Reforms in the Medical Devices Regulatory Framework

A response to the TGA Discussion Paper 17 December, 2010

Medtronic Australasia Pty Ltd
97 Waterloo Road
North Ryde, NSW 2113
www.medtronic.com.au

Index

1.0 Executive Summary

Medtronic Australasia support, in principle, reforms aimed at improving the visibility of oversight for medical devices and aid in the identification of products on the Australian Register of Therapeutic Goods (ARTG).

However, given that Australia represents two percent of the world medical device market, it would be concerning if any reforms were to remove the regulatory equity invested in the CE Marking process. In most cases sponsors have already invested significant time and cost into having product assessed by Conformity Assessment Bodies in Europe, assessing to the same Global Harmonisation Task Force (GHTF) essential principles used by TGA. Under the current system sponsors can have an appropriately reduced assessment pathway in Australia based on this equity. In addition reforms must not deviate from the GHTF framework and risk damage to international regulatory coherency.

Any reforms resulting in an increase to the regulatory burden of including products on the ARTG in Australia may introduce the risk of increasing the cost and time to market for medical devices, thereby potentially reducing patient access to life saving and life-changing medical devices. This would be at odds with government efforts over the past few years to reduce regulatory burdens and costs for business, while at the same acting to ensure timely access to cost effective new medical technologies.

The Therapeutic Goods Administration (TGA) currently assesses medical devices using a risk management model, just as occurs in other GHTF jurisdictions. This system combines a premarket review (or conformity assessment which can recognise the work done in establishing a European CE Mark) linked to the level of risk posed by the medical device after which there is robust post market surveillance. This system effectively balances the need to get effective new technologies to patients in a timely manner, while ensuring these technologies meet high standards of safety and efficacy. There are however areas of weakness in this system. Most notable are the lack of visibility both to the TGA and other stakeholders of exactly which products are approved for supply under the ARTG, and a perceived weakness of some Notified Bodies in Europe to act effectively as Conformity Assessment Bodies.

Whilst recognising the call for change, any added burden to industry and indeed to the TGA, should not be so onerous as to unnecessarily restrict the products brought to the Australian market or to increase approval times significantly. Unreasonable delays or escalating compliance costs have the potential to adversely affect consumers and deny them access to leading edge medical technologies which are available else where in the world. In jurisdictions where this has occurred, such as Japan, consumers have been forced to look offshore for medical treatment.

We do not believe there is any evidence that the current system of medical device regulation in Australia, or indeed in other GHTF regulatory systems around the world, is systemically failing. However there is clearly a need for consumers and medical practitioners to be able to better access information about the products listed on the ARTG and to gain information on the assessment processes both in Australia and internationally. We believe that some simple changes to process and transparency could address many of these concerns, along with the appointment of an Australian Designating Authority to assess and appoint 3rd party Conformity Assessment Bodies for the Australian market.

In the *Reforms in the Medical Devices Regulatory Framework* Discussion Paper released on October 25th 2010, various proposals were put forward and this response will deal with these individually in subsequent sections as well as provide some background information and comment.

2.0 Medtronic Profile

As an active participant in the Australian medical device environment for more than 37 years, and internationally for over 60 years, Medtronic has witnessed considerable change in the evaluation processes for new medical technology.

Medtronic is well-positioned to comment on the impact of existing processes and provide recommendations to improve process efficiency, reduce duplication and unnecessary complexity, as well as decrease regulatory costs that can combine to impede medical innovation in Australia.

Company Description
Medtronic is the global leader in medical technology- alleviating pain, restoring health, and extending life for people with chronic conditions around the world. Medtronic develops and manufactures a wide range of products and therapies with emphasis on providing a complete continuum of care to diagnose, prevent and monitor chronic conditions. **Each year, Medtronic therapies help more than seven million people**.

Founded
April 29, 1949 in Minneapolis, Minnesota, USA, by Earl E. Bakken and Palmer J. Hermundslie.

Global Presence
Medtronic conducts business in more than 120 countries, with the World Headquarters based in Minneapolis, Minnesota USA. Medtronic Australasia is headquartered in Sydney.

Workforce
Medtronic employs more than 38,000 people worldwide and more than 400 in Australia.

3.0 What is the problem to be addressed?

It is recognised that there have been recent questions asked regarding the adequacy of the TGA assessment of medical devices prior to entering the Australian market. We agree that the TGA needs to address these concerns.

However, it is important to note that many of these concerns do not appear to have a basis of evidence of any systemic problems with, or failure of, current regulatory processes, either in Australia or internationally in other GHTF risk based regulatory systems.

The TGA already assesses products based on risk categories, with the highest risk category devices requiring the highest level of documentation and review. The TGA does, in many cases, recognise the regulatory equity sponsors have invested in having these products reviewed in some other jurisdictions, most notably the EU. It is important to note however that a successful application in Europe does not automatically lead to an inclusion on the ARTG in Australia. The TGA can, and regularly does, question overseas assessments if it is not satisfied with the evidence supplied. Accordingly, TGA can, and does, reject applications if sponsors cannot address concerns raised.

While it is recognised that some stakeholders who made submissions to the Health Technology Assessment Review (HTA review) have concerns about the current processes, we are not aware of any serious attempt to provide evidence other than anecdotal of any systemic failure of the current system. In fact Australians enjoy an environment where the level of regulation of medical technologies, particularly those at the highest risk end of the scale, is equal to the best systems in the world and arguably better than most.

The evidence available from fellow GHTF members with similar risk based systems shows that these systems work. Furthermore, this studies show over-regulation not only impacts negatively the time to market for medical devices and the costs to industry, but more importantly the ability of patients to access lifesaving and life enhancing medical technology.

Until the release of this Discussion Paper and the preceding stakeholder pressure, the TGA had expressed views that the regulatory focus should be shifting away from increased pre-market assessment (where products had already received regulatory reviews in other jurisdictions) and moving toward focusing more resources on post market vigilance to better assess and respond to trends in product performance. We believe that this model is more appropriate

to the medical device market as it allows regulators to identify issues associated with batch manufacturing faults and long term design issues which are unlikely to be addressed by increased pre market review. Indeed most of the few examples that current stakeholders raise of specific product failures tend to support a case for strengthened post-market surveillance rather than increased pre market assessment.

We sense some of the issues leading to this Discussion Paper may be addressed by improved communication regarding the processes, rather than a change to the processes. This would be supported by examination of the documents provided by the HTA Review which provided the recommendation to examine the market entry processes by TGA. Much of the criticism was actually around the ability to access information about products on the ARTG and how they are assessed, rather than identifying a need for increased assessment. We note that the TGA has separately called for a review of transparency. We welcome this as an opportunity to allow the TGA itself to better communicate on this subject and reassure interested parties that high risk devices are being appropriately assessed against a set of internationally agreed essential principles. This is also an opportunity to enable the TGA to better provide education to stakeholders about the principles and imperatives for a risk based regulatory system.

4.0 The International Context

The TGA refers to a number of factors influencing the proposals in the Discussion Paper, some of which will be addressed with our response to the specific proposals, notably those around the competence of the European Notified Bodies. In general Medtronic is supportive of the work being done in Europe and by the TGA to improve regulation of and confidence in the Notified Bodies, however we do not believe that this requires significant changes to Australian regulation, rather the changes can occur in the area of designating appropriate Conformity Assessment Bodies for the Australian Market.

The TGA Discussion Paper also refers to the review taking place in the United States with regard to the Food and Drug Administration (FDA) 510(k) process. While we do not believe this has any direct bearing on the Australian situation - as the TGA does not use or recognise the US regulation processes - there is some interesting data from this market that is worth considering.

In a report prepared by Battelle Memorial Institute for the Advamed industry association entitled "*510(k) Premarket Notification Evaluation"*, it was shown that where the less rigorous 510(k) process was compared with the significantly more rigorous PMA process there was no demonstrable correlation between higher level review and reduced numbers of product recalls – in fact it showed the opposite. Between 2005 and 2010, 0.85% of the total of 2,825 devices

approved under the PMA process were recalled as compared to 0.16% of the total of 46,690 devices approved under the 510(k) process. This data does not appear to support a correlation between increased pre market assessment and improved patient safety. This is supported by additional data published in a report commissioned by the MDMA Industry body entitled "*FDA Impact on US Medical Technology Innovation*" which shows that these rare product recall events derive from issues that would be most effectively detected through strong post market surveillance and vigilance processes rather than by more expansive pre market data requirements. This report also outlines how over-regulation can negatively impact patients, innovation and industry, particularly domestic industry.

Australia is a founding member of the GHTF and is current chair. This organisation was formed to recognise the importance of having regulatory processes which were internationally coherent and soundly based upon agreed essential principles. This concept is extremely important considering that Australia represents about two percent of the world market for medical devices. With a market this size, there is a significant risk of reduced access to technology if reforms to regulatory requirements move more quickly than, and lose alignment with, those occurring in major markets such as the US and the EU.

5.0 Medical Devices vs. Pharmaceuticals

It is also important to note that significant differences exist between pharmaceuticals and devices. In terms of HTA of all kinds, the levels of evidence available for pharmaceuticals at launch may feasibly be higher due to factors such as; long patent lifetimes, long product lifecycles, size of markets and isolatable study factors.

Medical devices on the other hand are characterised by iterative and incremental product development. Often surgical procedures are required in order to use the device, creating insurmountable problems for blinding and control in any ethical fashion. At the same time the pace of technical development, that drives information and communication technology change, enables breakthroughs in medical technology to be brought rapidly to market and also for these technologies to be made rapidly redundant. Further, these technologies often address small and niche markets which do not generate the revenue required to invest in costly long term trials. This does not mean that these devices cannot be brought to market at acceptably low risk if proper design testing is performed and if manufactured and distributed under appropriate documented and audited quality systems.

The iterative nature of product development for devices means that it can often be difficult to draw the line between new products and existing products with design enhancements. Such enhancements can be made to improve everything from patient outcomes and quality of life, through to improved handling for

surgeons, reduced procedure times, less invasive procedures, lower cost more eco-friendly materials, packaging and many other factors.

The demand for improved evidence is valid and growing. Industry is rapidly changing to adapt to this demand and is committed to increasing the levels of evidence available where feasible. Despite this there will never be the same extent of high level evidence available for many medical devices that is often available for pharmaceuticals. Attempting to recreate systems developed for assessment of pharmaceuticals will fail and will stifle innovation and restrict access to breakthrough technology.

It is vital that as regulatory systems around the world evolve that this evolution is done in a consultative and coordinated manner to ensure that changes in requirements in geographies such as Australia do not get out of synchronisation with major markets such as the US and Europe. The alternative is technology lag which may seriously disadvantage Australian healthcare consumers.

6.0 Better Regulation Benefits Patients and Industry

In a February 2010 joint press release Minister Roxon and (then) Minister Tanner announced "streamlined approvals" for the assessment of medical technologies and procedures, which "means patients will have faster access to the latest safe and effective treatments, products and technology, and industry will have reduced costs in getting their products to market". This announcement, forming a part of the government's response to the completion of the Health Technology Assessment Review commissioned in 2009, was welcome news.

Other reviews in the immediately preceding three years had pointed to the need for more responsive and affordable arrangements to bring safe and effective medical technologies to patients in a timely manner. These included the Banks Report which looked widely at delivering better regulation, the Productivity Commission's Impacts of Advances in Medical Technology in Australia, and the HTA Review. Drawing attention to increasing regulatory burdens, Banks had noted:

In many areas, however, regulation has gone beyond what is sensible … the Taskforce found numerous instances where regulations are excessive and/or poorly designed or administered, and are thus imposing unnecessary compliance burdens on business.

The challenge posed in this current review is to deliver reforms in the medical devices regulatory framework that align with and complement the recommendations of the aforementioned reviews, and which do not lead to delays in product market entry or increase costs for industry. In looking at the implementation of recommendations from the HTA Review thus far, it is difficult

to find any examples where timeliness and cost-containment for industry have been delivered.

If this particular proposed reform is to meet these important objectives it will require significant revision from what is currently proposed, most of which as currently proposed would add significant burden and costs, and little of which promotes speed and cost effectiveness of process.

7.0 What if we get it wrong?

Medical device regulatory systems around the world balance ensuring acceptable patient safety standards with timely access to innovative technologies which can save and transform lives. Whilst there are multiple factors contributing to the decades of improved life expectancy for Australians over the past century, access to innovative medical technology is clearly amongst those factors.

If Australia imposes a regulatory barrier which is significantly higher than is required in other major markets such as Europe and the United States there is significant risk that access to medical technology will be limited. This is a realistic concern considering that Australia represents only two percent of the world market. Increasing the regulatory burden above that required in major markets could not only have a flow-on effect of stifling innovation but also increase costs of devices to patients, both through the need for manufacturers to recover the costs of additional regulation, and the reduced competition in the marketplace likely to result from the additional cost burden.

The impact of increased cost of market entry for niche products or smaller companies with lower market share should not be ignored. It is not inconceivable that it may only be viable for large companies to support the costs of registering products, thus decreasing competition in the medical device market and removing incentives for innovation. Even the larger companies will need to rationalise the cost of market entry with the potential market size and make decisions about what products to bring to the Australian market.

Another concern for industry (and ultimately for consumers) is that the TGA - and in fact the wider Australian regulatory workforce - may not have the capacity to undertake the assessment workload proposed. Currently, those higher class products which do not require a full conformity assessment go through a process which takes 4-6 months and costs $5-7,000. The proposal as read could move to a process which takes 12-18 months to navigate and costs $25-82,500 per submission.

There is a real risk that the volume of product which would shift to this process could overwhelm current TGA resources. Experience shows that there is a very limited excess workforce in this field in Australia. Consequently there is the

potential for timeframes for market entry to extend to 2-3 years. In an environment where the average lifecycle for rapidly changing and innovative medical technology is often three years or less, this is unsustainable. In most cases, sponsors cannot afford to maintain extra manufacturing lines for superceded product solely to support the Australian market.

The final factor is cost. If we were just to look at Proposal 2B(i) implemented as read and applied to those products currently listed but requiring re-registration, the cost to Medtronic could be approximately $12.5 million in transfer fees alone. Added to this would be increased ongoing cost of supply and the cost of proposed listing for other products, as well as increased company resources required to prepare and manage the submissions. This would be a major imposition for a larger company with significant market shares like Medtronic. For smaller companies it could be insurmountable and the risk of additional costs being passed onto consumers and payors is high.

An example of where this has already happened is Japan, which for many years has had regulatory processes which are out of step with other GHTF jurisdictions. There are a number of readily accessible papers written identifying the device and technology lag and corresponding disadvantages to Japanese patients.

At the very least it would seem to be imperative in this era of evidence-based medicine, that any changes to regulatory processes are also backed by evidence that they will be worth the resulting cost to industry, consumers and taxpayers. In our view neither the TGA, in this Discussion Paper, nor some of the more vocal stakeholders calling for increased pre market assessment have provided any such evidence.

Over-regulation or imposition of unreasonable demands for evidence can have the effect of both actively and passively denying Australians access to life changing and life saving medical technology. Over regulation biases the prevailing system towards aiming to prevent Type I (incorrect listing) errors (see table 1 below). Type I errors gain much popular attention as the results of the error tend to be highly visible and those who have been disadvantaged, tend to be publicly identified. However, for these reasons, the error is readily corrected and the harms are identifiable. There is no argument that systems and processes are required to reduce the risks of making Type I errors, however, there is no evidence of systemic failure of the current system in this regard.

There are however arguably even greater, although less newsworthy, dangers to consumers arising from a system which is overly biased towards prevention of Type I errors. Such a system increases significantly the risk of committing Type II errors, thereby unnecessarily denying access to effective technologies and risking health outcomes. Type II errors can cause greater disadvantage than

Table 1: Dilemma associated with Type I and Type II Errors

	Procedure is Beneficial	Procedure is Harmful
New procedure approved	Correct Decision	Type I Error: Allowing a harmful procedure. Victims are identifiable and traceable. Error is self-correcting
New procedure disapproved	Type 2 Error: Disallowing a beneficial procedure. Victims are not identifiable. Error is not self-correcting	Correct Decision

Type I errors as the harm it is not easily identifiable and therefore not easily corrected.

O'Malley, S. 2006, The Australian Experiment: the use of evidence based medicine for the reimbursement of surgical and diagnostic procedures (1998-2004). http://www.anzhealthpolicy.com/content/3/1/3

8.0 Regulatory Impact Statement

We note that the Productivity Commission has recently been somewhat critical of the rigour of regulatory impact statements (RIS) which have been produced in the past. In light of the serious impact of this proposed regulation for industry, government and ultimately consumers, we would suggest that particular attention be paid to producing an accurate RIS for any proposed changes. We believe this regulation, if implemented as proposed, would be of significant impact. This would then require properly researched cost benefit analyses for multiple options and consultation with industry to identify costs.

Of concern is that the Discussion Paper under the sections for each proposal entitled *Cost Implications,* appear to have made some very simplistic assumptions about the cost impacts. In many cases these are a long way from reality. The Medical Technology Association of Australia (MTAA) submission provides a more complete estimate of the potential cost impacts to industry. It would be very important that the final RIS produced is a significantly better researched document which takes into account the full costs of the proposals and quantifies any evidence based benefits to flow from the changes.

9.0 Addressing the Proposals

9.1 Proposal 1 – Reclassification of Joint Replacement Implants

Implications

While Medtronic does not currently market affected joint replacement implants we do support a more harmonised global regulatory system. The up-classification of these products in Europe and earlier TGA consultation in Australia last year recognised that these major orthopaedic implants are higher risk and need to be re-classified accordingly.

However, Medtronic also recognises the increased work load this will generate for the TGA (and industry) in order to reassess a considerable number of products. This increased workload for the TGA could result in delays in processing other applications.

Recommendations

The TGA will need to be aware of the workload to re-assess currently listed product in the transition phase and plan accordingly to allow for normal applications to be processed in a timely manner.

The TGA should consider that some of this workload could be shared by using designated Australian Conformity Assessment Bodies.

9.2 Proposal 2

The stated intention from TGA is to implement all sections of this proposal or none at all. Medtronic does not see these proposals necessary directly linked. In fact due to requirements, transition times and confidence building these proposals can not be implemented together as described unless transition times or implementation timelines are adjusted. We question the logic and intention behind this requirement.

No one would deny that the proposal to level the playing field to give local manufacturers the same route to market as importers is important but we should not lose sight of the fact that over 98 percent of all products are imported. A level playing field can be achieved merely by making the requirements for both local and imported products the same, rather than imposing what has been long regarded as an overly onerous process for Australian manufacturers on the importers as well.

9.3 Proposal 2A – Use of Third Party Assessment Bodies for Australian Manufacturers

Implications

This does not affect Medtronic directly as we are primarily an importer of medical devices into Australia. However Medtronic does not see the need for regulatory inequality and different requirements for Australian manufacturers and sponsors importing into Australia.

Recommendations

Medtronic supports this proposal but the TGA needs to ensure that the timing of this coincides with the approval or designation of Conformity Assessment Bodies operating in Australia, to prevent manufacturers choosing a Conformity Assessment Body which is later not approved, requiring them to have the conformity assessments carried out again.

9.4 Proposal 2B(i)

Implications

As it currently stands, this proposal will potentially require an additional $12.5 million in re-registration costs for Medtronic just to have products already included on the ARTG go through a new full conformity assessment. This conformity assessment is effectively a duplication as these products have already been through a Level Two Application Audit at the TGA and have conformity assessment evidence from a Notified Body. There has been no evidence provided to show that the TGA Level Two Application Audits have failed to stop unsafe devices entering the market.

The perceived weakness in the system is that unlike conformity assessed product which is reviewed every 5 years, the implantable class III and AIMD's are only assessed on application for entry onto the ARTG. This is contrary to the European system where there is a design review every 5 years.

Recommendations

Medtronic has put two recommendations forward for this section:-
A) Periodic Review of implantable Class III and AIMD Inclusions

The TGA continues with the current Level Two application audits for all implantable class III and AIMD but condition of inclusion on the ARTG is the issue of a Certificate of Review which expires after 5 years and requires the TGA to do an application review which would include:

1) Updated Design examination (Annex II-4) certificate and Design Examination Report.
2) Risk management File and
3) Clinical Evaluation.

In Medtronic's view the current Level III and AIMD process with the addition of the above recommendation should be sufficient to address inconsistencies in international alignment alone and does not require further reform.

B) Abridged Conformity Assessment

Medtronic believes that the changes proposed in our recommendation A) should be sufficient reform. However if the TGA were to proceed with the requirement for a TGA issued conformity certificate for implantable class III and AIMD devices, then the TGA should implement a system of levels of conformity assessment linked to the risk of the device. Thus an abridged conformity assessment for implantable class III and AIMD devices that do not contain tissues of animal origin, substances of microbial or recombinant origin, stable derivatives of human blood or plasma or medicines is proposed, with the TGA reviewing the conformity evidence already carried out by Conformity Assessment Bodies.

We propose the following abridged conformity assessment for those products which are CE marked:

1) Quality (Annex II-3) Certificate and Quality Surveillance Audit Report.
2) Design examination (Annex II-4) certificate and Design Examination Report.
3) Australian Declaration of Conformity
4) Essential Principles Check List
5) IFU/Labels
6) Risk Management File
7) Clinical Evaluation

We would also like to ensure that business rules are developed for the requirements and content of the clinical evaluation so that all the process is transparent and predictable.

The TGA should also consider other regulatory conformity assessments carried out by GHTF founding members such as PMA Approval in the United States or by Health Canada.

9.5 Proposal 2B(ii) – Applications to be Selected for Auditing

Implications

Medtronic understands that there may be increased regulatory oversight required on Class IIb implantables. However, in addition to the high cost of the reviews (an estimated added $300,000 for Medtronic), the impact of increased TGA workload and resulting increase in time to market should not be ignored.

With the added workload of this proposal and 2B(i) to the TGA's current workload, we foresee significantly extended timeframes for getting new Class IIb products onto the ARTG. Variations to the currently approved ARTGs could also be time-consuming considering the volume of changes across the industry in Australia.

Recommendations

Medtronic proposes an application audit which comprises the following documentation for a CE Marked device:

a) Australian Declaration of Conformity
b) IFU/Labels
c) Risk Management File
d) Clinical evidence supplied for CE marking.

Variations to Class IIb ARTG's should be by notification and follow the same process as described in Proposal 3(i).

9.6 Proposal 2C – Recognition of Third Party Assessment Bodies

Implications

TGA has consistently felt that not all of the European Bodies are not of a standard that they would be prepared to fully recognise under an MRA type arrangement.

However, it should also be recognised that although there are approximately 80 Notified Bodies, more than 85 percent of medical device assessments are covered by just eight Notified Bodies. This indicates that market forces are ensuring that the most competent Notified Bodies are receiving the bulk of the workload.

Medtronic fully supports proposals which would allow an Australian Designating Authority to designate specific Australian and International Conformity Assessment Agencies for Australia. This would allow for improved confidence, clarity for manufacturers and could allow for broader MRA type arrangements

and would make large gains in terms of the efficiency and speed to market called for by Ministers Roxon and Tanner in relation to the HTA review (see appendix).

Recommendations

Medtronic would like to propose that the TGA

1) Retain without question its role as the Australian Competent Authority.
2) TGA should retain its role as a Conformity Assessment body in order to issue Conformity Assessment Certificates to those manufacturers who choose to use this service.
3) In addition we recommend that an independent 3rd party take the role of Designating Authority who could transparently apply the same assessment standards to all Conformity Assessment Bodies for the Australian Market. The Joint Accreditation System of Australia and New Zealand JAS-ANZ may be an appropriate existing body who could take this role.

9.7 Proposal 2C(i) – Confidence Building for EU Notified Bodies Designated under the MRA

Implications

The TGA has carried out confidence building with Notified Bodies since 2002. This process has apparently not so far built any confidence, even though no evidence has been produced to show any specific concern with a Notified Body.

Recommendations

The TGA should carry out further confidence building which should be limited to a maximum of two years but also actively assess which Notified Bodies should be on the MRA 'approval' list. This confidence building and assessment should be used as a basis to begin the designation process as outlined above.

Once Australia has established a designating role and agency there would be very significant scope to broaden MRA style arrangements which could allow in practice for a Manufacturer to apply once to a Conformity Assessment Body to provide a conformity assessment certificate for both the EU CE mark and for the Australian ARTG inclusion application at the same time. This would be a major step forward in reducing costs and providing speed to market.

9.8 Proposal 2C(ii) – Recognizing Australian Third Party Assessment Bodies

Implications

The TGA is proposing further consultation on designating Conformity Assessment Bodies (CABs) for Australia.

Recommendation

Medtronic would welcome further consultation on this subject but would like to see this consultation start within six months of any legislative changes.

Medtronic would propose that in order to ensure regulatory equality for manufacturers and importing sponsors, the third party Conformity Assessment Bodies designated by the Australian Designating Authority be able to issue conformity assessment certificates to be used for application for entry to the ARTG.

The TGA needs to ensure that it retains regulatory oversight and independent control over all medical devices supplied in Australia. In order to do this the Australian Designating Authority needs to:-

a) Be the only organisation to designate Conformity Assessment Bodies for conformity assessment in Australia.
b) Assess Conformity Assessment Bodies to ensure only qualified Conformity Assessment Bodies are approved for Australian market entry requirements
c) As TGA wishes to continue also in the role of a CAB they can arrange for the designating Authority which could be JAS-ANZ or a similar independent body to provide assessment of TGA's CAB process based on the same criteria as applied to other CAB's. This would provide for equity and transparency of process.

9.9 Proposal 3(i) – Amending the way in which a kind of Medical Device is included in the ARTG

Implications

Medtronic supports this proposal to increase the visibility of which products are covered under an individual ARTG. The volume of low class devices and variation to individual ARTGs would be high.

Recommendations

This process should not be difficult and impose undue delays to the addition of variations to the ARTG. Medtronic proposes a fee-free notification system via the eBS system.

9.10 Proposal 3(ii) – Enhancing the Identification of Approved Devices

Implications

The stated rationale for this proposal is to identify that a therapeutic product is approved by TGA and identify the product in the event of a recall at some future date. In contrast to the assessment in the Discussion Paper that:

". . .this proposed change should not adversely impact on regulatory costs as sponsors are already required to publish their contact details on the information that accompanies the medical device."

This is a very different proposition. Contact details are generic and can be applied during the manufacturing/packaging process in the same way for every device for the Australian market. They can also be incorporated into the product planning process prior to receiving TGA listing. In contrast, the ARTG number is product specific and is not known until the time of approval. This would then involve product specific label printing and local application outside of the normal quality controlled manufacturing process. It is difficult without significant analysis to state the actual cost of this proposal however as an indicator Medtronic estimates it will ship 2.8 million units of ARTG included product this financial year. Under this proposal each one of these products would have to have a label manually applied with the correct product specific ARTG number. This adds significantly to costs and introduces an unnecessary point for error. In practice this label is unlikely to be referred to on any regular basis and as it is usually applied to packaging it is generally discarded when the product is used.

Recommendation

This proposal is unnecessary as it does not add to safety or efficacy of medical devices beyond what would be shown from proposal 3(i) which answers both the concerns.

9.11 Proposal 4 – Publication of Device Information on the TGA Website

Implications

Medtronic supports the supply of information to allow all stakeholders to make informed decisions regarding the giving or receiving of treatment. However consideration needs to be given to what kinds of information would be helpful

and for what audiences as well as the most appropriate and accessible medium to provide this information.

There is a need to consider the costs and resources required to produce this information if it is not required for other jurisdictions. The costs and resources required will very much depend in the information to be supplied and the medium used to supply and access this information.

Recommendations

Medtronic recommends that this proposal be the subject of a separate specific consultation process to examine the real need being addressed, the kinds of information already available and the medium to be used to supply the information. The increased information in the ARTG would make it easier for information on individual products to be accessed via the internet which may address some of this need.

10.0 Summary

Medtronic welcomes this opportunity to provide input into the discussion regarding proposed reforms to the regulation of medical devices in Australia and recognises the need for consumers and clinicians to be able to better access information about products listed on the ARTG and how they are assessed.

We believe this need can be addressed primarily through improved transparency and access to information. Where there is a real need for change to regulations we urge that this be evidence based and that proper cost benefit analyses are performed to support this. Where changes are made every effort needs to be made to reduce the impact on costs and timeframes which will ultimately impact consumers.

Appendix

THE HON NICOLA ROXON MP

Minister for Health and Ageing

THE HON LINDSAY TANNER MP

Minister for Finance

MEDIA RELEASE

27 February 2010

STREAMLINED APPROVALS PROCESS FOR MEDICAL ADVANCES

The Rudd Government will implement a series of reforms to streamline the process and reduce the cost involved with assessing new medical technologies and procedures for use in Australia.

A new report released today by the Minister for Health and Ageing, Nicola Roxon, and the Minister for Finance and Deregulation, Lindsay Tanner, recommends improvements to the way new health products, procedures and services are assessed for public funding, in line with international best practice.

The Government will begin work immediately to implement 13 of the 16 recommendations, and the remaining three longer-term recommendations will be subject to further consideration.

The *Report of the Review of Health Technology Assessment in Australia* is one of the first Better Regulation Ministerial Partnerships undertaken as part of the Rudd Government's commitment to using better regulation to drive productivity and reduce costs to business and the not for profit sector.

Better Regulation Ministerial Partnerships form a key part of the Rudd Government's deregulation agenda and have proved effective in ensuring a disciplined and coordinated approach to delivering regulatory reform across government.

"A more transparent, efficient and coordinated system of approving new health products, procedures and services is an important step in reforming our health system," Ms Roxon said.

"These reforms mean patients will have faster access to the latest safe and effective treatments, products and technology, and industry will have reduced costs in getting their products to market.

"We want proven medical advancements which meet appropriate safety standards to be available to the people who need them sooner."

The report recommends that organisations seeking Health Technology Assessment (HTA) be provided with a single entry point to receive, guide and monitor applications for reimbursement. More detailed information will be easily available from a central website, including how technologies will be assessed and how decisions are made.

It also recommends a streamlined approach so that technologies are subject to a level of assessment appropriate to the risks presented by the technology.

While the improvements would assist both patients and industry, the report also found that proper evaluation of new technologies is essential to the sustainability of Australia's health system in the longer term.

Lindsay Tanner said: "This is another example of how the introduction of a Better Regulation Ministerial Partnership is working towards addressing impediments to Australia's long-term productivity growth."

Lindsay Tanner said it is essential that applicants find the HTA system easy to navigate, while maintaining patient safety and ensuring value for money.

"The report outlines proposed reforms to actively assist the industry to achieve more timely assessments, improve transparency for all stakeholders and to remove duplication and overlap," Mr Tanner said.

The *Report of the Review of Health Technology Assessment in Australia* is available at www.health.gov.au/htareview and www.finance.gov.au

Media inquiries:
Minister Roxon's Office: Laura Ryan on 0409 945 476.
Minister Tanner's Office: Nardia Dazkiw on 0418 144 690.