Regulation Impact Statement

Changes to premarket assessment requirements for medical devices

A response to the TGA Exposure Draft, 10 May 2013

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1.0. Executive Summary.

Medtronic argues that option 1 of the Exposure Draft Regulatory Impact Statement (EDRIS), which the TGA has labelled as "No immediate action – requires no change to current arrangements" is in fact inaccurate. There have been actions taken which address the objectives such as the up classification of hip, shoulder and knee prosthesis, changes to the way field corrective action information is communicated via SARA and sharing internationally of post market surveillance information. The current framework also has a number of existing mechanisms, which if utilised effectively would allow the TGA to target emerging risks, without serious costs, delays in or lack of access by Australian patients to breakthroughs medical technology.

Medtronic also considers the conclusion of the EDRIS that option 2 is the preferred option is inconsistent with the stated objectives, specifically the primary objective to provide greater assurance that higher risk medical devices approved do not compromise public health and safety. Medtronic has put forward an alternative option 4 which is a combination of option 1 and 2, together with clear requirements for further post market surveillance.

1) The evidence for an increased level of premarket scrutiny for higher risk devices does not exist:-

- The two most recent issues widely reported in the media in Australia and worldwide, the ASR hip and PIP breast implants, should not be viewed as fundamental failures of the regulatory system.
    - PIP was fraud and cannot be regulated against.
    - ASR issues could not have been picked up by premarket assessment but were found by effective post market surveillance and use of a targeted registry.
- AIMD and Class III.
    - High level conformity assessment by notified bodies including a full design review.
    - Field Corrective Action (FCA) data indicate that AIMD's account for less than 1% of FCA's and Class III less than 8%, with 0.3% being implantable class III devices.
- Class IIb implantable
    - FCA's undertaken for Class IIb devices showed that 0.5% of recall actions conducted during the sampled period were for Class IIb devices identified by regulation 5.3 or the table of devices suggested to be captured by application audit.
- The evidence, for increased scrutiny for devices is questionable but Medtronic acknowledges the primary objective of the EDRIS to provide greater assurance that higher risk medical devices approved do not compromise public health and safety.

Medtronic does not believe that increasing pre-market assessment of high risk devices will achieve the stated objectives of the EDRIS but these objectives can be met by the following proposals

2) The primary objective to provide greater assurance that higher risk medical devices approved do not compromise public health and safety can be achieved by;

a) Increased Post Market surveillance and use of appropriate Registries in areas of identified high risk.

- Effective review and analysis of annual reports would give the TGA a clear indication of the performance and safety profile of a specific device family or even a specific product code.
- Sharing locally and internationally the information on Field Corrective Actions and Adverse Events.
- Targeted registries which would be better positioned to assist in identifying products which may be underperforming and allowed investigation and action in those cases.

b) With the diversity of products and new technologies, a single regulator within a country such as Australia, with a growing number of applications but a relatively static pool of expertise on the market poses significant workforce issues for regulators and industry alike. However by selecting notified bodies based on objective evidence with auditable criteria would allow the TGA to effectively utilise the resource constraint stated above with no additional costs and without compromising safety of the Australian public. Therefore Medtronic recommends that, the TGA takes on actions to:
    - Start a real confidence building with EU Notified Bodies.
        - TGA should be involved in this process either at the competent authority level or at the European Commission level.
        - Use of the single audit program (as per the IMDRF initiative)
    - Medtronic also recommends that TGA to become a competent authority and designate only those conformity assessment bodies qualified based on auditable criteria. The advantage of the proposed solution is:
        - Ultimate control remains under the jurisdiction of the TGA, who will be:-
            - Setting and monitoring public health and safety requirements.
            - Selecting, empowering, monitoring and evaluating competent testing and certification organisations.

3) The secondary objectives;

a) supporting the timely availability of medical devices to the Australian public;
    - Use of assessments carried out by qualified assessment bodies

b) minimising unnecessary regulatory burden
    - Share the regulatory burden globally and reduce duplication, minimise costs.

c) improving the ability for TGA to target emerging risks in a timely manner; and
    - Mandatory reporting of adverse events.
    - Effective use of annual reports.
    - Expiry on ARTG entries on high risk devices.
    - Use of targeted registries.

d) Continuing Australia's commitment to promoting alignment of international medical device regulation.
    - Harmonisation within IMDRF on single audit, quality and design dossier requirements.

Therefore Medtronic believes that by increasing only the premarket scrutiny will not achieve the objectives of the EDRIS and has proposed a range of measures which combine the options 1 and 2 with requirements for further post market surveillance that would help identify safety issues if any, with the included devices. The proposed option by Medtronic, therefore answers all the set objectives of the EDRIS.

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. This will also better the chances of availability of innovative and life saving devices to Australian population. Therefore Medtronic welcomes the opportunity provided by the TGA to provide comments on the proposed reforms.

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, Australia.

Workforce
Medtronic employs more than 40,000 people worldwide and more than 450 in Australia.

3.0. Overview.

Australia is a founding member of the GHTF group which has now evolved into the IMDRF. This group has done very valuable work to establish the basis of major regulatory systems around the world and in particular has established the essential criteria for evaluating medical devices in Europe and Australia. These systems have served the people of both Europe and Australia in very good stead.

In the recent past there have been a very small number of public health issues being identified in relation to the safety and efficacy of some medical devices. However it is a well-recognised fact that no regulatory system can provide 100% protection against any product related issues and agreed by the TGA themselves by the following statement in the EDRIS:

"No medical device is completely safe, or immune from failure, irrespective of the level of premarket scrutiny it has undergone. It is also generally recognised that medical devices are inherently different from medicines. For instance, it is not possible to accumulate a similar body of clinical trial data at the premarket stage. This makes postmarket surveillance critically important to the effective regulation of medical devices."

The reality is that product failures will occur in a tiny percentage of the tens of thousands of medical devices on the market. However it has been proven over the years that the risk of patients affected by product failures outweighs the millions who benefit from these devices every year.

The two most recent issues widely reported in the media in Australia and worldwide, the ASR hip and PIP breast implants, should not be viewed as fundamental failures of the regulatory system.

The ASR hip issues were identified by post market monitoring data using the orthopaedic registers. There may be valid questions around how the data was analysed in order to understand the problems and whether the problem was dealt with in the optimal timeframe. However the important aspect to note is that it was extremely unlikely that in the absence of very long term and very large scale pre market trials, (which are in most cases unachievable in the medical device space), the premarket evaluation could not have identified these issues.

The PIP breast implant issue was a fraudulent act perpetrated post approval could not have been prevented by any more rigorous pre market assessment. However, some increased post market vigilance measures such as spot audits and using existing legal avenues to prosecute offenders, may provide some deterrence to such fraudulent acts.

Medtronic believes that the foundations to the Australian Medical Device Regulations are already strong and can be built on (as with any other system).

3.1. Regulatory system developments.

The current review and changes within Europe to the Medical Device Directive have begun. These changes will address the known weaknesses in the designation and competency criteria of notified bodies. However despite these changes it is important to understand that there is no documented evidence that patients in Europe were any less safe than in the US or anywhere else and there is evidence that the current arrangements have been as effective as any other regulatory arrangements around the world.

In addition, there is no evidence to suggest the safety of New Zealand citizens is being put at any greater risk to that of the Australian citizens, but access to potentially lifesaving / life enhancing devices in Australia lags six to eighteen months behind New Zealand due to higher regulatory requirements. Another example of this device approval lag is between Europe and the US. The European system which forms the basis for the Australian system has provided access to lifesaving and life enhancing medical devices to patients on average three to five years earlier than the United States without any evidence to show that safety was compromised[1].

These reforms come at the same time as reforms in Europe and the discussions on the development of ANZTPA. The proposals are not aligned with those taking place in Europe especially around the review of notified bodies to ensure that there are competent and expert third party conformity assessment bodies in place. There has been much talk around confidence building but there has been no activity in this arena and there are no defined timeframes to provide confidence in the TGA's and NB's commitment to this process. On the contrary, the TGA is now proposing greater scrutiny of the documents already reviewed by the notified bodies and even reviewing the "report issued by the NB". This perpetuates and extends an already highly duplicative system, and does little to protect the safety of Australian citizens. Therefore this proposal to review the additional documents serves only to restrict access to potentially lifesaving medical technology.

In addition TGA confidence building as proposed is centred on reviewing outputs from European Notified Bodies which is a time and work intensive task and is inefficient. A much more efficient method is direct audit and management by TGA of the Notified Bodies themselves.

In its response to the ANZTPA proposal Medtronic had proposed the following model which would serve the TGA even if ANZTPA were not to go ahead.

This European-style model works well to cater for the enormous diversity of life-improving medical treatments and technologies provided to patients. Europe's current medical device legislation makes a more targeted and effective use of competent authority and regulator resources.

The competent authority (TGA) is in control of two main elements:

a) Firstly they set the public safety requirements and intervention mechanisms and
b) Secondly, they select and control competent, scientific certification bodies to do the technical and scientific review (Notified Body).

Ultimate control remains under the jurisdiction of the Competent Authority, i.e. the TGA.

This concept would translate in the legislation where TGA would in addition to post market surveillance and vigilance, have two broad tasks:

1. Setting and monitoring public health and safety requirements such as essential safety and performance requirements, clinical investigation, product classifications, product, technical and manufacturing standards, vigilance and market surveillance;

2. Selecting, empowering, monitoring and evaluating competent testing and certification organisations, called Notified Bodies, who must have the latest in scientific and technical competence, and be capable of checking both manufacturers and their medical devices in accordance with the regulations.

Confidence building needs to be finalised and a list of designated notified bodies needs to be in place as a matter of urgency. With the TGA as the competent authority and the use of designated 3rd party conformity assessment bodies, TGA would be able to ensure the best skilled and

competent reviewers (as these resources are available globally to the NBs as compared to a limited pool in Australia) are used to review products coming into Australia.

With the diversity of products and new technologies, a single regulator within a country such as Australia, with a growing number of applications but a relatively static pool of expertise on the market poses significant workforce issues for regulators and industry alike. However by selecting notified bodies based on objective evidence with auditable criteria would allow the TGA to choose only those notified bodies which are qualified under objective criteria without issues of national sensitivities.

3.2. The problem.

A number of recent reports have called for increased rigour of the TGA's premarket assessment process for higher risk, in particular implantable medical devices. The TGA, in response to those reports, senate enquiries and the HTA review, has proposed the following.

A Proposal Paper *Changes to premarket assessment requirements for medical devices*[2], released by TGA addresses:

- Increased scrutiny of conformity assessment as part of mandatory application audits prior to ARTG inclusion,
- Publication of medical device regulatory decisions,
- Abolition of requirement for TGA conformity assessment for Australian manufacturers of lower class medical devices.

The reports have called for increased rigour which requires the TGA to adhere more closely to the requirements or standards, whereas the TGA proposal is to increase scrutiny, which would add extra reviews of documents and will not result in the desired effect of with increased rigour.

TGA has stated that the changes are intended to ensure that medical devices are being approved for supply in Australia where the benefits outweigh the risks of supply based on evidence, with transparent decision making process. The TGA has highlighted particular concern regarding implantable devices due to the significant risk if an implant needs to be explanted.

Two examples are given of recent events in relation to the TGA's pre-market assessment process, the failure of the ASR hip joint replacement and issues with the PIP breast implants, both of which resulted in Senate Inquiries in 2011.

The changes proposed in this paper are intended to ensure that implanted medical devices and those which are surgically invasive or intended for long term use receive a greater degree of premarket scrutiny by the TGA.

Medtronic believes that some of the proposals of this reform will not achieve the desired outcome of identifying any unsafe medical devices prior to being placed on the market, but will simply add to an already large burden of cost and red tape.

3.2. Objectives of reforms examined by the EDRIS.

The regulatory reform proposals examined by this EDRIS indicate the primary objective as being:-

1) Provide greater assurance that higher risk medical devices approved do not compromise public health and safety.

While at the same time looking at the following secondary objectives:-

2) Supporting the timely availability of medical devices to the Australian public;

3) Minimising unnecessary regulatory burden and associated costs on the medical device industry (as these costs are passed on to users and funders of the health system);

4) Improving the ability for TGA to target emerging risks in a timely manner; and

5) Continuing Australia's commitment to promoting alignment of international medical device regulation.

4.0 Options being considered.

Medtronic has reviewed the options put forward and will comment on each option and whether we agree with the assumptions made in the EDRIS regarding the whether each option meet the objectives of the reforms. As requested in the EDRIS Medtronic will also put forward a fourth option which is a hybrid of the proposed options and we will show that it serves the objectives better than the proposed options.

Also as requested an assessment is provided of how the implementation of option 2 (the preferred option) will impact on Medtronic and includes the likely benefits or costs.

In the MTAA submission in response to the EDEDRIS[3] - a review of Field Corrective Actions (FCA's) from the TGA's System for Australian Recalls Actions (SARA) database for the last year (from July 2012), indicated that AIMD accounted for less than 1% of FCA's and Class III less than 8%, with 0.3% being implantable class III devices (the rest of the lower class devices accounted for 91% of the FCA's).

Further review of recall actions undertaken for Class IIb devices showed that 0.5% of recall actions conducted during the sampled period were for Class IIb devices identified by regulation 5.3 or the table of devices suggested to be captured by application audit.

This indicates that the current level of assessment for these classes of device is adequate and the perceived need for increased pre-market scrutiny for the higher risk devices unnecessary.

It also needs to be recognised that the reasons for FCA's are predominantly post market identified issues, requiring updates to device instruction or batch related quality issues which increased premarket scrutiny would not have identified.

4.1. Option 1.

The assumption in the EDRIS is that this option indicates no immediate action and that the existing arrangements are sufficient. In the reply to the consultation on *Changes to premarket assessment requirements for medical devices*[4] Medtronic indicated that the current mechanisms in place would not necessarily increase the rigour of premarket assessment but **if fully implemented** would ensure medical devices approved do not compromise public health and safety, by ensuring timely intervention when issues with devices are identified.

Annual reports for Class III, AIMD and Implantable IIb are currently required for three years after the inclusion of the device in the register. An annual report is an extensive review of all the complaint and adverse events worldwide for each device included on the ARTG. These reports take an extremely long time and require immense effort to produce, but feedback is not received from the regulator, in fact it is clear that these reports are not reviewed thoroughly and valuable post market data of high risk devices is not used to provide valuable early warning of developing issues.

If these annual reports were reviewed effectively this would give the TGA a clear indication of what is happening to a specific device family or even a specific product code.

The TGA has implemented or is in the process of implementing the following reforms:-

- Greater transparency with the identification of medical devices on the market. This will give visibility to the TGA of products on the market and understand what is covered under each ARTG.
- The up classification of hip, knees and shoulders from class IIb to class III, which bring these devices in line with the European classification.
- Patient contact registries
- Clinical Quality registries for Cardiac Products

In addition Australia benefits from significant changes already introduced in Europe and further changes which are proposed for Europe. These are significant changes which will give tangible benefits, and should not be written off so easily.

4.2. Option 2 - Modified proposals from January consultation.

This option is taking the three proposals from reforms paper and refining the criteria. Medtronic has already extensively reviewed the issues around these proposals in our submission on *Changes to premarket assessment requirements for medical devices*[4], in this submission we have only highlighted the key points and where applicable made comment where required?

4.2.1 Costing of option 2.

In 2012 Medtronic had 47 applications which are AIMD, Class III or Class IIb implantable. Of those 25 will now be affected by the modified proposals now indicated in option 2, these are AIMD's and affected Class III and Class IIb implantable's.

	Application Fees	Application Fees + STR	Application Fees + STR + AusPAR
2012 fees paid	$278,540		
2012 if option 2 was in place		$779,708	$808,436
Difference ($)		$501,168	$529,896
Difference (%)		280%	290%

There has been some confusion regarding the cost for a level 3 audit with $22,974 and $16,832 being quoted in the EDEDRIS, confirmation was given that the $22,974 should not have been in the EDEDRIS. Thus costing of option 2 was worked out using the new application fee quoted of $16,832, notified body direct cost of approximately $10,000 for a Summary Technical Report and $1,197 for a complex AusPAR publication. The increase in our direct costs is almost $530,000 or 290%.

It is unclear how the proposed reduced fees will be calculated when applications are grouped. Medtronic does not see a blanket 20% reduction for grouped devices as appropriate and would propose a more proactive fee calculation where the actual fee charged would be commiserate with the work required. Concern regarding the use of a full fee for a level 3 audit even if the same quality system documentation is used as supplied for similar kind of devices (only UPN different) but submitted at different times, this still would not need a full review thus should not be charged twice at the same rate.

We will also have indirect costs for the internal documentation for the manufacturer and local costs associated in doing these applications. The documentation costs and additional labour cannot be estimated without more detail but the main indirect cost will be time to market for products which have already been extensively conformity assessed and approved by other qualified assessment bodies.

From a Medtronic point of view we see no justification for this additional regulatory duplication which does not increase the safety of the Australian consumer, but simply duplicates conformity assessments already carried out by another regulator without any demonstrated need or benefit. In our view policy change which has significant financial, resource and time cost needs to be evidence based, both in terms of need for reform and for effectiveness of the proposed reforms. We have not seen the case made with direct evidence in either case for these proposed changes.

4.2.2 Proposal A.

Medtronic acknowledges that the EDRIS has reduced the scope of what devices will be effected by this proposal and acknowledges that it may still be justifiable to include class IIb implantable devices into a level 2 application audit (see Medtronic Option 4). However concerns regarding costs and increased time scales for approval remain together with how under the current system these class IIb implantable products will be identified (see below).

It is difficult to understand the rationale for the proposal to require a Level 3 audit for class III and AIMD products. The additional documentation is similar to that which was required for Class III and AIMD application audits when the 2002 devices regulations were initially introduced, however it appears that this proposal links this to an abridged TGA conformity assessment. It is not clear if the

intent is for these products are assessed in the conformity assessment section of the TGA. However if it is, this will significantly increase the burden on the sponsor in two areas. Firstly the cost which would be imposed appears to be disproportional to the additional review work proposed and secondly the current conformity assessment queue is already excessively long. Our experience is that timeframes are now moving past 18 months and towards 24 months.

It has been recently announced that Cardiac devices as will be supported in the post market space by the Cardiac registry. Medtronic put together a comprehensive review of the risks of increasing premarket review versus increasing post market surveillance (in our submission on *Changes to premarket assessment requirements for medical devices*[4]*)* which is where the evidence shows resources could be more effectively deployed to assist with the early identification of safety issues.

Effective utilisation of post market data collected presently, such as the annual report, will also provide the TGA an overview of the product performance worldwide, and provide an input into whether any further tools such as, specific registries are required to monitor further. Thus cardiac devices where it has just been announced that there will be a registry should not require further premarket assessment.

It cannot be overstated that both issues which are being used to justify these changes would not have been picked up by this proposal (A). The ASR hip issues were identified by post market monitoring by the use of orthopaedic registers. The PIP breast implant issue which was a fraudulent act perpetrated post approval could not have been prevented by pre market regulation.

The proposed additional Level 3 audit does not in our view increase rigour of assessment and serves only to increase duplication of regulatory effort with the associated increased costs and time delays.

The use of an instrument rather than regulation to target devices emerging risk needs to have clear boundaries to ensure actual risks are being targeted rather than perceived risk. A process to remove devices from the list once it is clear the device no longer needs to be targeted, also needs to be in place to ensure the most appropriate devices are targeted.

If this instrument is to be used then the requirement for regulation 5.3 is obsolete, and a review of products within 5.3 needs to be reviewed and those still considered a “greater risk” added to the instrument.

4.2.3. Proposal B.

Medtronic still supports in principle the publication of regulatory decisions which would improve transparency and accountability of the TGA’s decision making process. The concerns raised in our submission on *Changes to premarket assessment requirements for medical devices*[4], need to be considered as well as the cost.

4.2.4. Proposal C.

Medtronic supports the removal of the mandatory requirements for TGA direct assessment of all devices (other than those listed in regulation 5.3), which means that there is no disparity between local manufacturers and importers.

Medtronic believes that there is no justification for requiring mandatory direct TGA conformity assessment for any type of device (even those listed in regulation 5.3), which has previously undergone a European conformity assessment. Medtronic believes that moving to a fully third party conformity assessment model with TGA taking the role of Competent Authority which designates Notified Bodies, is the most effective way for the TGA to meet its commitments in the future. This then allows local manufacturers and importers to use the same route to market. The TGA in the role of Competent Authority can then designate which notified bodies it will accept based on objective and audited criteria and be able to make decisions based on fact to get a consistent quality and level of assessment by suitably qualified and experienced notified bodies. TGA confidence building needs to be finalised and a list of designated notified bodies needs to be in place as a matter of urgency.

4.3. Option 3.

Medtronic agrees with the conclusions of the EDRIS that this option does not meet with any of the objectives.

4.4. Option 4 – Medtronic's proposal.

Medtronic proposes a hybrid of option 1 and 2 combined with a commitment by the TGA to undertake confidence building of the European Notified Bodies and move the TGA to become a competent authority as described in section 3.1. There is some duplication of text within this section as rather than just referencing back to the body of text above we have copied the content where the discussion was made for either option 1 or 2 as well as the parts on confidence building. This was done so this section could be read as a stand-alone section and could be read fully.

Medtronic has considered the key issues and the objectives identified in the EDRIS. Also in order to make it clear the conclusions are tabulated and all options are compared, to the key issues and objectives.

4.4.1. Key issues.

The key issues have been taken from the EDRIS, but Medtronic has added another key issue and that is the confidence building of the Notified bodies

1) Increase level of premarket scrutiny for:

- AIMD and Class III.

Higher risk devices which are CE marked already undergo a high level conformity assessment by notified bodies including a full design review. The two most recent issues widely reported in the media in Australia and worldwide, the ASR hip and PIP breast implants, should not be viewed as

fundamental failures of the regulatory system. Reviewing the number of FCA's indicated that AIMD accounted for less than 1% of FCA's and Class III less than 8%, with 0.3% being implantable class III devices (the rest of the lower class devices accounted for 91% of the FCA's).

- Class IIb implantable

Medtronic acknowledges that it may still be justifiable to include class IIb implantable devices into a level 2 application audit. But Medtronic would like to understand the real risk of these devices as review of recall actions undertaken for Class IIb devices showed that 0.5% of recall actions conducted during the sampled period were for Class IIb devices identified by regulation 5.3 or the table of devices suggested to be captured by application audit.

It is questionable whether further premarket review would be appropriate, to give greater assurance that higher risk medical devices approved do not compromise public health and safety, even for these classes of products.

Conclusion on need for increased premarket scrutiny

The evidence, for increased scrutiny for devices does not seem to exist but Medtronic acknowledges the primary objective of the EDRIS to provide greater assurance that higher risk medical devices approved do not compromise public health and safety. Medtronic proposes that increased post market surveillance is the best way to achieve the primary objective and not increased pre-market scrutiny, as discussed below.

2) Transparency of decision making.

Medtronic still supports in principle the publication of regulatory decisions which would improve transparency and accountability of the TGA's decision making process. The concerns raised in our submission on *Changes to premarket assessment requirements for medical devices*[4], need to be considered as well as the cost.

3) Requirements for TGA conformity assessment for Australian manufacturers.

Medtronic supports the removal of the mandatory requirements for TGA direct assessment of all devices (other than those listed in regulation 5.3), which means that there is no disparity between local manufacturers and importers.

4) Confidence building with Notified Bodies.

Medtronic believes that there is no justification for requiring mandatory direct TGA conformity assessment for any type of device (even those listed in regulation 5.3), which has previously undergone a European conformity assessment.

Confidence building needs to be finalised and a list of designated notified bodies needs to be in place as a matter of urgency. With the TGA as the competent authority and the use of designated 3rd party conformity assessment bodies, TGA would be able to ensure the best skilled and competent reviewers (as these resources are available globally to the NBs as compared to a limited pool in Australia) are used to review products coming into Australia.

With the diversity of products and new technologies, a single regulator within a country such as Australia, TGA would be able to ensure the best skilled and competent reviewers (as these resources are available globally to the NBs as compared to a limited pool in Australia) are used to review products coming into Australia. The TGA in the role of Competent Authority can then designate which notified bodies it will accept based on objective and audited criteria and be able to make decisions based on fact to get a consistent quality and level of assessment by suitably qualified and experienced notified bodies. However by selecting notified bodies based on objective evidence with auditable criteria would allow the TGA to choose only those notified bodies which are qualified under objective criteria without issues of national sensitivities.

4.4.2. Objectives

1) The primary objective is to provide greater assurance that higher risk medical devices approved do not compromise public health and safety.

Medtronic does not believe that increasing pre-market assessment of high risk devices will achieve this objective as discussed above under key issues, but where this objective can be met is by the following:-

- Increase Post Market surveillance, and use of appropriate Registries in areas of identified high risk.

Effectively review and analysis of annual reports would give the TGA a clear indication of what is happening to a specific device family or even a specific product code.

Transparency on the sharing of information on Field Actions and Adverse Events. For example the SARA database shows over approximately the last 11 months that the higher risk devices account for less than 10% of field corrective actions and it needs to be recognised that the reasons for FCA's are predominantly post market identified issues or batch related quality issues, identified by the manufacturer, which increased premarket scrutiny would not have identified.

It is recognised that the National Joint Replacement Registry has been able to assist in identifying products which may be underperforming and allowed investigation and action in those cases. It has been recently announced that Cardiac devices as well, will be supported in the post market space by the Cardiac registry.

- Real confidence building with EU Notified Bodies.

This was discussed above in key issues but how this confidence building could take place has not been described.

The original Medtronic submission (*Changes to premarket assessment requirements for medical devices*[4]) identified that there are currently changes, both underway and proposed, to the way in which Notified bodies are designated and reviewed in order to strengthen the EU regulatory system. The TGA should be involved in this process either at the competent authority level or at the European Commission level to get first-hand knowledge of various Notified Bodies or the designating competent authorities.

Use of the single audit program not only to standardise quality auditing practice to a clear defined level but also to be able to observe the surveillance activities on the CE marking of medical devices.

- TGA to become a competent authority and designate only those conformity assessment bodies qualified.

This is a good option where ultimate control remains under the jurisdiction of the Competent Authority, i.e. the TGA.

This concept would translate in the legislation where TGA would in addition to post market surveillance and vigilance, have two broad tasks:

- Setting and monitoring public health and safety requirements such as essential safety and performance requirements, clinical investigation, product classifications, product, technical and manufacturing standards, vigilance and market surveillance;
- Selecting, empowering, monitoring and evaluating competent testing and certification organisations, called Notified Bodies, who must have the latest in scientific and technical competence, and be capable of checking both manufacturers and their medical devices in accordance with the regulations.

Further detail is given in section 3.1 of this document or the previous submission.

Secondary objectives:-

e) supporting the timely availability of medical devices to the Australian public;

Use of assessments carried out by qualified assessment bodies

f) minimising unnecessary regulatory burden and associated costs on the medical device industry (as these costs are passed on to users and funders of the health system);

Share the regulatory burden globally and reduce duplication, minimise costs

g) improving the ability for TGA to target emerging risks in a timely manner; and

- Mandatory reporting of adverse events for medical device sponsor and education to both HCP and other users of medical devices that incidences of device failures should be reported.

- Use of annual reports.

- Expiry on ARTG entries on high risk devices requiring review of risk management and clinical evidence every 5 years.

- Use of targeted registries

h) Continuing Australia's commitment to promoting alignment of international medical device regulation.

- Harmonisation within IMDRF on:-

1) Single audit and quality system requirements (this would then help give the TGA the confidence in order not to require a level 3 audit which primarily includes conformity assessment of the manufacturer) and

2) Design Dossier requirements (STED/common content) (This would help the TGA to audit the NBs with a larger common denominator and less country specific requirements)

5.0. Conclusions.

We are unsure why reforms need to be "packaged" and why in Option 2 proposal A and C are linked, as either can go ahead without the other as they relate to different classes of product. The conclusions of Medtronic's submission are shown below in table format. The table is similar to that in page 42 of the EDRIS with an option 4 added as well as the extra key issue. We have also used a colour code to identify whether specific issues are 1) addressed (green), partially addressed (orange) or not addressed (red).

	Option 1	Option 2	Option 3	Option 4 (Hybrid)
Key Issues				
1) Increased level of premarket scrutiny				
AIMD and Class III implantable	Increased Post Market	Level 3 Audit	Expanded CA	Increase Post Market and use of Registries
Class IIb implantable	Increased Post Market	Expanded Level 2 Mandatory Audit	Expanded Level 2 Mandatory Audit	Expanded Level 2 Mandatory Audit
Other issues				
2) Transparency of decision making	Not Addressed	Publication of TGA decisions	Publication of TGA decisions	Publication of TGA decisions
3) Requirements for TGA conformity assessment for Australian manufacturers	Not Addressed	Abolishment of requirement	Abolishment of requirement	Abolishment of requirement
4) Confidence building of Notified Bodies	Not Addressed	Addressed, but no substance	Not Addressed	Addressed, by actively seeking out details of the designation process from CA or EU commission

Objectives				
Primary objective				
1) Greater assurance that higher risk medical devices approved do not compromise public health and safety	Increased Post Market	Duplicative review of documentation already reviewed including a review of the review.	Totally duplicative assessment of a product already conformity assessed by another qualified assessment body	1) Increase Post Market and use of Registries. 2) Real confidence building with EU Notified Bodies. 3) TGA to become a competent authority and designate only those conformity assessment bodies qualified.
Secondary objectives				
1) Timely availability of medical devices	No change to current arrangement, with duplicative assessment.	If in applications section work load will increase so timeframes will increase, especially for Class IIb Implantable.	Long timelines 18 months plus within TGA.	Use of assessments carried out by qualified assessment bodies
2) Minimising regulatory burden and costs	No change to the regulatory burden, costs still high.	Increase in regulatory burden Significant increase in costs	Increase in regulatory burden Significant increase in costs	Share the regulatory burden globally and reduce duplication, minimise costs
3) target emerging risks	Use of current annual report data to assess the risk of a product.	Using instrument to list products identified at risk is reactive not proactive. Increasing premarket review does will only allow the TGA to review new applications not those products on the market.	Not addressed	1) Train users on the requirements of Adverse Event reporting. 2) Use of annual reports. 3) Expiry on ARTG entries on high risk devices requiring review of risk management and clinical evidence every 5 years. 4) Use of targeted registries.

4) promoting alignment of international medical device regulation	Does not address	Partial Addressed	Does not address	Harmonisation within IMDRF on:- 1) single audit and quality system requirements, 2) Design Dossier requirements (STED/common contents)

6.0. References.

[1] EU Medical Device Approval Safety Assessment, A comparative analysis of medical device recalls 2005-2009. **Boston Consulting Group**, January 2011
and
Regulation and Access to Innovative Medical Technologies, A compaEDRISon of the FDA and EU Approval Processes and their Impact on Patients and Industry. **Boston Consulting Group**, June 2012

[2] Changes to premarket assessment requirements for medical devices: Proposal paper**. Australian Government. Department of Health and Ageing. Therapeutic Goods Administration**. Version 1.0. January 2013.

[3] MTAA comment paper on TGA Exposure Draft - Regulation Impact Statement: Changes to premarket assessment for medical devices. **Medical Technology Association of Australia.** 3 June 2013

[4] Changes to premarket assessment requirements for medical devices. A response to the TGA Proposal Paper January, 2013. **Medtronic Australasia Pty Ltd**, March 2013.