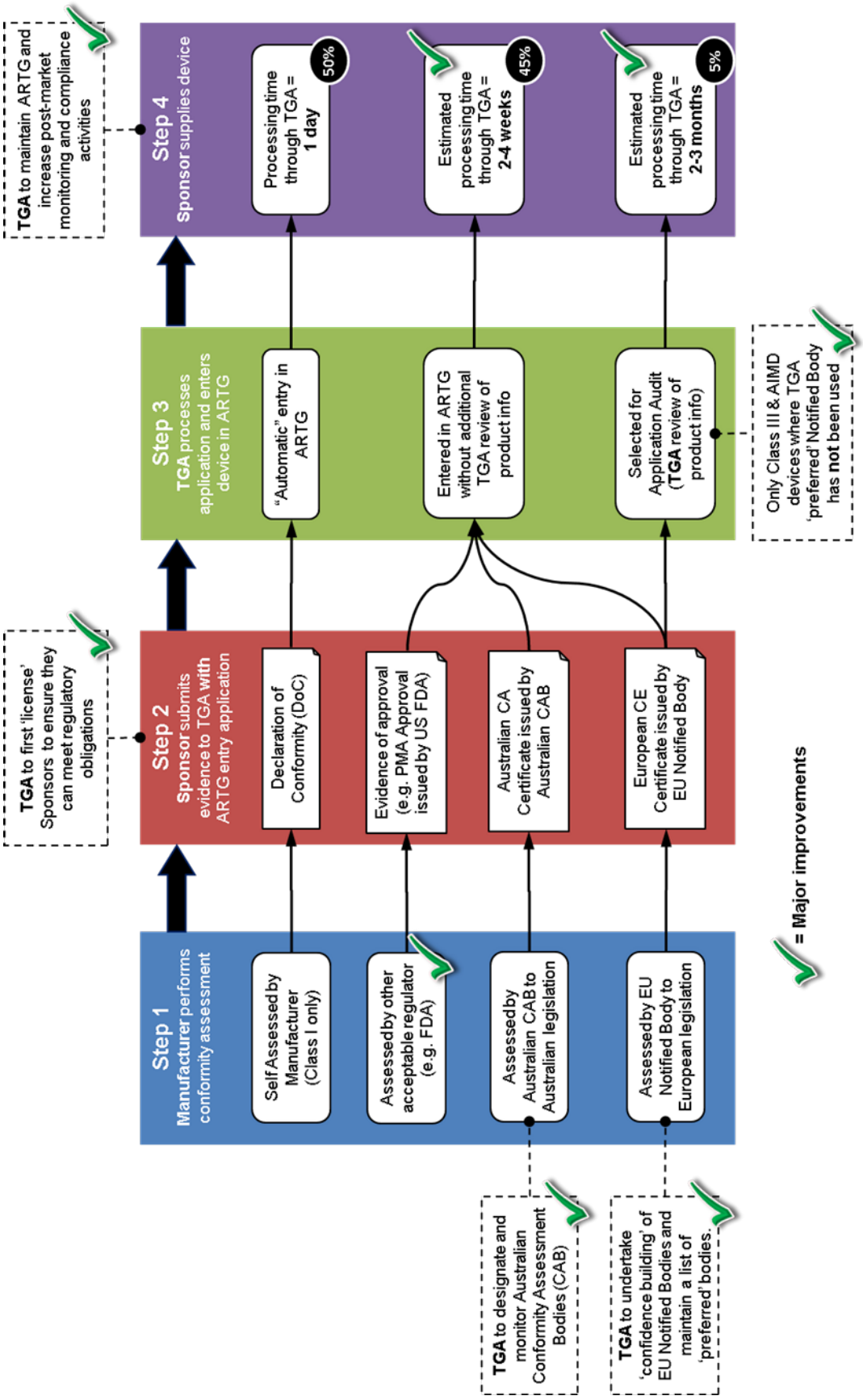

Figure 2 - Proposed Regulatory Supply Pathway for Medical Devices in Australia

A proposed improved regulatory system

The proposed regulatory pathway shown in Figure 2 includes a number of differences to the current system shown in Figure 1, many of which relate to the involvement of TGA at different stages in the pre-market assessment process.

> **!** It is important to note that these proposed changes do not affect the inherent product requirements and standards that must currently be met by all medical device manufacturers, such as the need to implement and maintain a QMS, and for all devices to comply with the Essential Principles for safety and performance.

The key features and main differences between the current and proposed regulatory pathways are described in the following table:

Proposed key features	**Differences and advantages**
1. TGA to designate third-party conformity assessment bodies to conduct assessments to Australian requirements.	Instead of performing its own conformity assessment reviews of manufacturers and devices, it would be more efficient use of TGA resources to act as a 'Designating Authority' in a similar way to EU Competent Authorities (such as the UK's MHRA). This would open the Australian market to competition from a number of assessment bodies who may wish to be designated to perform conformity assessment reviews according to Australian regulations. Increasing competition would likely result in decreasing costs and shorter assessment times for Australian businesses, compared to the current TGA monopoly on providing this service. Under the proposed system the TGA would assess a Conformity Assessment Body's (CAB) organisational structure, operational policies and procedures, and particularly the skills and competence of personnel involved in medical device authorisations. TGA is renowned globally for astute auditing skills and these skills would easily be transferrable from medical device manufacturer audits to designating assessments of CABs. Once a CAB has been designated as appropriate for conducting assessments to Australian regulatory requirements, the TGA would conduct periodic audits to monitor and assess the quality of the medical device authorisations. This is a much more efficient way of ensuring that devices entering the market meet Australian regulatory requirements. TGA is already participating in a pilot scheme with three other International Medical Device Regulator Forum (IMDRF) members (Brazil, Canada and USA) and will be able to recognise QMS assessments conducted by Auditing Organisations (CABs) designated by the participating Regulatory Authorities. The Medical Device Single Audit Program (MDSAP) commenced in early 2014 and Auditing Organisation criteria has been documented. TGA's participation in the MDSAP program could be easily transferred to designation of Australian CABs to conduct both quality management system assessments and, for higher risk classification devices, design examinations.

Proposed key features	Differences and advantages
	MTAA has long argued that TGA's role as the pre-market evaluator and post-market regulator involves a degree of perceived conflict of interest, as there is no check of the quality of the conformity assessments it undertakes. The proposed model removes this ambiguity and provides the regulator with oversight of third-party assessment bodies.
2. TGA to build and maintain confidence in EU Notified Bodies.	Since most medical devices supplied in Australia will continue to be supported by CE certification issued by EU Notified Bodies, an important and necessary part of this model is for the TGA to build and maintain confidence in those bodies. By doing this the confidence of other stakeholders (such as patients and health professionals) in the Australian regulatory system would be improved, and it would allow the TGA to move its limited resources into increased post-market activities by lessening it's involvement in pre-market reviews and avoiding unnecessary duplication of effort. If TGA were to maintain a 'preferred' Notified Body (NB) list (those that they have successfully undertaken confidence building activities), then this would serve as a point of difference between those manufacturers using recognised competent NBs, and those using NBs of less well known origin and abilities.
3. TGA to no longer conduct conformity assessment certification reviews.	Instead of requiring Australian manufactured devices, and the sub-set of high risk devices designated by the regulations (those containing medicines or animal origin materials), to obtain TGA issued certification, manufacturers of those devices would be able to choose their own assessment body. This would level the playing field for all manufacturers (whether they are Australian or based overseas), and would eliminate the current duplication in TGA conducting their own separate conformity assessment review in addition to the equivalent assessment conducted by another qualified and experienced assessment body. It would be important for the TGA to remove itself from providing a conformity assessment service under this proposed model, since it would be a conflict of interest for them to continue this activity, whilst at the same time being involved in the designation of their competitors (see key feature above). It is estimated that this change would result in the 5% of devices required to undergo TGA conformity assessment review, to enter the Australian market in as little as 2-4 weeks (when supported by CE certification from a TGA 'preferred' Notified Body), rather than the 9-24 months currently experienced. A minor change to the regulations would be required to implement this improvement.
4. Regulatory approvals from other jurisdictions to be utilised.	In addition to the generally accepted European CE certification, it is proposed to allow manufacturers to use other equivalent regulatory approvals from recognised competent regulators.

Proposed key features	Differences and advantages
	For example, this could be in the form of: • US FDA Pre-Market Approval (PMA), which is considered to be comparable to the European and Australian Design Examination (DE) review, or • Health Canada product licence. This would not include acceptance of US FDA 510(k) approvals, as they would not be considered equivalent to the Australian regulatory requirements. For example, this would allow sponsors to import certain devices that have approval to be supplied in the US, but that are not supplied in Europe, perhaps because the manufacturer has chosen not to commercialise their product in the EU. The regulations already allow TGA to accept certificates from different jurisdictions as it sees fit, so this improvement would not require any further change to the regulations.
5. The unnecessary 'Manufacturers Evidence' step (2a) to be removed.	The current TGA process (not the regulations) requires the Australian sponsor to first submit a copy of the conformity assessment certification (known as 'Manufacturers Evidence') to the TGA for acceptance before they can use that evidence to support a separate application for entry in the ARTG. Processing times for the Manufacturers Evidence submission vary but can take anywhere from 2 weeks to over a month depending on the workload of TGA at the time. The proposed model eliminates this step and instead replaces it with a requirement to simply attach a copy of the evidence to the application for entry in the ARTG. It is estimated that making this change to the TGA's electronic application process would alone result in a 3-4 week reduction in the time it takes to get a product to market in Australia. As this is only an internal TGA process, no change to the regulations is required to implement this improvement.
6. Fewer devices to be subject to a duplicative product review.	Currently all Class III devices and Active Implantable Medical Devices (AIMD) supported by a European CE certificate must undergo an application audit by TGA (review of product information) regardless of the perceived quality or abilities of the Notified Body that conducted the assessment and issued the certificate. Under the proposed model only those high risk devices supported by CE certification issued by an EU Notified Body that has not been subject to confidence building by TGA would be required to undergo a pre-market application audit. This would in theory provide an incentive for manufacturers to use an EU Notified Body that is preferred by TGA (i.e. TGA has gained and maintains confidence in it). It is estimated that this would result in only 5% of all devices undergoing an application audit prior to entry in the ARTG, compared to approximately 15% currently. Due to the anticipated reduction in workload TGA would be able to conduct fewer application audits in less time than currently,

Proposed key features	Differences and advantages
	thereby improving timely access to medical technology. A minor change to the regulations would be required to implement this improvement.
7. TGA to shift resources from pre-market activities to post-market monitoring and compliance.	Due to the reduction in effort required by TGA during the pre-market assessment phase, the saving in resources could be applied to TGA's post-market activities, such as processing adverse event reports, detecting product failures sooner and enforcing regulatory actions for non-compliance. For a long time MTAA has suggested that TGA operate more like an EU Competent Authority. However, TGA has not been supportive of this suggestion arguing that they would lose the skills and technical knowledge of the employees that currently perform medical device pre-market assessments. MTAA does not believe this is a good reason to regulate in a particular way, as the regulator's resources should be matched to the legislation, rather than the other way around. In any case, MTAA suggests that the skill and technical ability of TGA staff performing pre-market assessment activities could be transferred to post-market monitoring, which requires a strong understanding of the documentary evidence held by manufacturers for the purpose of thorough investigations of adverse events. The added resources in post-market surveillance would increase TGA's ability to conduct adverse event investigations in a timely manner and work with the device sponsor and manufacturer to ensure that if the device is faulty, appropriate corrective actions can be taken. Post-market monitoring is crucial to the safe and effective use of medical devices. Problems appear primarily in relation to sporadic manufacturing issues, which are not apparent or easily detected at the pre-market stage, particularly for implantable devices due to the way they wear over time in the complex environment of the human body. No change to the regulations is required to implement this improvement.
8. TGA to 'licence' Australian sponsors.	Under current regulations, sponsors (suppliers) of medical devices certify that they can obtain evidence of conformity from the manufacturer within 20 days. This requirement means that the sponsor must have an active relationship with the manufacturer of the device. Sponsors are often not aware of their responsibilities under the regulations, including post-market and record keeping responsibilities. This is evident from the reports on TGA's Device Adverse Event Notification (DAEN) database. The relationship of a sponsor with the manufacturer is vital to ensuring that adverse events and complaints are fed back into the design and development process. Under the proposed model TGA would 'license' sponsors to supply medical devices in Australia. The licensing of sponsors would include checks of an active relationship with the manufacturers, and that appropriate systems and resources are in place to meet the ongoing requirements of the regulations (for example, ability to report adverse events

Proposed key features	Differences and advantages
	and adherence to a recognised industry code of practice). Amendments to the regulations would be required to implement this improvement.
9. Improving the visibility of devices in the ARTG.	MTAA has suggested that the way products are entered in the ARTG should be changed to enable easy identification of medical devices currently or previously available for supply in Australia. Amendments to the regulations may be required to implement this improvement.

Staged implementation of the proposed improved system

MTAA acknowledges that many of the proposed improvements to the regulatory system will require legislative changes, international cooperation, and changes to internal TGA processes and IT systems. Therefore, it is proposed that these improvements be rolled out in a staged manner over a period of 2-3 years, rather than trying to make all the changes at the same time. It is proposed that the major changes be made in the following stages:

Stage	Description
1. Remove Regulation 4.1 requiring Australian manufacturers, and certain Class III devices, to obtain TGA Conformity Assessment certification prior to entry in the ARTG.	This could be done immediately, and would still allow manufacturers the option of using the TGA for conformity assessment certification if they did not want to obtain CE certification from an EU Notified Body (for example, small Australian manufacturers who have no interest in supplying their products in the EU). Manufacturers holding TGA conformity assessment certificates could choose to replace this with other CE certification, however this would require any new applications for Class III or AIMD devices to undergo an application audit by TGA prior to entry in the ARTG, as is currently required under Regulation 5.3. MTAA does not believe that there is any need to wait for confidence building activities to be undertaken before this change is implemented, as any high risk devices previously subject to TGA conformity assessment (such as those containing medicines or animal origin materials) will still be reviewed by TGA during a pre-market application audit prior to being included in the ARTG.
2. TGA conducts confidence building activities with EU Notified Bodies and/or EU Competent Authorities to generate a 'preferred' Notified Body list.	This could be achieved through: • the Australia-EU Mutual Recognition Agreement (MRA) which already includes a provision for confidence building, and • TGA's ongoing involvement in the IMDRF Medical Device Single Audit Program (MDSAP). Once complete, TGA could exclude devices from having to be selected for an application audit prior to entry in the ARTG where the manufacturer uses a CE certificate issued by one of the 'preferred' EU Notified Bodies. A minor change to Regulation 5.3 would be required.
3. TGA ceases operating as a Conformity Assessment Body (CAB) and designates third-party CABs to issue Australian CA certificates.	This phase would require additional time to conceive and implement, possibly a period of 2-3 years. During development of this framework TGA would need to be able to maintain their own CA certification services until enough CABs have been designated and Australian manufacturers have arranged to transfer their certification to one of the new CABs.

SWOT analysis of the proposed improved regulatory system

Strengths	**Weaknesses**
• Greater confidence in the abilities of conformity assessment bodies. • Greater confidence that sponsors are meeting their regulatory obligations. • Reducing red tape without reducing patient safety. • Faster access to medical technology. • The designation model would suit the needs of NZ under ANZTPA. NZ industry has voiced concerns about the TGA premarket approval process.	• Public and political perception that the regulator has less control. • Retraining of regulator and industry staff
Opportunities	**Threats**
• Best practice regulation through ANZTPA. • Increase resources in post-market activities will increase the regulator's reaction time, improving patient safety. • Increase resource in post-market activities will support the ability of the regulator to report to other sectors of health care on medical device use issues to encourage the quality use of devices. • Local conformity assessment body expertise will create jobs. • Local manufacturer access to conformity assessment bodies that assess products for other jurisdictions and introducing them to the requirements of other countries. • Sponsor licensing.	• Consumer concerns. • Political environment. • Significant redrafting of legislation (ANZTPA).

Risk mitigation

Risk	**Mitigation action**
Public and political perception that the regulator has less control.	Public and political education of the system with respect to the designation of conformity assessment bodies and licensing of sponsors, and transparency of this process. Increase post-market activities and advice to the healthcare system from the regulator will give greater confidence that the most efficient actions to protect patients are being taken.
Retraining of regulator and industry staff	As both TGA and industry staff has good knowledge of regulatory requirements, retraining in new or expanded roles should not be a major issue.
Consumer concerns and political environment	Public transparency of the system with respect to designation of conformity assessment bodies and licensing of responsible sponsors.
Significant redrafting of legislation	Redrafting of regulations will be required with ANZTPA – the joint agency is an opportunity to get things right.

7. Conclusions

MTAA is able to provide many specific examples of red tape in the current medical device regulatory system, many of these examples have been previously tabled with TGA through consultations and regulatory forums.

As described in MTAA's response to TGA's recent Regulation Impact Statement (RIS) for changes to pre-market assessment, the proposed additional pre-market requirements for high risk devices will not prevent another high profile device failure, such as PIP breast implant or ASR hip replacement issues. It is the TGA's ability to analyse, trend and react to post-market feedback quickly that will ultimately improve patient safety.

The designation and ongoing monitoring of conformity assessment bodies will provide much greater confidence that thorough assessments of medical devices are conducted by people with appropriate qualifications and expertise.

The licensing of sponsors will provide the regulator with confidence that sponsors are capable of supplying medical devices to the Australian market, and are aware of their ongoing regulatory obligations throughout the product lifecycle.

MTAA believes the proposed changes outlined in this paper will improve TGA's efficiency and value for money, result in significant cost savings for Australian businesses and, most importantly, improve health outcomes for Australian patients.