Medical Technology Association of Australia

Reforms in the Medical Devices Regulatory Framework December 2010

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MEDICAL TECHNOLOGY FOR A HEALTHIER AUSTRALIA

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1. Executive Summary

Australia has a world-class system for the regulation of medical devices, both in pre-market assessment and post-market surveillance. It is founded on the harmonised model developed by the Global Harmonization Task Force (GHTF). Its system is risk-based with a requirement for increasing levels of evidence as the risk of the product increases. It is a regulatory system that has shown that it works well for Australian patients, with product recalls primarily initiated by the manufacturer. Australia is a small market, no more than approximately 2% of the global market. The regulatory balance between patient safety and access to innovative products has been proportionate.

What has not been established in the Discussion Paper is the clear evidence that the changes proposed by the Therapeutic Goods Administration (TGA) are necessary to address a demonstrated public health concern. Notwithstanding this, the Medical Technology Association of Australia (MTAA) and its members accept that there may be room for improvement in some aspects of the regulatory balance. There have been several inquiries[1] into the impediments to bringing new technologies to market in Australia and, while MTAA acknowledges that there are several dynamics driving further reforms, the recommendations from these reports should not be neglected.

Reforms must ensure that the balance is maintained between protection of patient safety and access by those patients to innovative technologies. The balance will be significantly diminished if the cost and processing constraints are excessive.

MTAA proposes in this submission, solutions to the issues identified by the TGA in its Discussion Paper which maintain the balance referred to. MTAA strongly recommends that further consultation be undertaken with the industry to ensure the workability of some of the reform proposals. Without a parallel process review, the additional administrative burden on TGA and cost to industry will be significant.

2. Summary of MTAA response

General

MTAA recommends that TGA ensure an appropriate balance between the requirements for pre-market assessment and post-market surveillance. A significant increase in the requirements for pre-market assessment, beyond the requirements of comparable markets, or beyond the reasonable requirements of a risk-based system to ensure patient safety, will have a detrimental effect on the uptake of innovative medical technologies in Australia.

MTAA recommends that TGA develop and publicise a strategy for resourcing the implementation of the proposed changes in advance of the implementation dates.

MTAA recommends that TGA work with industry to refine the UPI and variant requirements, and reform the GMDN database before implementation of any of the reforms proposed in the Discussion Paper.

[1] Productivity Commission, 2005 *Impacts of Advances in Medical Technology in Australia*, Research Report;
Regulation Taskforce, 2006 *Rethinking Regulation: Report on the Taskforce on Reducing Regulatory Burdens on Business*, Report to the Prime Minister and Treasurer;
Productivity Commission 2008, *Regulatory Burdens: Manufacturing and Distributive Trades*, Research Report

MTAA recommends that in order to encourage gradual transition of products, and to avoid the rush of applications at the end of the transition period, TGA waive annual fees for early transitioning products.

MTAA recommends that TGA establish a permanent business liaison function within TGA to work with sponsors to assist with queries and facilitate training on legislative requirements for therapeutic goods and, in the short term, the proposed reforms.

MTAA recommends that TGA review its fee structure and adjust it to take into account the additional registration requirements arising from the reforms.

Proposal 1 – reclassification of joint replacement implants

MTAA recommends that reclassification of Class IIB implantable orthopaedic joints as Class III devices be undertaken with a Level 2 application audit and then issued with a TGA conformity assessment certificate following a review of the design examination report.

MTAA recommends that TGA quarantine components of superseded implantable systems retained for revision or repair procedures and accept Class IIB level certification for these items.

MTAA recommends alignment of transition periods with a four year transition for the reclassification of implantable orthopaedic joints.

MTAA recommends a staged implementation of reclassification, starting with full joints and moving to partial joints at a later date

Proposal 2A – use of third party conformity assessment bodies for Australian manufacturers

MTAA supports Proposal 2A.

Proposal 2B(i) – devices requiring a TGA Conformity Assessment Certificate to be issued

MTAA recommends that TGA issue a conformity assessment certificate on the basis of a Level 2 application audit and review of a design examination report.

Proposal 2B(ii) – applications to be selected for auditing

MTAA recommends expanding the current application audits to include products approved by Health Canada and US FDA as the basis for an entry in the ARTG.

MTAA recommends that TGA implement a statutory timeframe.

Proposal 2C(i) – confidence building for EU notified bodies

MTAA recommends a two year period for confidence building with alignment of requirements between approval of Notified Bodies outside Australia, and those within Australia, with TGA as the accreditation authority.

MTAA recommends the use of JAS-ANZ processes or equivalent for accreditation purposes and consideration of inclusion of bodies such as those accredited by US FDA and MHLW in Japan.

Proposal 2C(ii) – recognising Australian third party assessment bodies

MTAA recommends that TGA take on the role of the accreditation authority to accredit conformity assessment bodies in Australia. If TGA is to be a conformity assessment body then it must be independently assessed by a body such as JAS-ANZ.

Proposal 3(i) – amending the way in which a kind of medical device is included in the ARTG

MTAA recommends that TGA provide for identification of medical devices on the ARTG through a fee-free notification system, supplemented by post-market audit.

MTAA recommends that the transition period be extended to two years.

Proposal 3(i) – enhancing the ability to identify devices that have been approved by the TGA for supply in Australia

MTAA recommends using the enhanced disclosure under Proposal 3(i) as the mechanism to improving medical device identification, coupled with an expanded search capability of the ARTG.

MTAA recommends that TGA consider the implementation of a global UDI as a tool to assist with device identification and not to replicate requirements that are already under active development in other GHTF founding member jurisdictions.

MTAA recommends consideration of the use of e-labeling as an option for sponsors of medical devices supplied in Australia.

Proposal 4 – publication of device information on the TGA website

MTAA recommends that the publication of device information on TGA's website be trialed in a small scale, voluntary pilot with implementation on a broader scale only after positive assessment of the pilot, including consumer support.

3. About the medical technology industry

MTAA represents the manufacturers, exporters, importers and distributors of medical technology products in Australia. Medical technologies are products used in the diagnosis, prevention, treatment and management of disease and disability. Products range from commonplace, everyday items such as surgical gowns, bandages and syringes, to high technology items such as implantable cardiac and orthopaedic devices, cochlear implants, in vitro diagnostic products and diagnostic imaging equipment such as ultrasound, computed tomography (CT), magnetic resonance imaging (MRI), and positron emission tomography (PET) machines. Many newer products combine biological products with biomechanical devices, and employ converging technologies.

Sales of medical technology in Australia in 2008/2009 were $7.4 billion, with $1.6 billion earned from exports of medical technology manufactured in Australia.

Approximately 80 per cent of the medical technology products used in Australia are imported and nearly all of the products manufactured in Australia are exported. The industry employs over 17,500 people. It is a highly innovative industry which invests heavily in research and development.

4. MTAA submission to the HTA Review

In its submission to the Review of Health Technology Assessment in May 2009, MTAA stated that it saw the Review as an opportunity to implement reforms to an area of the healthcare system overdue for examination[2]. Medical technology is a key contributor to optimal patient health outcomes and offers smart solutions to many health challenges. An efficient, transparent and flexible health technology assessment system underpins the value of medical technology.

These arguments followed similar positions put to, and accepted by, several earlier reviews by the Productivity Commission[3]. In submissions to the Productivity Commission extending over several years MTAA has advocated a system that enables:

- A streamlined process for the registration, assessment and reimbursement of new technologies
- A process that is aligned or at least harmonised globally so that Australian companies are not disadvantaged by the imposition of additional burdens
- A transparent process so that requirements are clearly understood and articulated and applied in a uniform manner
- An accountable process that is open to review in the event that an element of the process has been applied incorrectly.

These principles remain relevant to ensure that the benefits of innovative medical technology are provided to Australian patients without unnecessary barriers.

5. MTAA response to TGA's regulatory reform proposals – general comments

The Australian market for medical devices is approximately 2% of the global market. Almost every product supplied in Australia is supplied in other markets, often with comparable regulatory systems (the EU, the USA, Canada). While recognizing the need to ensure that products entering the Australian market are safe and efficacious, the regulatory barriers to entry need to recognize the risk-based nature of global regulation of medical devices. Unlike pharmaceuticals, it is not feasible to have the full range of clinical evidence developed prior to registration. Australia's system of regulation of medical devices is calibrated to take account of the balance between pre-market requirements for evidence (the higher the risk that the product carried, the greater the evidence requirement), and post-market surveillance by which sponsors and users of technologies can identify and react to adverse (or potentially adverse) issues.

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[2] MTAA submission to *Review of Health Technology Assessment* May 2009, accessible at http://www.mtaa.org.au/pages/images/Health%20Technology%20Assessment%20Review%20MTAA%20submission%20May%202009%20final.pdf

[3] Supra at footnote 1

The level of evidence required for pre-market assessment of medical devices can be complicated:

- Medical technologies face challenges in being subject to randomized clinical trials (RCTs) because of evolving product modifications, and the clinical learning curve. The combination of these events means that there is rarely the 'steady state' required for an RCT
- The efficacy of a medical technology depends not only on the product itself but also on how it is used. The need to adjust for user characteristics complicates the design and analysis of clinical studies.

The difference between pharmaceuticals and other medical technologies becomes manifest when examining the different types of evidence required for registration. The main source of data for clinical efficacy assessment of pharmaceuticals is phase III randomised controlled trials (RCT). For medical technology the total amount and level of data may vary.

For a new medical technology it may not be the case that level 1 or level 2 evidence[4] is available at the time of registration, and randomised trials against comparators are more uncommon. The clinical evaluation of a new technology needs to take into account the totality of the evidence and ensure that the evidence is relevant to the research question at hand. Well-designed observational studies, indirect treatment comparisons and other newer methods are valid evidence platforms on which to base decisions.

The assessment system for registration of medical technology products entering the Australian market must have the following features:

- Transparency
- Predictability
- Reasonableness of requirements including the level of evidence.

MTAA recommends that TGA ensure an appropriate balance between the requirements for pre-market assessment and post-market surveillance. A significant increase in the requirements for pre-market assessment, beyond the requirements of comparable markets, or beyond the reasonable requirements of a risk-based system to ensure patient safety, will have a detrimental effect on the uptake of innovative medical technologies in Australia.

Although TGA does have a robust assessment system, one area where MTAA acknowledges there may be need for review is in the products classified as Class IIB implantable devices. This classification allows a multitude of different systems with the same intended purpose, as long as they are from the same manufacturer source, to all be included under the one ARTG entry, thereby concealing the identity, and TGA awareness, of these individual systems. This is most apparent for orthopaedic implants such as hips and knees, which are separately tracked in the Australian National Joint Replacement Registry (NJRR) and while apparent to the orthopaedic community are otherwise invisible to TGA.

[4] National Health and Medical Research Council. *NHMRC additional levels of evidence and grades for recommendations for developers of guidelines*. Retrieved 20 May, 2009 from http://www.nhmrc.gov.au/guidelines/_files/levels_grades05.pdf.

MTAA's proposals in this submission all follow a central theme of assisting TGA to increase oversight of medical devices, an objective with which industry agrees in principle. However the methods which TGA employs to establish increased oversight need to be carefully evaluated to ensure that unnecessary burden and impractical requirements not be evoked to achieve this goal.

As the majority of medical devices supplied in Australia are sourced from GHTF founding member countries, validation of these products has typically already undergone rigorous review by other equivalent regulatory bodies, and their safety and efficacy has already been established. It is questionable whether TGA's aim to establish its own oversight of these products improves safety or efficacy outcomes. TGA's proposal to establish revalidation threatens to create a regime of redundancy as well as resource, cost and time blowouts.

TGA's capacity to resource the proposals in the Discussion Paper will be crucial. Historically TGA has struggled to recruit additional and well trained staff. Industry will need assurances that the influx of the high numbers of applications for conformity assessment certification, applications for entries in the ARTG, and the potential high numbers of application audits required for transitioning products will not adversely affect processing of routine applications.

MTAA recommends that TGA develop and publicise a strategy for resourcing the implementation of the proposed changes in advance of the implementation dates.

The Discussion Paper proposes two different time frames for transition. MTAA questions why these proposed transition periods cannot be the same length of four years. If the two year period for the orthopaedic joints, for example, is based on the idea that overseas products would already be certified and the requisite technical documentation has been compiled, the length of the transition period underestimates the time it could take to prepare the necessary numbers of applications. At this stage it is uncertain how many Class III applications will be required given the poor understanding of unique product identifiers and their associated variants which in turn determines the number of applications that will be required and the compilation of separate technical dossiers to support those applications.

The requirements for entry into, and the uniqueness of, the ARTG were not factors which influenced the revised classification of implanted hip, knee and shoulder joints in the EU[5]. The costs and time involved in developing applications based on TGA's vague and inconsistent definitions of Unique Product Identifiers (UPIs) and associated variants at the Class III and AIMD levels are likely to become prohibitive. For some time MTAA has been trying, without success, to develop criteria for UPIs and variants that are more readily understandable. TGA needs to work with the industry to solve this problem before the proposals are implemented. Clear and easily understood guidance will need to be produced by TGA in conjunction with the industry.

Similarly, the problems created by the separate (and unique) TGA GMDN database needs also to be urgently resolved with industry. The impact of the Australian GMDN coding affects the numbers of ARTG entries required which in turn affects the numbers of applications that are needed. This then results in higher regulatory costs.

[5] Directive 2005/50/EC

MTAA recommends that TGA work with industry to refine the UPI and variant requirements, and reform the GMDN database before implementation of any of the reforms proposed in the Discussion Paper.

While companies should be encouraged to submit applications early to transition their products during the course of the relevant transition periods, annual charges for any of those applications approved during the transition period should be waived until the end of the transition period. This will overcome the problem encountered in past transitions where sponsors may not have submitted applications until towards the end of a transition in order to minimise any annual charges for applications approved during the transition period.

MTAA recommends that in order to encourage gradual transition of products, and to avoid the rush of applications at the end of the transition period, TGA waive annual fees for early transitioning products.

In order to ensure that sponsors understand the requirements of the reform proposals, as they are implemented, TGA should resource a business liaison function within TGA to work with companies to answer questions and assist with understanding of guidance materials. This function could also have responsibility for training sponsors on any new requirements.

MTAA recommends that TGA establish a permanent business liaison function within TGA to work with sponsors to assist with queries and facilitate training on legislative requirements for therapeutic goods and, in the short term, the proposed reforms.

MTAA has included in this submission an indicative cost impact of the reform proposals. The costs are significant. Because TGA operates as a fully cost-recovered agency, it must review its fee structure so that the additional registration requirements arising from the reforms do not impose unreasonable additional cost. Without a commensurate adjustment to fees, companies will have no option but to reconsider the products used in the Australian market. This is particularly the case for products used for revision surgery or repair procedures where the cost to replace one item in a system is minimal compared with replacement of the entire system.

MTAA recommends that TGA review its fee structure and adjust it to take into account the additional registration requirements arising from the reforms.

6. Proposal 1 – reclassification of joint replacement implants

MTAA accepts that there is a good argument to require implantable hip, knee, and shoulder joint implants to be reclassified as Class III. The reclassification ensures that the Australian regulatory system remains aligned with that of the EU (which it most closely resembles). It also aligns more closely the proposed product information available through the ARTG with the more detailed information published by the NJRR.

The discrepancy in product information is inherent in the way Class IIB devices are represented under current ARTG inclusion requirements, and will be solved by reclassification where individual systems are separately called out and assessed. At present, the classification allows a multitude of different systems within the same intended purpose, provided they are from the same manufacturer source, to be included under the one ARTG entry, resulting in a lack of transparency of the

individual systems. This submission considers other implants, addressed by Proposal 3, at Section 13.

MTAA has identified the following issues that need to be addressed with the reclassification of joint replacement implants:

- The reclassified products will require a greater level of documentation, not just for each application, but for a much greater number of applications. Although most companies will already have this documentation available due to the recent European reclassification, there will be some differences. The additional burden is that TGA has proposed that it act as sole assessor

- Any change must ensure that the definition of "load bearing" is the same in Australia as it is in the European Union

- A critical aspect is that of UPIs and the associated variants. As discussed in Section 5, TGA has yet to provide practical criteria for these terms or publish the reasons for the decisions made about the UPIs or variants needed by each applicant. Because Class III submissions have to be separately submitted for each UPI, the effect on the volume of applications could be very significant

- TGA has added partial joints to the requirements for reclassification. While there is some debate about the extent of the reclassification by the EU (as the Directive has not been implemented consistently), MTAA believes that reclassification in Australia should be undertaken in two stages with reclassification of full load bearing joints initially, and extended to partial joints at a later time. While NJRR outcomes data suggests that partial joints have increased incidents, it is not clear whether this is attributable to design issues, or other factors. Further analysis should be undertaken before reclassification of partial joints is fully implemented. A staged implementation will also ensure that sponsors have sufficient evidence to support registration at the Class III level for all components.

MTAA recommends a staged implementation of reclassification, starting with full joints and moving to partial joints at a later time.

- Orthopaedic systems are frequently upgraded and previous systems discontinued. Companies are loath to continue registration for discontinued products, especially with the volume of additional documentation required for an upgrade to Class III. However this creates an issue with items for revision or repair procedures.

  An implant can last many years in a patient. If one part of that implant requires revision, and to avoid removing the entire implant with concomitant loss of bone and a more complex procedure, it is clinically preferable to replace the segment requiring the revision. However the segment would not be registered on the ARTG as a Class III product because the system has been discontinued. There is a good clinical need to make such items available without the complex requirements for new products. In the Discussion Paper TGA suggests the Special Access Scheme procedure could be used to address this situation.

This is not unprecedented as the EU suggested the same solution. But there are flaws with this approach. Firstly, in the mid-1980s there was a significant increase in the number of joints implanted, and this has continued. As patients are now living longer, they are outliving their prostheses and as revisions invariably occur by 15 to 20 years, it is expected that there will be an exponential requirement for revision components in comparison to past experience. The SAS program is unlikely to provide an appropriate solution should the exponential numbers prove to be correct.

Secondly, the products supplied through the SAS process do not receive reimbursement on the Prostheses List. Patients could be financially disadvantaged. If the revision components cannot be economically provided, patients could conceivably require total joint replacement which could adversely jeopardise clinical outcomes. A solution is for TGA to quarantine superseded items used only for revision or repair procedures and to accept Class IIB level certification for these items, provided that the system has not demonstrated any adverse safety issues.

MTAA recommends that TGA quarantine components of superseded implantable systems retained for revision or repair procedures and accept Class IIB level certification for these items.

MTAA proposes that the existing approved Class IIB implantable joints be re-entered in the ARTG as Class III devices based on Level 2 application audits. Clinical evidence should be based on the post market history of the products rather than requiring companies to develop additional data. In most cases Class IIB implantable joints are supplied in Australia on the basis of CE certification. To require a separate assessment so that TGA can issue its own certification is difficult to justify, especially when the additional costs, resources and timeframes are considered. MTAA proposes that review of a design examination report following a Level 2 application audit for transitioning implanted joints should be the only additional evidence needed as a basis of issuing TGA conformity assessment certification. This procedure is analogous to a clearly defined abridged conformity assessment certification process.

MTAA has been provided with indicative costings from member companies demonstrating the cost impact of requiring full TGA conformity assessment with reclassification compared with a Level 2 application audit and review of the design examination report. For smaller companies the comparison is approximately ten-fold with indicative costings ranging from $2 million for a full TGA conformity assessment compared with $200,000 for an application audit and review of design examination report. For larger companies the comparison is approximately five-fold - $4 million compared with $1 million.

MTAA recommends reclassification of Class IIB implantable orthopaedic joints as Class III devices be undertaken with a Level 2 application audit and then issued with a TGA conformity assessment certificate following a review of the design examination report.

To ease some of the administrative burdens on the TGA and aid implementation for the industry, MTAA proposes that there be a transition period of four years for the reclassification of the orthopaedic joints to ensure that additional documentation can be developed.

MTAA recommends alignment of transition periods with a four year transition for the reclassification of implantable orthopaedic joints.

7. Proposal 2 – general comments

As a general comment, MTAA questions the need to link all three proposals referred to under Proposal 2. Each could be looked at separately.

TGA has previously explored the issue of third party conformity assessment. The majority of submissions proposed that appropriately validated third party assessors be used to address current TGA workloads. This additional support will become essential if TGA implements the requirements for reclassification of orthopaedic joints.

In order to fulfil the regulatory oversight demanded of TGA, the third party bodies would need to be reviewed and approved by TGA. This provides the necessary TGA oversight without requiring TGA to examine each application. However the authority and responsibility structure needs to be carefully positioned for a number of reasons:

- TGA needs to take on the role of a Competent Authority, as currently practiced in Europe, overseeing the various Notified Bodies or Conformity Assessment Bodies (CABs) and undertaking post market surveillance

- Unlike the arrangements in Europe where each country has a Competent Authority, with consequential variability of third party oversight, TGA should be the single arbiter over CABs that certify products for supply in Australia. If TGA itself retains the role of a CAB then an independent accreditation body such as the Joint Accreditation System of Australia and New Zealand (JAS-ANZ) may be required to accredit TGA to supply conformity assessment certification

- CABs should be assessed by TGA to validate their inclusion as approved Notified Bodies for Australian entry assessment. This requirement supports a longer transition period to ensure a viable number of approved CABs.

The processes outlined above would ensure that TGA retains complete oversight and attests to an independent control over the safety and efficacy of medical devices supplied in Australia.

8. Proposal 2A – use of third party assessment bodies for Australian manufacturers

MTAA supports Proposal 2A.

TGA will need to consider the timing of cessation of the requirement for TGA conformity assessment by Australian manufacturers if and when other CABs are operating in Australia so that manufacturers can have adequate time to plan for their certification requirements.

9. Proposal 2B(i) – devices requiring a TGA Conformity Assessment Certificate to be issued

MTAA has canvassed its concerns with Proposal 2B in Section 5. The additional regulatory costs in obtaining separate TGA conformity assessment certification for products which have already been covered by CE certification, or approved by the

US FDA or Health Canada, will result in significant added cost, potentially prohibitive to some companies.

MTAA has been provided with indicative costings from member companies demonstrating the cost impact of requiring full TGA conformity assessment certification for Class III implantables and AIMDs compared with a Level 2 application audit and review of the design examination report. For smaller companies the cost comparison is approximately four-fold with indicative costings ranging from $400,000 for full conformity assessment certification to $100,000 for a Level 2 application audit with review of the design examination report. For larger companies the cost comparison is approximately ten-fold, ranging from $12 million to $1 million. In addition annual recurrent costs range from $500,000 to $200,000 for larger companies and $100,000 to $50,000 for smaller companies.

MTAA argues that evidence in addition to EU certification, PMA approvals by the US FDA or Class IV approvals by Health Canada should be sufficient for TGA to issue its own conformity assessment certification. This process would be analogous to reviewing additional evidence such as a design examination report in conjunction with a Level 2 application audit as is the case for the current abridged conformity assessment process.

The same approach for TGA to issue conformity assessment certification is suggested for products containing materials designated by the TGA.

MTAA recommends that TGA issue a conformity assessment certificate on the basis of a Level 2 application audit and review of a design examination report.

If the product does not have CE certification or prior approval in the US or Canada, then full TGA conformity assessment certification would be required.

The suggested processes are depicted in the diagram at Attachment A, titled “TGA Approval Class III Implantable, AIMD and including TGA designated materials”.

10. Proposal 2B(ii) – applications to be selected for auditing

MTAA understands the perceived need to subject implantable Class IIB products to Level 2 application audits. However the costs associated with mandatory audits could be significant for many companies and will require further detailed review.

MTAA has been provided with indicative costings from members which range from $10,000 to $1 million for mandatory Level 2 application audits.

MTAA proposes that TGA extend the current application audits of CE certified products to also include products approved by US FDA and Health Canada.

The suggested process for CE certified products as well Class IIB implantable products approved by the US FDA and Health Canada is depicted in the diagram at Attachment B titled “TGA Approval Class IIB Implantable”.

MTAA recommends expanding the current application audits to include products approved by Health Canada and US FDA as the basis for an entry in the ARTG.

TGA should implement a statutory timeframe for the assessment of all mandatory application audits so that industry can better plan and budget for this additional requirement in the product delivery cycle in Australia.

MTAA recommends that TGA implement a statutory timeframe.

11. Proposal 2C(i) – confidence building for EU Notified Bodies

TGA has had confidence building processes in place with EU Notified Bodies since at least 2002. Notwithstanding this, MTAA recognises that the level of use of the MRA by European medical device manufacturers has been low. MTAA also recognises that TGA needs to increase its level of confidence in certificates issued by third party assessment bodies.

If further confidence building is to be undertaken, a two year process is appropriate. The objectives and outcomes of the confidence building process should be published.

TGA should consider having the same ongoing certification/recognition processes for conformity assessment bodies in Australia, and for existing Notified Bodies in Europe, that wish to participate in the medical devices annex of the MRA. This would result in a consistent and auditable process for the TGA. The objectives and outcomes of the ongoing certification processes should be published.

MTAA recommends a two year period for confidence building with alignment of requirements between approval of Notified Bodies outside Australia, and those within Australia, with TGA as the accreditation authority.

The MRA continues to have value for companies manufacturing in the EU and supplying medical products in Australia. Assuming that the proposed confidence building period is undertaken, MTAA would welcome discussions with the TGA and the Department of Foreign Affairs aimed at extending the scope of the medical devices annex of the MRA. Increasing the scope would encourage more companies to take advantage of the treaty.

Under the EU MDD, Notified Bodies issue different certificates depending on the conformity assessment annex(es) chosen by the manufacturer. It is unclear from the Discussion Paper if TGA contemplates accepting all kinds of certificates.

TGA should work with industry to determine which Notified Bodies should be considered to continue with, or become part of, the MRA. TGA could then approach the Competent Authorities that designated the nominated Notified Bodies for further advice. TGA representatives could also be nominated to be part of the regular EU Notified Bodies Operation Group audit program of Notified Bodies.

TGA should also consider coverage of bodies which are not EU Notified Bodies recognized under the MRA, for example, Underwriters Laboratories, which serves as an accredited body for the US FDA. Consideration could also be given to bodies recognized by Japan MHLW to perform assessments of Japan Class II devices, but which are not affiliated with EU Notified Bodies.

MTAA suggests that TGA model the confidence building/accreditation processes on JAS-ANZ for accreditation of certification companies and EU Competent Authorities designation of Notified Bodies.

MTAA recommends the use of JAS-ANZ processes or equivalent for accreditation purposes and consideration of inclusion of bodies such as those accredited by US FDA and MHLW in Japan.

12. Proposal 2C(ii) – recognising Australian third party assessment bodies

MTAA fully supports the proposal to engage in further consultation on Proposal 2C(ii). The additional consultation should be initiated within six months of the enactment of the suggested legislative amendments.

The accreditation options and role for TGA with respect to issuing conformity assessment certification are consistent with MTAA's submission to the Review of Health Technology Assessment.

MTAA recommends that TGA take on the distinct function of being an accreditation authority to assess, audit, and certify conformity assessment bodies based in Australia or overseas.

If TGA also provides a conformity assessment service then that service should be accredited by an independent authority such as JAS-ANZ. In this way companies could choose between conformity assessment certification services and the TGA.

MTAA recommends that TGA take on the role of the accreditation authority to accredit conformity assessment bodies in Australia. If TGA is to be a conformity assessment body then it must be independently assessed by a body such as JAS-ANZ.

13. Proposal 3(i) – amending the way in which a kind of medical device is included in the ARTG

MTAA understands and accepts the need for identification of medical device products that have been approved for supply in Australia for each entry in the ARTG. However MTAA also recognises that this change will impose a considerable administrative burden on companies.

The most practical way this identification process can be achieved is through a fee free notification process to the TGA using its online eBusiness system. The process should be by notification only and not require any prior validation by the TGA before the information appears in the ARTG. After transition, any additional products to an ARTG entry should not require a variation application, but be included by a notification process. TGA carries out post market audits on products entered in the ARTG. Confirmation of the bona fides of products notified to TGA should be undertaken in the same way.

A requirement for a variation application for new products after the end of the relevant transition, is likely to result in an unnecessary influx of applications. This will impact on processing rates for other applications. A small poll of members indicated that some companies could be introducing medical devices that need to be separately identified under an ARTG entry at the rate of one per week. If that figure is extrapolated for the approximate number of medical device sponsors and then moderated to allow for differences in company sizes, the figure of 200 to 500 variation applications are likely to be submitted to the TGA each week. As the

proposal suggests that these new products could not be supplied until the variation application is processed, unacceptable delays in the supply of those products are likely.

MTAA recommends that TGA provide for identification of medical devices on the ARTG through a fee-free notification system, supplemented by post-market audits.

There needs to be further consideration of product identification options for the ARTG to ensure appropriate identification of products. Once the product identification details are agreed, TGA should develop a facility through its IT or eBusiness system for sponsors to input and maintain this information. The time period for sponsors to provide the required information is too ambitious – a longer transition period should be allowed.

MTAA recommends that the transition period be extended to two years.

14. Proposal 3(ii) – enhancing the ability to identify devices that have been approved by the TGA for supply in Australia

The stated rationale for the proposal to enhance identification of products is to:

- Identify that a product is approved by TGA
- Identify the product in the event of a recall at some future date.

Where a recall is prompted by a company/sponsor, the ARTG number is already known. Having an ARTG number on a product will not improve the capacity to identify and remove it.

If Proposal 3(i) is adopted, the enhanced information made available through the ARTG provides an appropriate level of assurance that the product in question is approved for supply in Australia.

MTAA does not support a requirement to over-label every product with the ARTG number. The cost to industry to provide the ARTG number with a medical device may be prohibitive. It is estimated that it will cost between $250 to $500 per product per company to provide product-specific labelling and modify inventory systems. It is not feasible for manufacturers to print additional labels as the ARTG number is not known when IFUs and other materials are being printed. With an estimate of between 1 and 1.5 million medical devices which could presently be entered in the ARTG, the total cost to industry could range from $250 million to $750 million for this proposal alone.

The provision of additional reliable and efficient search facilities within the ARTG database to search for individual products would obviate the need to provide ARTG numbers with the products.

MTAA recommends using the enhanced disclosure under Proposal 3(i) as the mechanism to improving medical device identification, coupled with an expanded search capability of the ARTG.

Unique Device Identifier

Regard should also be had to the work which the US FDA is undertaking in developing a Unique Device Identifier (UDI). US FDA is expected shortly to release draft regulations for the introduction of a UDI for medical devices. UDI is made up of code (ie. standards which can be either GS1 or HIBCC) plus carrier (which is the physical representation of the code eg. bar code or other human readable form or RFID) plus database (which uses UDI code as a key).

US FDA is building a database which will be housed outside the US to enable access by all regulators and users (which may be a cloud computing solution). Apart from the regulatory applications of device identification, US FDA has identified the introduction of UDI as also improving traceability of devices to address counterfeit products.

The GHTF has recently released a draft proposal for a guidance document on UDI[6]. The aim of a UDI, as outlined in the draft proposal[7] includes:

- Providing a single, globally-accepted source for positive identification of medical devices. Health care professionals and patients will no longer have to access multiple, inconsistent, and incomplete sources in an attempt to identify a device, its key attributes, and a designated source for additional information

- Ensuring the adequate identification of the device through its distribution and use

- Providing rapid access to key attributes relating to the device. The UDI system will allow rapid retrieval of information from a dedicated data base system that focuses on the identification of devices

- Simplifying integration of information on device use into medical records, ensuring compatibility with electronic health records.

In addition, the traceability capability can facilitate the resolution of device problems by:

- Making it possible to more rapidly identify devices involved in adverse events. UDIs will be available for inclusion in adverse event reports, allowing greater accuracy in reporting, and more rapid aggregation of related reports

- Providing for more rapid resolution of confirmed problems. UDIs will allow health authorities to more rapidly collate and analyse problem reports and identify the most-appropriate solution to a particular concern. UDIs will also allow more accurate target safety alerts, recalls, and other corrective actions on the specific devices that are of concern

- Providing a single, globally-accepted "key" that can be used to link and integrate existing government, hospital, and corporate data bases that relate to medical devices.

[6] http://ghtf.org/documents/AHWG-PD2-N2R2.doc posted 22 November 2010
[7] Ibid pages 3-4

MTAA recommends that TGA consider the implementation of a global UDI as a tool to assist with device identification and to not replicate requirements that are already under active development in other GHTF founding member jurisdictions.

e-Labelling

On 9 November 2010 Health Canada issued a notice on electronic labeling requirements for certain medical devices, to take effect immediately. The use of e-labelling provides the industry with the opportunity to meet labeling requirements in a less burdensome manner. The notice covers information that would normally be provided on directions for use with devices that are not intended for sale direct to the public.

The notice provides that e-labelling may be provided on CD or DVD, accompanying the device at the time of sale or delivery. The CD/DVD must be packaged with, or accompany, the device in a manner which alerts the user to its purpose. The information should also be easily navigable.

For other class IV devices, the information can alternatively be provided in a downloadable format from the internet. The internet address must accompany the device at the time of sale or delivery, and alert the user to its purpose.

MTAA recommends consideration of the use of e-labelling as an option for sponsors of medical devices supplied in Australia.

15. Proposal 4 – publication of device information on the TGA website

There are mixed views within industry on the proposal to publish device information on TGA's website. MTAA welcomes the opportunity to explore this proposal in further detail.

Industry recognises the need for all consumers to be better informed, especially when it involves decisions about their health. However, companies have raised the following practical issues:

- Information is currently available on company websites, typically aimed directly at the patient level. Providing more technical/scientific information on the TGA website by copying the IFU or other technical information may not provide any material additional to what is already present on the company website

- The vast range of medical technology makes it impractical to be able to define the requirements for providing information on medical device products that is not already available on IFUs or product information

- With the implementation of Proposal 3(i), increased information in the ARTG about medical device products being supplied in Australia means that information on specific products can be more readily accessed via the Internet

- Many devices do not need an IFU, a manual or other document as it is obvious what the device is used for. The Essential Principles recognise that some medical devices may not require instructions or user manuals. For

example, cotton wool balls, gauze swabs, cotton tips, stethoscopes, compression bandages, ostomy pouches, exam gloves, dentures removable by the patient, hypodermic needles, scissors, artery forceps, tissue forceps, tissue clamps, excavators, osteotomes and chisels, skin closure devices, light stands do not need explanatory information to be supplied. For some products the “instructions” are on the pack. e.g. plastic dressing strips.

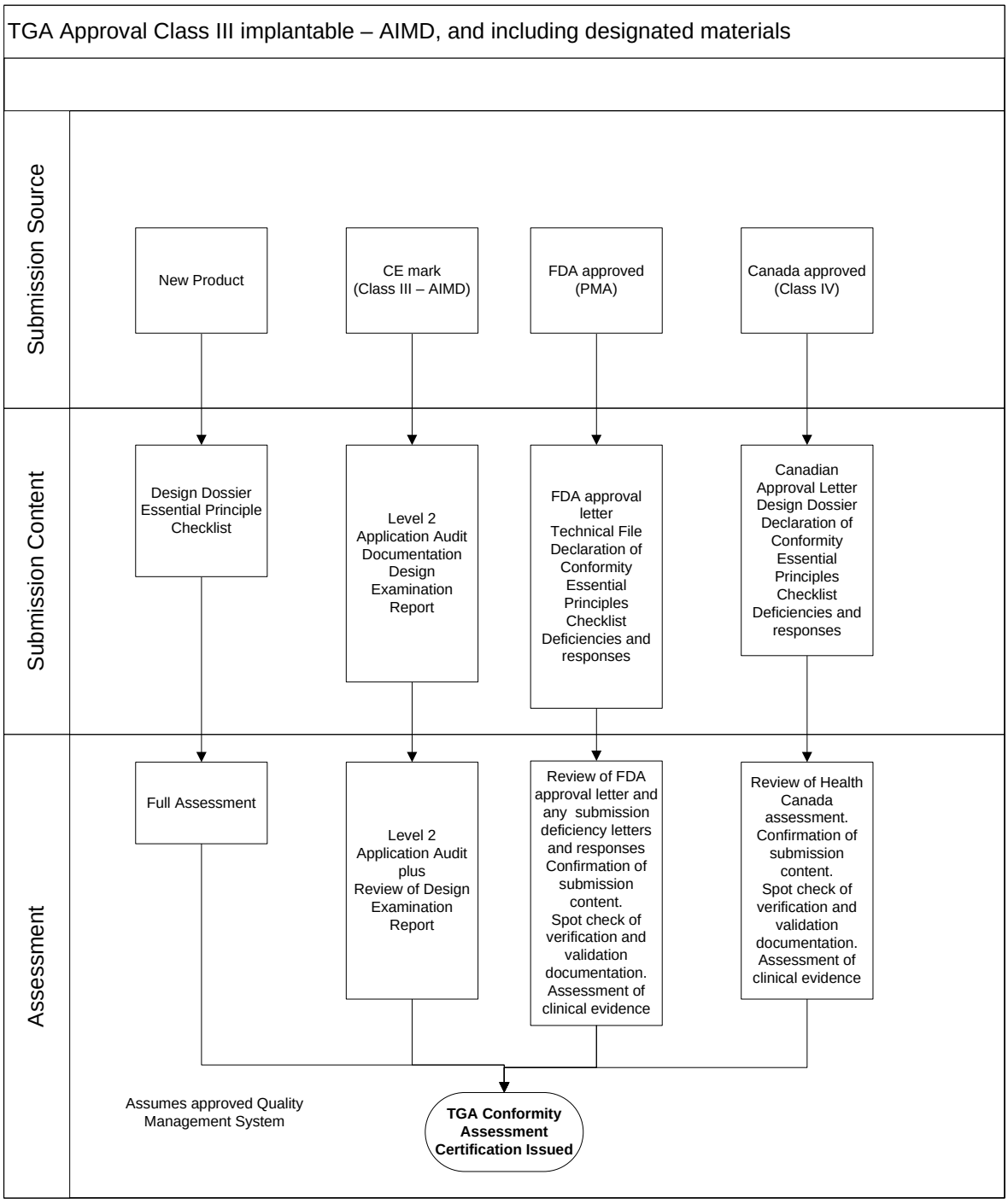
MTAA proposes that this proposal be trialed in a small scale pilot to establish the feasibility of providing product-related information for consumer use, and assessing consumer response to that information. The pilot should be undertaken on a voluntary basis. Any implementation of this proposal should be iterative and only after positive assessment of the pilot.

MTAA recommends that the publication of device information on TGA’s website be trialed in a small scale, voluntary pilot with implementation on a broader scale only after positive assessment of the pilot, including consumer support.

16. Cost impact of reforms

The cost implications of many of the reform proposals make it imperative that there be a well-considered Regulatory Impact Statement (RIS), which should include industry input to ensure that all cost impacts are identified and costed.

Attachment A



Attachment B