Inquiry into the Regulatory Standards for the Approval of Medical Devices

Supplementary Submission to the Senate Community Affairs Committee – October 2011

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1.0 Introduction

Medtronic welcomes the opportunity to provide this supplementary submission to the Senate Community Affairs Committee Inquiry into the Regulatory Standards for the Approval of Medical Devices. In doing so we refer the committee to the original Medtronic Submission made in July 2011 which stands in its entirety and which gives details of Medtronic. The purpose of this supplementary submission is to address some specific areas which on examination of the Hansard records of the proceedings, we feel may require further clarification and emphasis. Medtronic stands ready to discuss these with the committee if called upon to do so.

2.0 Global Regulatory Harmonisation

During the hearings there seemed to be some uncertainty as to what the role of the Global Harmonisation Task Force (GHTF) is and has been with regard to Medical Device Regulation.

The GHTF has been in existence for close to 20 years and has 5 founding members including Australia, the European Union, the US, Canada and Japan. The GHTF goal has been to develop a set of best practice principles for medical device regulation and to achieve greater convergence between systems. Another key benefit is information and experience sharing between regulators.

None of the work of the GHTF is binding on any member and each member retains the right to operate their regulatory system independently as they see the best interests for their jurisdiction. The fact that Australia is a member of the GHTF and uses some harmonised principles in the operation of the regulatory system does not, in most cases, mean that there is automatic acceptance of products approved in other jurisdictions. Depending on the risk class of the product TGA does undertake its own assessments of the documents and clinical evidence presented for registration in other jurisdictions. The exception to this is for some products manufactured in the European Union and which fall under a specific mutual recognition arrangement. In most cases TGA can, and regularly does, question these assessments and from time to time rejects listings where it is not satisfied with the evidence presented, even for products approved in other geographies.

More information on the GHTF can be found at the following website.
http://www.ghtf.org/

3.0 Recalls

Some claims were made that it appeared there may have been less product recalls in Australia than in similar jurisdictions. TGA did speak to this in evidence and we note the apparent discrepancy in the numbers presented by AHIA and the numbers provided by TGA in its evidence.

In our experience the only reason a recall would not take place in Australia after being applied in another jurisdiction would be if there were no affected products in the Australian market.

It should be noted that in many cases recalls apply to manufacturing batches rather than the fundamental design of the product. It may be that a batch or a variant of a product is recalled but the product is not withdrawn in total from the market. Thus, it is possible that no products from a batch or variant affected by a recall have been shipped to Australia.

During the hearings it appeared that there was also some uncertainty about what is meant by a recall and a withdrawal. There are also other actions which can be taken including Hazard Alerts, Safety Alerts and Product Notifications. If members of the committee need a more detailed understanding of these, they are set out in the TGA Uniform Recall Procedure for Therapeutic Goods which can be found at the following internet address.
http://www.tga.gov.au/pdf/recalls-urptg.pdf

However, Medtronic understands that a withdrawal generally only takes place without triggering a Recall or Hazard Alert when it is done for reasons not related to quality, safety or efficacy.

4.0 Evidence Requirements

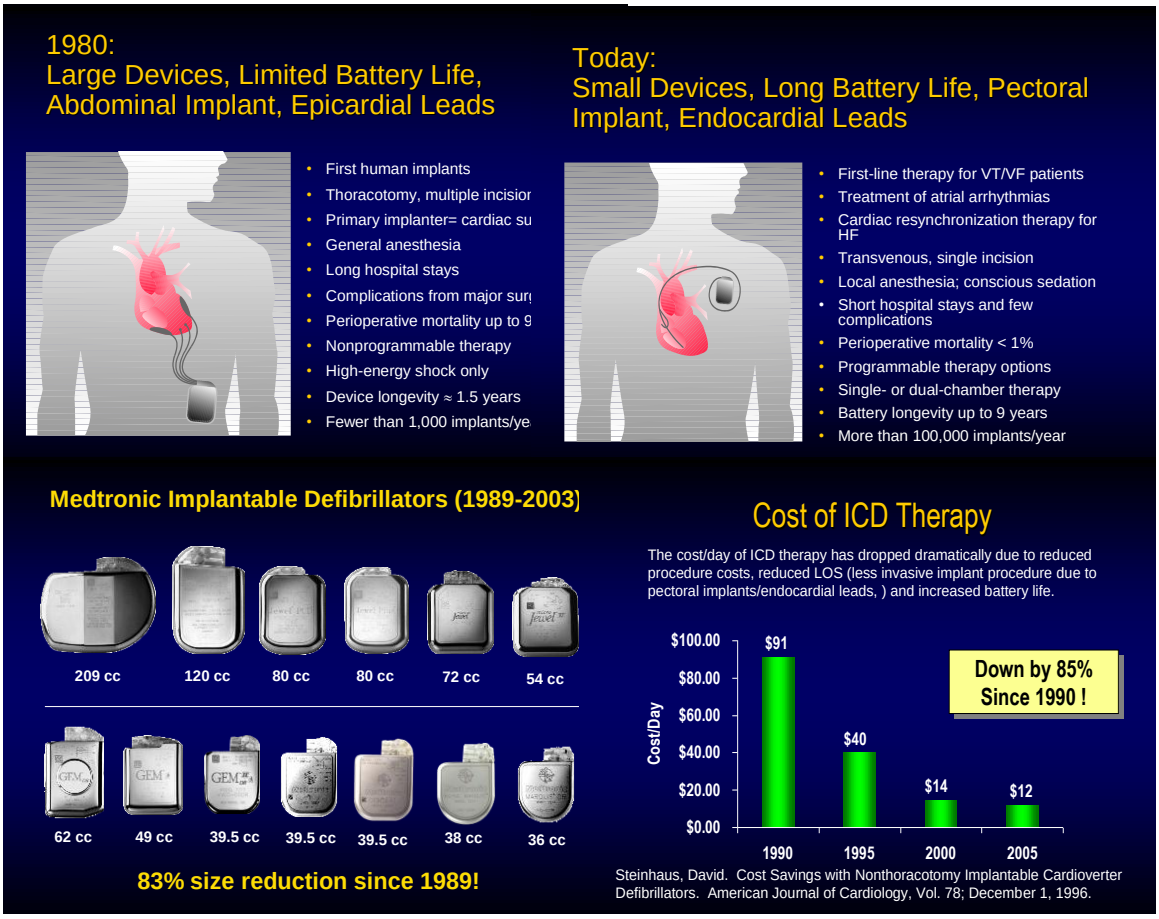
It is a reasonable and responsible position to take to assert that new technologies should receive an appropriate and fit-for-purpose level of evaluation from both a safety and a cost effectiveness perspective. With this in mind it is important to note that while it is undeniably possible to identify a few examples where new technologies have resulted in poor outcomes for patients, it is more usually the case that the evolution of technology can be proven to have major benefits for patients.

We challenge any suggestion that it is of no consequence that a medical device be prevented from entering the market because it does not arrive with the same level of evidence a pharmaceutical product may have. This displays both a lack of acknowledgement of the different challenges for medical devices in collecting evidence, the difference in the rate of development of new technology, and most

importantly, the incremental nature of development of technology. **Critically, it ignores the fact that denial of access to beneficial technology may cause just as much harm to patients if not more.**
Those who make policy must take the time to carefully understand the risk benefit equation and the fact that if a system lets a technology through that subsequently causes harm to patients, it is disastrous for those individual patients and their families as well as publicly damaging for governments, regulators, physicians and manufacturers. However, the harm in this case can be identified; support and compensation provided to the patient and further harm prevented by stopping supply.

On the other hand if potentially life saving and life changing technologies are prevented from entering the market, **the harm caused by denying access to these patients cannot be easily identified; the harm continues to occur unabated and no support can be provided to those harmed**. This may be a more difficult concept to get the attention of media and others in the public sphere but it is extremely important for those considering responsible public policy.

A good example of the iterative nature of medical technology development and the benefits of this development is the Implantable Cardioverter/Defibrillator (ICD).



In the space of around 15 years the size of an ICD has dropped by more than 80%, at the same time the simplification of the insertion procedure has reduced deaths from complications associated with the implant from around 9% to significantly less than 1%. Battery life increased from around 1.5 years to now over 9 years saving patients from multiple replacement surgeries and the risks that go with those and accordingly the cost per day of therapy has reduced by around 75%. In addition to this the information about the patient's condition stored in the device and the flexibility of the software controlling the devices has increased exponentially allowing physicians to better tailor treatment and reduce complications even further. This was not achieved in one large step; it has been a process of incremental development with a new updated model available every 12-18 months.

Medtronic is also concerned that the current application of a very academic and pharmaceutical-based approach to economic assessment of medical devices by the Medical Services Advisory Committee (MSAC), as well as poorly outlined and implemented internal processes, will have the same effect and may well also limit access to life saving and beneficial technologies in Australia.

5.0 Pre Market Assessment vs Post Market Surveillance

The legitimate concern for public safety in the area of regulation of medical devices most effectively addressed by looking for practical areas where the surveillance of the performance of products, once they have entered the market, and the mechanisms to act upon that information can be improved. Medtronic and the industry stand ready to actively engage and consult with government and regulators to meet these objectives. On the other hand measures that attempt to increase the already rigorous, risk-based, pre-market assessment hurdles will quickly find that they meet the law of diminishing returns in terms of increased safety and will undeniably restrict and delay access to life saving and life changing new technologies, as well as significantly increase costs.

Medtronic is concerned that some of the proposals outlined in the TGA discussion paper entitled *Reforms in the Medical Devices Regulatory Framework* may well cross that threshold. Members of the committee can access Medtronic's complete response to this at this internet address: http://www.tga.gov.au/pdf/submissions/consult-devices-reforms-101130-submission-ma.pdf

6.0 Regulation and Reimbursement in France

In evidence it was suggested to the Committee that the "French System" might be a better way for Australia to evaluate and reimburse new medical devices.

We are not experts in the operation of the “French System”. In the short timeframe available we have not been able to fully research and check each aspect of this information but there is a good outline of the French process published by the International Society for Pharmacoeconomics and Outcomes Research (ISPOR) on their website
http://www.ispor.org/HTARoadMaps/FranceMD.asp

However in our view the French system, whilst it has some different nuances reflecting the different structure of their healthcare systems, in many respects parallels the Australian system, and has quite similar tests for the reimbursement of medical technology.

Regulatory entry is governed by the French Competent Authority AFSSAPS which ensures that products entering the market in France have been assessed as meeting the Essential Principles required to gain a CE mark. In most respects these Essential Principles are the same as those required under Australian Law and regulation and applied by the TGA.

Separate to the regulatory gateway there are a number of reimbursement gateways for medical devices, broken into:

- a DRG (activity based funding/efficient price) process which is similar to that operated by some State governments for funding and which is being rolled out on a national basis in Australia.
- A procedure-based evaluation process for Procedure Codes which is similar to the work MSAC does to recommend MBS codes for Medicare reimbursement.
- A product based insurance list based on a benchmark benefit level for products similar to others on the market which is broadly similar to the Prostheses List process.
- This is supplemented by a more detailed evaluation process to set benefits for new types of products that don’t have existing comparators (this is currently being developed as a part of the HTA Review implementation process for the Prostheses List).

One thing that does stand out in France, is a process which actively allows less proven new therapies to come to market early under a special evaluation process which requires the collection of clinical data to review the performance of the product on the market. This is one area we think may have merit for further consideration.

It is our view that the HTA review has already extensively covered Australian reimbursement systems. Recommendations have been made after extensive and broad consultations and the recommendations are currently being implemented. While there are still opportunities for consultation on aspects of the implementation and management of these recommendations, we don’t see

great value in re-opening the fundamental bases of this process before it has been fully implemented and the results evaluated.

7.0 Summary

We appreciate the opportunity to provide this supplementary submission and hope that it may assist to clarify a number of issues raised during public hearings.

Medtronic strongly supports the goal of providing a system of Medical Device Regulation which provides protection for Australian consumers. At the same time there is also an imperative to ensure this is appropriately balanced with recognition that timely access to breakthrough technologies, which can change and save lives, is equally important.

This balance is best achieved by retaining the existing world's best practice pre-market regulatory framework and strengthening this where necessary, appropriate and practical with enhanced post-market surveillance activities which can include well designed and managed post-market registries.

If it would assist the committee Medtronic would be happy to provide more information on any aspect of our submissions or appear to give evidence.