DEVICE TECHNOLOGIES
First Choice

Reforms in the Medical Devices Regulatory Framework

Submission by Device Technologies Australia Pty Ltd
December 2010

Executive Summary

This document provides comments and recommendations by Device Technologies Australia Pty Ltd (DT) on the proposals made by the TGA in the Discussion Paper: *Reforms in the Medical Devices Regulatory Framework,* dated 25th October, 2010.

Device Technologies Australia welcomes any future opportunity to work closely with the TGA and other interested bodies to further develop these proposals. Additional examples and in-depth analysis of options or alternatives for implementation could be provided.

The proposals presented by the TGA in general contradict the Review of Health Technology Assessment (HTA) in Australia, released in December, 2009 which states:

> *"HTA is a key tool for the Australian Government to achieve its overall objective of delivering a safe, effective and efficient health system that is fiscally sustainable in the long term"*
>
> *"A key objective of the HTA Review is to address the regulatory burden on business that results from HTA processes, to ensure that those processes are efficient, measured and proportionate."*

The TGA has neglected to fully consider the ramifications of the implementation of these objectives, which are highly cost and resource intensive.

Despite this, Device Technologies appreciates the pressures that the TGA is under to increase the pre-market assessment of some medical devices. Therefore, whilst DT does not agree with many of the TGA proposals, a common goal (to deliver safe, efficacious and quality medical technology) is recognised and alternative measures which would also meet a perceived need for increased pre-market surveillance are presented in this document.

It is apparent that the goal of increasing pre-market scrutiny of these products need not require the TGA to apply the most stringent regulatory review process. A more appropriate mechanism can be applied whilst still achieving this goal and providing a balanced regulatory burden on both industry and government resources.

Due to extremely high costs incurred by industry if these proposals were to be implemented, the final cost of medical devices to end-users and taxpayers would be significantly increased. It would not be financially feasible or sustainable for industry to completely absorb these costs. Sponsors and manufacturers would have no choice but to directly recoup this. Such an increase in costs is not justified by the perceived, yet currently undetermined, increase in patient safety and clinical outcomes.

DT considers that significantly more detail be provided to the medical device industry in order to remove uncertainties and assumptions made when determining comments and outcomes. Both a Cost Recovery Impact Statement and further consultation is required before these proposals can be progressed for implementation.

About Device Technologies Australia Pty Ltd

Device Technologies Australia is a major supplier of leading edge medical equipment and consumables to hospitals and healthcare professionals throughout Australia and New Zealand. As an independent company DT is able to source and supply the most technologically advanced medical devices and to support these with professional services and training.

DT currently maintains over 900 ARTG inclusions for medical devices across 18 areas of speciality, including Anaesthetics and Critical Care, Cardiac Specialties, Endoscopy, Interventional, Medical Imaging Technology, Ophthalmology and Optometry, Orthopaedics, Plastic and Aesthetic Surgery, Robotics and Surgical Instruments. Medical devices of all risk classifications are currently supplied.

Summary of Recommendations and Proposals

DT proposes a comprehensive cost impact survey and Regulatory Impact statement is conducted by the TGA to fully investigate the impact of these reforms on the industry.

Proposal 1

DT does not support implementation of Proposal 1 on the basis that current post-market surveillance is proving effective in monitoring these devices, and increasing the classification will not facilitate access to new and improved technologies.

DT proposes that other methods, more appropriate to the Australian regulatory system, be investigated to increase the pre-market assessment of joint replacement implants.

If Proposal 1 proceeds:

DT proposes an exemption for non-transitioned joint replacement components for revision only.

DT proposes that the annual fees and application audit fees are waived for joint replacement implants during the transition period.

Proposal 2A

DT supports the use of third party assessment bodies for Australian manufacturers and considers that this proposal can be implemented regardless of the implementation of Proposal 2B.

Proposal 2B(i)

DT does not support the implementation of Proposal 2B(i).

DT proposes that alternate measures are investigated, other than implementation of Conformity Assessment, to address any concerns that NB assessment of Class III implantable medical devices is insufficient.

DT proposes that a third level of medical device application audit be created specifically to address the additional assessment requirements for Class III and AIMD implantable devices.

If Proposal 2B(i) proceeds:

DT proposes that the below items are fully developed and published prior to any implementation:

- Scheduled reduced fees for TGA Conformity Assessment
- the TGA's business rules regarding abridgments and reductions of CA fees and assessments
- the TGA's business rules for selection and timing of on-site manufacturer facility audits

DT proposes that:

- All CA application and assessment fees (including onsite audits) are reduced on a sliding scale, with greater reduction earlier in the transition period.
- Any surveillance or other associated fees incurred during the transition period are reduced.

Proposal 2B(ii)

DT does not support this proposal due to lack of detail provided within the consultation discussion paper.

DT strongly recommends this proposal does not proceed without further comprehensive investigation and subsequent consultation with industry.

If Proposal 2B(ii) proceeds:

DT proposes that the TGA implement methods to ensure faster processing times for level two application audits.

DT proposes a significant fee reduction following a comprehensive cost impact survey

Proposal 2C(i)

DT supports the implementation of a confidence building program in principle.

DT does not support the option suggested to 'only accept CE Certificates from MRA Notified Bodies as Manufacturer's Evidence'.

DT proposes that a definition and route for gaining designation as an 'MRA Notified Body' is developed.

DT does not support the option suggested to 'require all applications supported by non-MRA Notified Bodies to undergo a mandatory application audit'.

Proposal 2C(ii)

DT proposes that the TGA investigate, develop and put into place a system by which third party assessment bodies can apply for designation to be given authority to issue Australian Conformity Assessment Certificates.

DT proposes that the TGA complete this process within two years.

Proposal 3(i)

DT cannot support implementation of this proposal as outlined as there is insufficient detail to determine the impact and feasibility.

DT proposes the following arrangements would assist industry to be in a position to support Proposal 3(i):

- Class I non-sterile, non-measuring devices are excluded
- Identification is through a **fee-free notification system for all classes**
- Removal or amendment of model or trade names should not incur a fee or undergo review by the TGA
- Information is automatically accepted post-market audits used to review content
- Identification by model or trade name is determined by the sponsor
- Flexibility is employed due to the vast range of product types and naming conventions used within the medical device industry.
- The TGA perform an analysis (with input from industry) of the number of applications that expected to be received and develop a resourcing plan.

DT proposes a significant fee reduction following a comprehensive cost impact survey

DT proposes the TGA implement methods to ensure faster processing times for applications to vary inclusions.

Proposal 3(ii)

DT does not agree that the method proposed is the best approach and a number of aspects presented in this document must be considered.

DT proposes that Regulation 10.2 and EP 13.2 be reviewed to allow more appropriate labelling of current sponsor details.

Proposal 4

DT does not support the proposal that similar publications, as are currently made for medicines, should be applied to medical devices.

DT recommends that

- The need and specific benefits be clearly determined for this proposal
- Any implementation of Proposal 4 should not be mandatory
- Further discussion with stakeholders should occur prior to any implementation.

DT agrees that information about medical device assessments should be published but this should not include device literature

DT proposes that the TGA publish information about the decisions made during the assessment process which will reassure the public and industry that appropriate assessment has been conducted and the devices have been found to meet the regulatory requirements.

DT does not believe that decisions regarding rejected applications should be published

Summary of Transitional Time frames

Proposal	TGA Proposed transition period	DT Proposed transition period
1	2 years	**4 years**
2A	None	None
2B(i)	4 years	**6 years**
2B(ii)	None	None
2C	None	none
3(i)	1 year	**3 years**
3(ii)	1 year	**3 years**
4	None	None

Summary of Estimated Costs

Proposal	Estimated costs (AUD)
1	**116,250**
2A	not applicable
2B(i)	**3,600,000**
2B(ii)	**55,000**
2C	not applicable
3(i)	**561,600**
3(ii)	undetermined
4	undetermined
Total	**4,332,850**

The above cost estimate of over $4.3 million does not include resources and infrastructure costs which would also be a significant addition.

Note: See the relevant sections for how these figures were determined.

GENERAL COMMENTS

The consultation period given, at just over 1 month, is very short considering the number of proposals, significant legislative changes involved, and the impact these would pose on both the Australian government and medical device industry. With this short time frame, at an extremely busy time of year for the industry, a complete and detailed review of these proposals is difficult.

However, DT has endeavoured to accurately explain and present both the complications and the impact that implementation of each of these proposals, either separately or in combination, would have. An analysis of transitional costs and timeframes is presented.

With these reform proposals, there is a clear shift from the TGA's recent focus on post-market surveillance to pre-market surveillance. This raises the notion that portions of the post-market surveillance should be removed if implementation is to proceed.

Further investigation and consideration must be carried out by the TGA regarding the effect of these proposals if implemented at the same time. This is particularly important for Proposal 1 and 2 as this will have a significant impact on costs and planning required by industry in the supply of joint replacement implants. Additionally the relationships and effects of Proposals 2A, 2B, 2C and their respective parts must be more closely considered and investigated to determine an appropriate and least burdensome sequence of implementation if these were to go ahead.

In past transitional periods, it has been evident that application processing times are not commensurate with industry or government expectations. Full and proper investigation into government resources required to fully accommodate the immense influx of a diverse range of applications related to all proposals must be conducted. A plan must then be actioned so that the TGA can develop and engage these resources prior to implementation of the respective proposals.

The nature of the medical device life cycle is such that it is driven by innovative iteration on the basis of improving technology and delivery of that technology to healthcare systems internationally. Significant increase in the pre-market regulatory burden of medical devices does not take into account, nor facilitate, this development process. Increased regulatory burden such as proposed in the discussion paper will prohibit the opportunity for medical device sponsors and manufacturers to bring new technologies, often with improved quality and safety, to the Australian community.

When determining appropriate pre-market scrutiny, a balance must be struck between appropriate regulatory consideration and risk, based on either evidential risk or post-market evidence of adverse performance.

The move to TGA Conformity Assessment certification for all Class III implantable devices, of Proposal 2B, is a move away from the intent of the Australian legislative framework, which seeks to take into consideration the assessments already carried out by European authorities. Such a move has not been shown to be warranted by adverse market performance or prohibition of devices in Australia which are allowed for supply in Europe. It

is good practice for the Australian regulator to build upon investigations carried out elsewhere in the world by competent bodies with demonstrated expertise, such as the Notified Body (NB). This allows a faster route to market and does not exhaust government and industry resources to do so.

The TGA recently removed the requirement for NB evaluation reports to be submitted during all level two application audits. This would suggest that there is no concern with the quality of assessments performed by Notified Bodies and there is therefore no justification that a problem exists with the issuing of CE certificates or the evidential review performed by the NB.

Therefore, **DT believes that NB reviews and resulting CE certificates are sufficiently accurate to provide basis for TGA applications as Manufacturer's Evidence and this process should not be altered.**

It would be expected that if concerns surrounding NB evidential review had arisen, reinstating these requirements may be a more appropriate way of dealing with any inadequacies of NB assessment. If there are particular gaps between what is acceptable to NBs and what is acceptable to TGA for pre-market assessment, then it is these particular items that should be reviewed by the TGA, and not the whole of the CA process.

Therefore, **DT proposes that alternate measures are investigated, other than implementation of Conformity Assessment, to address any concerns that NB assessment of Class III implantable medical devices is insufficient.**

One such measure could be for the TGA to assess the degree of application audit documentation required based on a risk assessment of the Notified Bodies by the TGA.

For example, if particular concerns exist regarding the competence of particular European Notified Bodies, then, with sufficient evidence, those organisations should be singled out and use of their CE Certificates undergo greater scrutiny during the TGA application process. A blanket rule for implementation of TGA Conformity Assessment for Class III implants should not be the alternative.

Assumptions have been applied in order to provide comment on the proposed reforms:

- Comments are based on multiple proposals being implemented by existing regulatory team within the company. The regulatory resources available to each company and to the industry are not uncapped.

  It should be noted that if a number of the proposals go ahead concurrently it will be difficult to recruit experienced regulatory personnel at a reasonable remuneration and within a short timeframe.

- There is an assumption that any proposals put into legislation will have the same start date

- Only transitional costs have been considered in this document due to time constraints. Annual and other ongoing costs, such as Conformity Assessment

Surveillance Audits and Changes to devices subject to Conformity Assessment have not been accounted for.

DT considers that neither Proposal 3(i) or 3(ii) are necessary to address the concerns as expressed. Current systems in place through the supply chain and accounting functions provide consumers and HCPs with the necessary information to substantiate ARTG Inclusion. The TGA also has access to this information through identification of the sponsors by consumers or HCPs when there is a doubt to ARTG validity for particular products.

Both Proposals 3 and 4 have very little detail given and therefore in depth comments and accurate costs are difficult to provide. Further development of these proposals and subsequent industry consultation must occur before any plans are made for implementation.

DT estimates that on average the products covered under an ARTG inclusion are updated (products added, deleted, amended, superseded, etc.) at an extremely high rate.

Has the TGA considered the number of applications it would receive on an annual basis for such variations and planned for adequate resources to assess and process these? A conservative estimate might be that every ARTG inclusion would require at least one application to vary the record once per year.

Given the increased volume for applications to be assessed it is important that the TGA carefully consider the above and have reasonable expectations when developing a resourcing and implementation plan.

There is constant and ongoing administrative work to support this and the fee structure and resource requirements for any proposals which impact this must be thoroughly analysed.

SPECIFIC COMMENTS

Proposal 1 – Reclassification of joint replacement implants

Despite previous consultation on this issue, the necessity of this proposal remains arguable. There are currently stringent post-market requirements for joint replacement implants, which allow in depth post-market surveillance, through annual reporting requirements and the National Joint Registry.

It has not been shown that increasing the pre-market regulatory burden by increasing the device classification for joint replacement implants will benefit the Australian public. Benefits must be measured in both improved clinical outcomes balanced by access to state of the art medical technology. Increasing the classification of these devices will increase costs, time to market, and is therefore likely to result in rationalisation of the devices available to the Australian healthcare system.

DT does not support implementation of Proposal 1 on the basis that current post-market surveillance is proving effective in monitoring these devices, and increasing the classification will not facilitate access to new and improved technologies.

Whilst GMDN Codes apply to all medical device classes in the Australian regulatory system, the UPI and Variants apply only to Class III medical device inclusions.

Although these have been the subject of industry and TGA collaborations, appropriate UPI, Variants and GMDN Codes for joints have not yet been fully investigated, reviewed and implemented. This will take some time yet to resolve, and changes must be completed prior to commencement of any transition. This will avoid inconsistencies and errors due to unforeseen complications in these technical areas of the application process and ensure both the TGA and Industry are of the same understanding in application of the characteristics.

All three concepts are specific and unique characteristics required for including products on the **Australian** Register of Therapeutic Goods (ARTG). It is very important to note that these characteristics are not key aspects of regulatory approvals in other jurisdictions and therefore did not impact on decisions made in those jurisdictions to increase the device classification of joint replacement implants.

DT proposes that other methods, more appropriate to the Australian regulatory system, be investigated to increase the pre-market assessment of joint replacement implants.

Such a method may include applying a pre-market level two, post-market targeted or other application audit to these kinds of medical devices. This would avoid the issue of applying UPIs to joint replacement implants and provide a more appropriate cost and resource burden on both industry and the TGA.

DT proposes an exemption for non-transitioned joint replacement components for revision only. These devices should remain on the ARTG as Class IIb medical devices and somehow marked as 'for revision only' on the public view of ARTG, and as a condition of entry on the ARTG. These devices would be monitored by post market activity with the joint registry along with the TGA's own post market ARTG inclusion monitoring programmes.

This exemption could be put into place on the condition that the inclusions would be reviewed for validity within a specific time frame, perhaps after five or ten years. The company would then need to justify continued inclusion based on device performance or market requirements, and prior to an automatic expiry/cancellation at that time.

Device Technologies does not consider that using the Special Access Scheme (SAS) for revision components is reasonable, appropriate or feasible. This is due to the complications and resources required (both on government, community and industry) in administering such a scheme on an ongoing basis for a large range of products. Additionally, there is no reimbursement available to privately insured patients for devices supplied under the SAS.

It is concerning that the proposed classification rule includes "implantable load bearing component" devices. There is currently no definition of load bearing components and this could lead to uncertainty. DT suggests that definitions should be aligned with Europe.

Whilst the final number of applications would need to be determined it is foreseeable that the TGA would experience significant increase in their processing workload for Class III applications. The TGA will need to conduct a thorough survey of all joint sponsors to determine application numbers. This will be important to ensure adequate resourcing for this proposal both for processing of transitional applications and so as not to impact on other Class III applications. A Regulatory Impact Statement will be essential for this.

Transitional Timeframe

If the proposal were to be implemented without alteration, the transition period proposed is not sufficient. A four year transition would provide a more appropriate timeframe for adequate clinical evidence to be prepared, and for the additional Australian specific documentation to be prepared (for example the clinical evidence expert report which is not required in other countries).

If the proposal is to be implemented without alteration, and the current system involving Class III level two audit requirements were utilised, a sponsor would need to follow the process below during the transitional period.

Step	Duration
Assess currently supplied products affected by this proposal	1 month
Determine necessary applications based on structure (e.g. whether or not products/applications can be grouped, UPI, GMDN, variants, intended purpose etc.)	3 – 6 months – many variables to be considered, e.g. new GMDNs
Analyse financial costs (application & audit fees, annual fees, regulatory resources and associated costs)	1 month
Allocate and receive budgetary approval (rationalise product range dependant on budgetary approval)	6 – 12 months
Allocate regulatory resources for both Australian sponsor and manufacturer	1 - 6 months – depending on other projects / new regulatory resources required

Step	Duration
Determine additional documentation requirements	1 – 2 months
Source above from manufacturer	2 – 4 months
Prepare and submit eBS applications, pay application fees	1 – 2 months
Final review and submit application audit documents, pay audit fees	1 month
Wait for TGA assessment of submission and additional questions	3 – 6 months
Prepare and respond to additional questions & requirements	1 month
Wait to receive approval of inclusion in the ARTG.	1 – 3 months

The process as outlined above could take from **22 – 45 months** and therefore a transition time of two years (24 months) is likely to be inadequate for many sponsors. **DT proposes that** a **transition period of four years would be most appropriate.**

If level two audit requirements were to be altered for joints because of simultaneous implementation of Proposal 1 and 2, the process outlined above would still be followed however further time may be required to allow for the additional requirements which are as yet unknown. (This is in reference to comments by Shelley Tang during the Consultation in Sydney on November 16th, 2010, where it was indicated that in an attempt to reduce the burden on sponsors for joint devices being required to be audited as Class III, which would later also be required to be assessed for Conformity Assessment, further information could be requested to satisfy the Conformity Assessment requirements at the time of the Class III audit). It is unclear as to what documentation this would entail.

Transitional Cost Analysis

Device Technologies estimate that 15 Class III medical device applications for joint replacement implants would require lodgement during the transition period.

The following assumptions have been used:

- current Class III application fee ($1,050)
- current Level Two application audit fee ($5,650)
- current annual fee ($1050) would apply (This is taken into account as it would be additional to the annual fee already incurred for the Class IIb ARTG inclusion)

The estimated cost for Device Technologies to comply with implementation of this proposal is **$116,250 (not including staff resources,** as this is too difficult to estimate in such a short period of consideration).

In order to reduce the costs, **DT proposes that the annual fees and application audit fees are waived for joint replacement implants during the transition period.** This will also encourage early submission of joint replacement implants applications.

Proposal 2 – Third Party Assessment Bodies and Supporting Reforms

Device Technologies does not agree that all sub-components of Proposal 2 should be applied as a single packet of reforms

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

Device Technologies supports the use of third party assessment bodies for Australian manufacturers and considers that this proposal can be implemented regardless of the implementation of Proposal 2B.

See Proposal 2C for further comments.

Proposal 2B – Increasing pre-market scrutiny for implantable medical devices

Device Technologies recognises the social and political perception that higher risk implantable medical devices supplied to the Australian healthcare market should undergo a greater level of pre-market regulatory evaluation.

However, it is not agreed that the level of assessment for Class III implantable medical devices should be TGA Conformity Assessment.

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

DT does not support the implementation of Proposal 2B(i). DT does not agree that moving to full Conformity Assessment for all Class III & AIMD implantable devices is necessary and most particularly, does not accept that the current level of post market experience for these devices is sufficiently negative to warrant such rigorous, costly and time consuming assessment.

It should be noted that in November, 2008 the TGA reduced the Level Two Application Audit requirements (which included Class III & AIMD implantable devices). The requirement to submit:

- Third party quality management system audit reports;
- Third party design examination or type examination audit reports;
- The Essential Principles Checklist; and
- Sterilisation process validation reports (Validation reports for special processes);

was removed. Assessment was refocussed towards clinical evidence and risk analysis, which was welcomed by industry as more appropriate assessment for these devices. The option remained for the TGA to request these documents if necessary but DT is not aware of this occurring.

If it is determined that assessment should now be increased for Class III and AIMD implantable devices, then it would be reasonable to expect reinstatement of the requirement for these documents (or other specific documents of interest to the TGA) to be provided, rather than applying the most stringent level of assessment available.

DT proposes that a third level of medical device application audit be created specifically to address the additional assessment requirements for Class III and AIMD implantable devices. This level might include documents such as the Notified Body reports, critical supplier details and other specific parts of the existing Conformity Assessment supporting documents, but would not be a complete CA review.

After the transition period it would be reasonable to expect that both industry and the TGA would have developed greater understanding and ability to prepare and process CA applications. However, CA applications would still be expected to take 12-24 months from CA lodgement to ARTG inclusion. This length of time poses a significant delay for critical and innovative technologies such as Class III and AIMD implantable devices. These devices are constantly under development and iterative release due to continued product development and advances in medical technologies and materials. The benefits to be gained through the stringent CA review process are questionable. Any perceived benefits must be compared to the delay and disadvantage to the Australian healthcare system in its ability to deliver state of the art medical technologies to an increasingly aging community.

Additionally, whist new (non-transitional) devices are awaiting approval via the CA process, there is no reimbursement available for devices supplied under the special access schemes.

Therefore the implementation of Proposal 2B(i) unnecessarily extends time to market and access to technologically sound and efficacious devices for **all** consumers. This situation would be exacerbated for the private healthcare sector due to lack of reimbursement and can only discourage further uptake of private health insurance.

Transitional Timeframe

If proposal 2B(i) is implemented as described by the TGA in the Consultation document, the following steps would need to be taken with associated timeframes for completion:

Application Step	**Duration**
Assess currently supplied products affected by this proposal	1 month
Determine necessary CA applications, estimate costs and resources required.	2 months
Advise manufacturers of changed regulations and discuss if transitional applications should proceed	1 – 3 months
Allocate and receive budgetary approval (rationalise product range dependant on budgetary approval)	6 – 12 months
Allocate regulatory resources for both Australian sponsor and manufacturer	1 - 6 months – depending on other projects / new regulatory resources required
Prepare eBS CA applications and supporting CA documents	6 – 12 months
Submit eBS CA applications, pay fee	2 weeks
Final review and submit CA supporting documents	1 month

Application Step	Duration
TGA performs preliminary review & issues fees	3 months
TGA performs remainder of review, sponsor and manufacturer responding to any queries, provide supporting documentation, facilitate on-site audit if necessary, pay additional fees, etc, until CA Certificates are issued.	8-15 months
Determine ARTG applications based on structure (e.g. whether or not products/applications can be grouped, UPI, GMDN, variants, intended purpose etc.)	1 month
Prepare and submit eBS ARTG applications, pay application fees	1 month
Wait to receive approval of inclusion in the ARTG.	2 weeks

Therefore, the total transitional timeframe is between **2 years 8 months** and **4 years 10 months.**

Considering the worst case scenario timeframes, a four year transitional period is not sufficient. Also taking into consideration the multitude of applications to be prepared by each sponsor, staff resources are expected to be very stretched during the transitional period. In this case, a 6 year transitional period would be more appropriate and allow for staggering of the applications into two or more phases by each sponsor. This will assist both industry and the TGA as the sponsors will gain experience from the earlier CA applications submitted which will enable improvement and greater understanding of the assessment process towards the middle and end of the transition period.

DT proposes a 6 year transitional period if Proposal 2B(i) is implemented without alteration.

Transitional Cost Analysis

Medicines have published scheduled **reduced** fees for abridgement of conformity assessment and similar business rules need to be published for devices.

Currently DT has great difficulty in estimating costs associated with CA applications due to lack of guidance surrounding the TGA's business rules regarding abridgement and reductions, as well as selection and timing for on-site audits. This will only be exacerbated if this proposal is implemented as the volume and variety of applications for Conformity Assessment will greatly increase.

For example DT is currently budgeting for CA submission for one manufacturer with two products. Over the past five months a number of phone calls, emails and a pre-submission meeting have not resulted in a definitive cost estimate for these two products. A rough estimate is possible however the reality is that a commercial entity does not have unlimited funds and must budget these costs in advance. The actual cost is not available to the sponsor until the TGA's invoice is received after their preliminary review of the supporting documents.

DT proposes that the below items are fully developed and published prior to any implementation of Proposal 2B(i):

- **Scheduled reduced fees for TGA Conformity Assessment**
- **the TGA's business rules regarding abridgments and reductions of CA fees and assessments**
- **the TGA's business rules for selection and timing of on-site manufacturer facility audits**

DT has identified 64 devices (from 10 manufacturers and including joint replacement implants) which would need to undergo TGA Conformity Assessment under Proposal 2B(i). None of these manufacturers or devices has previously undergone TGA Conformity Assessment.

The following assumptions have been used:

- Each manufacturer would apply for Schedule 3, Part 1 (Full Quality Management System Certificate) at current fee ($23,800)
- One application for Design Examination Certification would be required per identified device at current fee ($46,900)
- One onsite audit is required per manufacturer at an estimated cost of ($40,000) including all travel, accommodation, meals and assessment hours

Therefore, the estimated cost for DT to comply with implementation of this proposal is over **$3.6 million.** This figure does not include:

- additional staff resources required by the manufacturer
- additional staff resources required by the sponsor
- ongoing CA renewal and surveillance fees
- CA change notification and assessment fees

These aspects are too difficult to estimate in such a short period of consideration.

If Proposal 2B(i) goes ahead, **DT proposes that:**

- **All CA application and assessment fees (including onsite audits) are reduced on a sliding scale, with greater reduction earlier in the transition period.**
- **Any surveillance or other associated fees incurred during the transition period are reduced.**

This will encourage early preparation and submission as well as ease the burden on the industry to submit these applications.

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

DT does not support this proposal due to lack of detail provided within the consultation discussion paper.

Greater detail must be provided regarding costs and the level of application audit to be conducted. These issues are of particular relevance if Proposal 3(i) is also to be implemented.

The risk versus benefit of increased assessment of all Class IIb implantable devices must first be thoroughly investigated. The result of this assessment must be sufficiently significant to justify the increased regulatory burden of cost, additional assessment time and additional regulatory resources required by the manufacturer, the sponsor and the TGA.

Additionally there are several details which need to be clarified:

- Would the same level of application audit be applied to all Class IIb implantable devices?
- If not, which application audit level would be applied for which types of Class IIb implantable devices?
- Would a separate level of application audit be developed specifically for Class IIb implantable devices?
- Would abridged audits be available?
- If Proposal 3(i) were to be implemented, would additional audits, and at what level, be required each time new models are added to the existing ARTG approval for Class IIb implantable devices?
- If so, how would the fees be structured? Audit fee? Variation fee? Other fee?
- Confirmation is required that existing included Class IIb implantable devices would not be subject to targeted application audit.
- Is Proposal 2B(ii) intended to apply only to product Class IIb and above? Or is it intended to apply to all class of products?

With so much uncertainty, it is not possible to adequately assess the impact of this proposal and therefore **DT strongly recommends that Proposal 2B(ii) does not proceed without further comprehensive investigation and subsequent consultation with industry.**

Reimbursement considerations

DT also expresses concern that this proposal will greatly impact on industry due to controlled reimbursement. The Prostheses List for reimbursement of surgically implanted devices controls the price of these products within the private healthcare sector, which generally means the same price applies to the public system.

With the imposition of a large audit fee (for example, current level two application audit fee of $5,650) on top of the application fee (currently $810), as well as potential multiplication of this for addition of new models, industry will have no option but to pass these increases on to their customers, with a significant gap remaining to be paid by the patient.

The alternative of industry absorbing these increased costs is not viable or sustainable. Therefore it is foreseeable that some medical devices will become unavailable for supply in Australia should this proposal be implemented without recognition and mitigation by the government.

Transitional Timeframe and Transitional Cost Analysis

The discussion paper *implies* that the TGA will not perform a review of existing Class IIb implantable medical devices. This requires confirmation, but assuming that this is correct, **DT agrees that no transitional period is required and there will** be **no costs incurred for this aspect of the proposal.**

If this assumption is not correct, clarification and further consultation with Industry is required before proceeding.

Ongoing Timeframe and Cost Analysis

However, on an ongoing basis, implementation of Proposal 2B(ii) represents a significant increase in time to market, application costs and resource expenses for industry.

Historically, DT has lodged an increasing number of Class IIb implantable medical devices applications since the end of the 2007 transition period, at a rate of 20%. At minimum, this is expected to continue, resulting in estimated 7-10 applications for each of the years 2011 and 2012.

Time and cost for 7-10 applications for Class IIb implantable devices

	Current regulations	Proposal 2B(ii)	Increase
Application Cost	$5,670 - $8,100	$45,220 - $64,600	**approx. 800%**
Annual Cost	$5,670 - $8,100	$5,670 - $8,100	0%
Time to market	2-4 months	6-12 months	**300%**

These costs are estimated based on the following assumptions for Proposal 2B(ii):

- The current application fee would remain the same ($810)
- A level two application audit would be applied to all new Class IIB implantable medical device applications (current fee $5,650)
- The current annual fee would remain the same ($810)

If this proposal is implemented, **DT proposes that the TGA implement methods to ensure faster processing times for level two application audits.**

As previously indicated in this document, a comprehensive cost impact survey must also be conducted prior to implementation and fees such as the above are significantly reduced.

Proposal 2C – Recognition of third party assessment bodies

Over the past 8 years (since introduction of the current Medical Device Regulations) there has been ample opportunity for the TGA to plan, execute and complete confidence building programs with EU Notified Bodies, yet this has not occurred.

Neither of the proposals in 2C provides commitments that confidence building nor designation of Australian third party assessment bodies, would occur. Both proposals only refer to 'commencing discussions' and 'further consultation' on these issues.

The TGA has failed to address the concerns raised in the HTA review for progression on these issues.

Proposal 2C (i) – Confidence building for EU Notified Bodies designated under the MRA

This proposal appears to be poorly thought out and presented:

- There is no timeframe proposed or indication given on what activities would be commenced
- There is no timeframe or indication given as to when the planned activities and confidence building would be completed
- There is no indication of what would be required of Notified Bodies
- There is no actual commitment to perform the confidence building
- The term 'sharing of product assessment' is very broad and can be interpreted a number of ways. The current use of the CE or MRA certificates as Manufacturer's Evidence could be viewed as sharing product assessments. Further detail to provide clarity is required
- Clarification is required on why the TGA would require review of the definition of CA and what this would involve

Whilst **in principle DT supports the implementation of a confidence building program,** further details are required in order for this proposal to be properly evaluated and commented on.

DT does not support the option suggested to 'only accept CE Certificates from MRA Notified Bodies as Manufacturer's Evidence'.

One reason for this is that many CE Certificates are issued for USA, ASEAN or other manufacturer countries which are not part of the European Communities and are therefore excluded from the EU-Australian MRA. Manufacturers in these regions are much more likely to use Notified Bodies based outside of Europe and therefore unlikely to be an 'MRA Notified Body'. This would cause extreme restriction of trade for other areas of the world, most significantly the United States of America, as the bulk of medical devices imported into Australia are from the USA.

DT proposes that a definition and route for gaining designation as an **'MRA Notified Body' is developed.**

DT does not support the option suggested to 'require all applications supported by non-MRA Notified Bodies to undergo a mandatory application audit'.

Three reason for this are:

- The many CE certificates used for low class devices, whose risk profile does not warrant an exhaustive application audit process even if the NB used by that manufacturer is a non-MRA NB. The current list of MRA NBs is extremely small compared to the total list of available NBs.
- The increased time and cost to market for low risk, high volume devices would not be sustainable for industry to supply of these devices
- All TGA applications currently submitted which are supported by CE certificates are currently assessed at some level by a TGA assessor. (Would this option mean that all applications submitted using CE certificate issued by an MRA designated Notified Body would not undergo this assessment and would be automatically processed as if they were MRA certificates?)

These options should not be implemented until details are clarified, industry has been given further opportunities to provide comments and the impacts of such conditions are fully evaluated.

This is of extremely high concern as part of the proposal presents the possibility that CE certificates are only accepted if they are from an MRA Notified Body. This will be impossibility if confidence building was to fail and no designated bodies existed.

Cost implications and timeframes cannot be assessed due to the lack of information presented in the discussion paper.

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

With this proposal, there is still no commitment that a third part assessment body will be designated or that a program where third parties can apply for designation will be implemented.

DT proposes that the TGA investigate, develop and put into place a system by which third party assessment bodies can apply for designation to be given authority to issue Australian Conformity Assessment Certificates. Further consultation with industry would be required; however, there is no need to hold up other parts of Proposal 2 while this process takes place. **DT proposes that the TGA complete this process within two years.**

Proposal 3 – Amending the way in which a medical device is included in the ARTG and enhancing identification of approved devices.

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

It is important that safety and performance are monitored by the TGA's post market activities; however the level of monitoring should be comparative to the risk level for the class of device.

DT cannot support implementation of this proposal as outlined as there is insufficient detail to determine the impact and feasibility. The following points require clarity and further investigation:

- The TGA needs to confirm which kinds of devices will be required to undergo assessment of the model names prior to updating of the ARTG entry. The Discussion Paper refers to assessment if the kind of device is Class IIb or above but also refers to assessment of the kind of device more generally. The proposal needs to be specific so that relevant comment can be submitted.
- What level of assessment is proposed for the TGA to make a decision on a new or existing ARTG entry? Would this be the same or different for new and existing?
- What fee is proposed for these assessments? The current variation fee is $360. This is too high a fee for a variation to a lower class device, particularly as new models will be added on an ongoing basis and such a fee will be prohibitive.
- During the transition would entries requiring updates be automatically accepted or would they require review before models are accepted onto the inclusion? Would this vary depending on the class of the device or be across the board?
- Search capabilities will be important for product details and the TGA needs to seek advice from industry to ensure search functions are meaningful and efficient.
- What facility and requirements would be in place to remove product details?

  A company may decide to cease supply of certain products in Australia for commercial or other reasons. A manufacturer may also decide to cease supply either within Australia or globally for a number of reasons. Under any of these scenarios some, but not all, products covered by the ARTG inclusion may need to be removed from the public view and the ARTG.

  This is currently not required as this level of detail is not part of the ARTG inclusion and is not publicly accessible (except for UPIs on Class III & AIMD inclusions). Therefore the deletion of such information must be considered. The TGA has provided no information as to whether or not this action would incur a fee or how such an action would be carried out. This additional management of ARTG inclusions will also require additional regulatory resources for industry and the TGA.

- What time frames will apply to adding, amending or deleting product identification details?

- What will the process involve if when assessing these applications to vary an ARTG record, the TGA doesn't agree with the manufacturer's selected GMDN code?

  Each TGA assessor cannot be familiar with all products so it is reasonable to assume that assessment will take time and may be difficult for many products. DT is concerned that this may lead to differences of opinion as to appropriate GMDN codes.

  No rejection or cancellation should be made on this basis without due consultation with the sponsor, particularly as it is the manufacturer's responsibility to select appropriate GMDN codes. In recent experience rejections have occurred without the sponsor being given an opportunity to provide product information and justification to confirm the details of the application as lodged.

DT proposes the following arrangements would assist industry to be in a position to support Proposal 3(i):

- Class I non-sterile, non-measuring devices are excluded
- Identification is through a fee-free notification system for all classes (i.e. variation applications would not be required and updating to include new models in existing inclusions would not incur a fee, nor be reviewed, prior to the entry being updated)
- Similarly, removal or amendment of model or trade names should not incur a fee or undergo review by the TGA
- The information must be automatically accepted and the TGA use a post-market auditing program to review content
- Device identification by model or trade name should be determined by the sponsor according to what is most appropriate.

  Flexibility is needed here due to the vast range of product types and naming conventions used within the medical device industry. If criteria are too strict it could be difficult for industry to comply in entirety.
- The TGA perform an analysis (with input from industry) of the number of applications that could reasonably be expected to be received and provide a plan on how the TGA resourcing would accommodate this.

  There are currently approximately 55,000 ARTG inclusions for medical devices.

<u>Considerations for low risk devices</u>

It is unclear if this proposal is intended to capture Class I and other low risk medical devices. DT have provided the comments below on the assumption that as low risk devices are not specifically excluded in the discussion paper the TGA does intend to capture these in Proposal 3(i).

As Class I devices are currently auto-included with no pre-market assessment, it is unclear how this proposal would relate to existing auto-inclusion process. Would the initial models notified be automatically included and a variation required for subsequent additions?

Currently, Class I medical device inclusions are monitored post market by both random and targeted reviews, review of GMDN codes used in Class I applications, the restriction of specific terms used in the intended purpose and the targeting of reoffending sponsors. This is a more appropriate and less onerous method of post market surveillance for Class I devices.

Class I devices, at the lowest level of risk, would be expected to have the least amount of problems needing oversight by the TGA. It would be beneficial for statistics on this to be released in further rounds of consultation on this proposal. GMDN codes commonly used in Class I applications are less specific so have the greatest number of products (models) per inclusion. These then require constant variations to the products covered by the inclusion and under this proposal would consume valuable resources for both the TGA and industry that could be better spent monitoring higher risk devices.

Contrary to the consultation document (p. 22 3rd bullet point) this proposal will not allow the HCP to find the correct ARTG entry. See Case Study below, which shows that low class devices cannot easily be identified by name in all cases and existing processes are more reliable.

Current practice is for the HCP to contact the supplier for the ARTG number. This practice of confirmation via the existing supply chain works for the majority of requests and is certainly sufficient for the lower class devices. If the HCP is concerned that the device is not adequately included they can request further evidence or notify the TGA whose role it should be to investigate the issue with the supplier.

Case Study

Magill Forceps – manufactured by Manufacturer A
Magill Forceps – manufactured by Manufacturer B
Magill Forceps – manufactured by Manufacturer C

All are Class I and may have different GMDN codes as there are multiple GMDN codes which may be selected in application process. All are therefore different kinds of devices and would have separate inclusions.

A healthcare practitioner searches for Magill forceps on the public view and all three are displayed. The practitioner doesn't know who the manufacturer is as these are reusable forceps and the labelling has been discarded. The HCP would therefore not be able to identify the correct ARTG inclusion.

Transitional Timeframe

A more realistic transition period must be given. This is not a simple data entry task, analysis would be required to ensure the most appropriate model/trade names are used and the project is comprehensively and efficiently undertaken.

DT estimates that for its current 960 ARTG inclusions, being analysed and processed at an optimistic rate of 2 inclusions per day, would take one person **2 years, 2 months** to complete (allowing for annual leave, public holidays etc.).

As this is an additional resource to existing regulatory staff, it would also cost DT in time and resources for recruiting and training, as well as the additional staff salary and other overheads incurred. With limited experienced regulatory personnel available, recruitment and training can take between **6 and 9 months.**

Therefore, DT proposes a minimum transition period of three years is necessary for Proposal 3(i).

Transitional Cost Analysis

The TGA have indicated in the discussion paper that there would be no fees applied during the transition period. DT agrees that this is appropriate.

However, as described above, the additional resources (e.g. staff member salaries, recruitment and training) required to perform transitional updates would be significant and must be included in an analysis of costs to the industry.

Ongoing Cost Analysis

Device Technologies currently has 5 regulatory staff, performing updates to internal documentation at an estimated minimum of 30 times per week. If DT was to incur a fee of $360 each time (the current fee to vary an ARTG inclusion), the annual cost estimate for Proposal 3(i) alone would be a minimum of **$561,600.**

Under this proposal, there are many ARTG inclusions which Device Technologies would need to update once per month, while there are others that would not need updating every year, so this would be expected this would even out across the company and similar circumstances would apply across the industry.

Therefore, on an industry wide basis, it is not at all excessive to estimate that each ARTG inclusion would require update, under this proposal, at least once per year. At present, there are almost 55,000 ARTG inclusions for medical devices, which would therefore result in approximately 55,000 applications annually (a rate of over 1000 per week).

As described elsewhere in this document, **DT proposes:**

- **A comprehensive cost impact survey must be conducted prior to implementation and fees such as the above are appropriately reduced**
- **The TGA implement methods to ensure faster processing times for applications to vary inclusions.**

Proposal 3(ii) – Enhancing the identification of approved devices

DT recognises the importance for all stakeholders to be able to identify devices that have been approved for supply in Australia. The method by which this is done must be tenable, effective and cooperatively determined so as to ensure compliance and value to the community. It must also be at minimal cost to industry so that this can be absorbed rather than passed on to consumers.

DT does not agree that the method proposed is the best approach and the following aspects must be considered:

- Medical devices are very different to medicines with different risks and generally have a different group of users. It is not automatically relevant to require the same level of product identification for devices as is required for medicines.
- The majority of medical devices are used by Health Care Providers operating within a recognised healthcare facility. These users request and obtain ARTG inclusion details through the existing supply chain, in the same way that they obtain the product.

  In many instances packaging & labelling is disposed of on receipt into a hospital or facility department so that adding the ARTG number to the packaging will not add any benefit to users.

  There would be very little benefit for the additional cost and burden of implementing this proposal for the small number of devices used by consumers outside of the healthcare settings.

  Devices supplied outside of the healthcare system without oversight by a healthcare practitioner are likely to be of very low risk and it is not clear how providers or consumers would benefit from the provision of an ARTG number.
- The Discussion Paper states that this change should not adversely impact on regulatory costs for sponsors as sponsors are already required to publish their contact details on the information that accompanies a medical device. This is an incorrect assumption.

  The current requirement is for sponsor name and address to be provided on the labelling and this is common to all products supplied by that sponsor. However the ARTG number is specific to certain products only and therefore this is not a generic addition.
- Significant changes would be required for the majority of sponsors to implement such a requirement. Depending on the appropriate method selected by the sponsor options for adding the ARTG number would be different. Options could include;
  - Adding the ARTG inclusion to the invoice
  - Adding the ARTG inclusion to a leaflet supplied with the Device
  - Adding the ARTG inclusion number to the actual device – not possible for the majority of devices, either because product is sterile, unable to be opened without compromising packaging, too small or inappropriate surface to label, compromises use etc
  - Adding the inclusion number to the packaging and /or labelling of the device – difficult for many sponsors as they are unable to open outer packaging to label eaches in multiple packs
  - If a distributor company was unable to have the manufacturer amend their existing labelling, the company would have to prepare, print and find additional resources to add adhesive labels to all product. As this would be a manual process it would be subject to human error.

- It is very likely that the majority of sponsors will require some kind of computer systems or software upgrade, design or replacement in order to allow for additional information to be printed.
- Complications that may arise during this process are that
    - In general sponsors don't have control of labelling and need to rely on manufacturers to implement changes such as label design.
    - Separating Australian stock from global stock (currently not required) – manufacturer will have large stock holdings for current requirements so to add in ARTG details will require new run for Australian specific requirement.
    - Smaller companies may require specialised software incurring expense, management of the changes, training etc.
    - Other sponsors may have other difficulties once they have fully investigated and understood the impact of this proposal. Industry has not been given sufficient time to properly address this.
- **DT proposes that Regulation 10.2 and EP 13.2 be reviewed to allow more appropriate labelling of current sponsor details.**

  The invoice and packing/delivery paperwork is the most appropriate method of recording these details for many sponsors as these are provided with every single medical device and are always retained by the consumer as part of important financial and supply chain records. They are not discarded, unlike the labelling and packaging of most devices. They also have greater capability to be amended or re-designed to include further information if required. This is currently where DT provides Rebate Codes for its customers and this enhancement has been welcomed by customers.

  If this proposal was to be implemented it is critical that there is greater allowance for flexibility as to how the information can be supplied to the user. There is wide variance in the feasibility of options available to sponsors to provide this information as generally the sponsor does not manufacture the device.

Transitional Timeframe

The proposed transition period of 12 months is inadequate to perform the following necessary steps for such a large project;

- Investigate the options and most practical for each product range
- liaison and negotiation with each and every manufacturer
- Identifying and sourcing additional infrastructure
- Budgeting for additional infrastructure (up to a year in advance)
- Budgeting, sourcing, hiring and training implementation and maintenance staff
- Testing and implementing changes
- Roll out across whole company (will vary greatly depending on size of company and number of products)
- Monitoring and maintaining process.

DT proposes at least a three year transition period for Proposal 3(ii).

Transitional Cost Analysis

As discussed above, the TGA's assumption that Proposal 3(ii) should not adversely impact industry is grossly misinformed. Whilst there would be no application costs there would be significant planning, infrastructure and development costs necessary for industry to comply. This needs to be taken into consideration in a comprehensive cost impact survey.

It is difficult to estimate these costs in the short period of time provided. Further consultation is necessary along with exploration of more acceptable options.

Proposal 4 – Publication of device product information on the TGA website

Extending the publication of device product information on the TGA website needs to be further considered before implementation. This is most important in order to ensure that the benefit sought, on behalf of the patient and consumer, can be met without unduly burdening the industry whose responsibility it will be to provide this information.

DT has a number of comments and concerns to note for this proposal.

- DT believes all consumers have a right to, and should be encouraged to, fully participate in the management of their own and their family's health.
- Much of the information intended to be available to the public is currently available on company websites or the manufacturer's website.
- A great deal of the information prepared for medical devices is directed to the physician, which is appropriate as they are the experts and user of the device, although it may be used in, on or for a patient. The language used may be technical, medical or scientific as relevant to the device and its use.
- To the untrained consumer much of this may be meaningless, open to misinterpretation, or potentially cause unnecessary anxiety. It could lead a patient to put at risk their treatment due to delaying or questioning the medical or surgical choices being offered to them without sufficiently understanding the entire process.
- For the sponsor to be required to re-word all information for a device not intended to be used outside of a hospital or clinical setting in language easily understood by the average lay person is unnecessary.
- There is already a huge amount of information available to every Australian through the various public search engines on the internet. Many physicians and other interested parties express concern as to the already existing level of inappropriate self-diagnosis and the level to which this is increasing.
- The physician is the most appropriate person to explain medical devices used on a patient to that patient. DT does not consider that this is the role of the sponsor for the vast majority of devices. The sponsor is able to, and does, provide brochures and device information packages to the physician to pass on to patients as relevant.
- Many devices are not required to be supplied with user documentation. One of the reasons for this is that the intended user will be very familiar with the type of device and won't require further information. If the sponsor were required to prepare information to put on the TGA's website, which was not required as part of the application process it is clear that this would be an additional burden and cost on the part of the sponsor and manufacturer. It is not clear how this would benefit the consumer who would generally never have access to these devices.
- It may be worth considering if this proposal would be relevant to certain types of medical devices rather than all. It may of greater benefit to consumers of OTC devices, for example, but of little value for surgical instruments, theatre equipment and general hospital consumables for example.

- Unlike medicines which generally have very high volume per unit, medical devices have a much lower volume and greater number of individual devices. This is highly relevant when considering the perceived benefits versus the cost of implementing and maintaining Proposal 4.
- Medical devices also have more frequent changes, more iterative model upgrades and improvements which would require regular updating of information as published.
- As such information would presumably be viewed as advertising of the medical device; difficulties may eventuate in the preparation for each and every device. International brochures do not always comply with the advertising requirements in Australia and this would additionally need to be assessed for each device. There may also be some conflict with existing advertising codes and guidelines.
- The discussion paper refers to systems implemented by the FDA for the publication of medical device information. The FDA regulatory system is very different to the Australian system in many ways so it is not clear why the TGA would wish to align this aspect of regulation with the FDA in isolation.

Implementation of Proposal 4 would impose an unnecessary and costly additional workload on the sponsor, particularly if it is intended to be implemented for all classes and all types of devices. The preparation, submission, monitoring and maintenance of information for large numbers of ARTG inclusions would require additional resources at an additional cost for all Australian sponsors. These costs would be incurred with no obvious benefit for the sponsor and would of necessity be passed on to the purchaser of these devices.

Therefore, **DT does not support the proposal that similar publications, as are currently made for medicines, should be applied to medical devices.** Any program developed should be specific to medical devices, with limited comparison and reliance on what is appropriate for medicines.

DT recommends that

- **The need and specific benefits be clearly determined for this proposal**
- **Any implementation of Proposal 4 should not be mandatory**
- **Further discussion with stakeholders should occur prior to any implementation.**

DT agrees that information about medical device assessments should be published, but this should <u>not</u> include device literature such as Instructions for Use, Labelling, Brochures or any other confidential documentation which is submitted to the TGA during the assessment process.

An increase in transparency and accountability for TGA decision making processes will not be gained by publishing device literature.

DT proposes that the TGA publish information about the decisions made during the assessment process which will reassure the public and industry that appropriate assessment has been conducted and the devices have been found to meet the regulatory requirements.

For example, a statement from the TGA could be released (added to the Public Summary of the ARTG inclusion, not on a separate website) which includes a brief summary of the documents (e.g. IFU, labelling) reviewed, as relevant to the risk classification, and that these were found to meet the essential principles.

For Class I auto-inclusions, a statement such as '*This ARTG inclusion has been auto-included on the register due to its low risk classification. This ARTG inclusion is subject to targeted and random post-market review programmes'.*

A similar approach could be implemented to publish decisions made during targeted or random post-market reviews. Such a summary could be added to the Public Summary after the review.

In combination with a public education programme, this will significantly increase the level of understanding that consumers hold with regards to the level of assessment conducted by the TGA for different medical device risk classifications. It will also provide visibility

Rejections

DT does not believe that decisions regarding rejected applications should be published. In many cases rejections are the result of honest mistakes or unintentional errors. An application may be rejected simply because of a difference of opinion between the TGA and manufacturer on the GMDN code or other administrative issues.

These should be viewed in a positive light as opportunities for improvement for the sponsor and manufacturer. It is difficult to see the benefit to the public and industry in publishing this information.

Rejected applications are also subject to lengthy appeal timeframes. Publication of such information could prejudice the marketplace before the sponsor has an opportunity to rectify the cause of rejection.

Even if the information was published after the close of any appeal process, this information could be interpreted as extremely negative by consumers and prejudice them against a particular supplier, affecting the consumers' opinion of the product when the cause of the rejection is most commonly administrative.

ABBREVIATIONS

ARTG	Australian Register of Therapeutic Goods
CA	Conformity Assessment
DT	Device Technologies Australia Pty Ltd
eBS	TGA eBusiness Services
HCP	Health Care Providers
NB	Notified Body
SAS	Special Access Scheme
SKU	Stock Keeping Unit
UPI	Unique Product Identifiers