Medtronic

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# Comments on TGA Consultation

## Designation of Australian Conformity Assessment Bodies for Medical Devices

03 January 2017

## 1. Executive Summary

Medtronic welcomes the opportunity to respond to the: *Designation of Australian conformity assessment bodies for medical devices – Implementation which was opened on November 16, 2016.*

We recognize the position of the TGA as the national regulator charged with insuring the quality, safety, efficacy and timely availability of therapeutic goods, and that the TGA must balance the risk of a device failing against the timely availability of a medical device.

Medtronic supports the option of introducing CABs designated within Australia as an alternative to conformity assessments performed by the TGA. Medtronic believes that there are efficiency gains of using CABs that will ultimately benefit the health outcomes of the Australian patients.

## 2. 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 Operational Headquarters based in Minneapolis, Minnesota USA. Medtronic Australasia is headquartered in Sydney, Australia.

*Workforce*
Medtronic employs more than 70,000 people worldwide with more than 1200 people in Australia.

## 3. Overview and specific comments

Many of the comments are specific to various sections and are tabulated for easy reference.

**Section: Introduction**

**No comments**

**Section: Scope and Context**

| Page Reference | TGA Question | Medtronic Comment and recommendation |
|---|---|---|
| 9 | Should designated Australian conformity assessment bodies (subject to capability etc.) be able to provide conformity assessment certification for all medical device applications? Should some device types or classes continue to be required to hold TGA conformity assessment certification? | The proposal to restrict high risk devices under 4.1 is not acceptable. All device classes should be able to use the option of utilising the Australian CAB. The rationale is based on the following reasons:<br>• It is noted that any organisation that will potentially apply for Australian CAB operation will be an organisation with global operations and therefore will have the relevant resources and expertise.<br>• It is also noted that even though the review process for the high risk implantable products is complex, there are only a limited organisations worldwide that have expertise in this area and therefore only those who have the expertise will apply and will be approved thereby eliminating any risk to Australian patients or public health and<br>• Excluding high risk devices may result in the model being financially non-viable for the Australian CABs. |
| | Does your organisation market devices to countries relying on 'home market' regulatory approval? How would this proposal impact on this? | No.<br>Medtronic does not currently manufacture any products in Australia and therefore "country of origin" is not applicable. |
| Context | Are there other key issues which should be considered in developing this proposal? | The TGA Regulations for Medical Devices are based on EU model and therefore adequate consideration should be provided to the "approved" Notified Bodies as per the revised EU MDR when applications are submitted for Australian CAB.<br><br>Medtronic would like to see due consideration be given to the Conformity Assessment from a European Notified Body. The aim should be to reduce the duplication of efforts in review of the same documentation by Australian CABs.<br><br>The ideal outcome would be for companies to lodge one application to the European Notified Body (also acting as an Australian CAB) and the assessment is carried out at the same time avoiding duplication of efforts. |

**Section: Cost recovery and Competitive Neutrality**

| Page Reference | TGA Question | Medtronic Comment and recommendation |
|---|---|---|
| 12, Cost Recovery | Should the costs of designation be recovered directly as fees from conformity assessment bodies, or is it appropriate that some or all costs be recovered through other mechanisms such as charge on all medical device sponsors? | The costs of designation should be recovered directly as fees from the CABs and the CABs should be allowed to set their own charges.<br>It is not appropriate to charge the rest of the Medical Device sponsors for assessment costs for the services which they have not used. |
| 12, Competitive Neutrality | Are there other competitive neutrality concerns for the Designating Authority function that you can identify? | It is important that the Designating Authority apply the same rules to the TGA Conformity Assessment as to the Australian CAB. |

**Section: TGA Conformity Assessment Function**

| Page Reference | TGA Statement | Medtronic Comment and recommendation |
|---|---|---|
| 15 | TGA would continue to offer a full suite of conformity assessment functions. Is this important to you or your organisation? | This will not be required for multinational companies such as Medtronic which has headquarters outside of Australia and whose products are assessed in various regions around the world. |
| | Do you or your organisation have an interest in seeking designation as a conformity assessment body? What are the issues which would affect your decision to apply for designation? | Medtronic has no interest in seeking designation as a CAB. |

**Section: Designation Framework**

| Page Reference | TGA Statement | Medtronic Comment and recommendation |
|---|---|---|
| Page 19 | Should the designation framework be aligned to MDSAP requirements, European requirements or a hybrid? | It is recommended to be continued to be aligned with the EU requirements. This would attract the European Notified Bodies to apply and become Australian CAB. |
| | Should particular aspects of each system be adopted for a hybrid approach? | We are not supporting a hybrid approach. |
| | How might alignment to MDSAP and / or European framework be managed as international regulatory convergence develops? | The current alignment with the European regulations should be continued and any changes to those should be managed as per current practise. |
| Designation Criteria | Are the listed criteria appropriate and comprehensive? | The list is comprehensive; however, the recommendation is to follow a standard such as:<br><br>*ISO/IEC 1702X series of standards Conformity assessment - Requirements for bodies providing audit and certification of management systems.* |

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|---|---|---|
| | Are there particular issues which should be considered in developing these criteria for the regulatory framework? | The criteria for "competitive neutrality" should be applied in that whatever designation criteria are applied to the Australian CABs, same should be applied to the TGA's CA section as well. |

**Section: Operational Arrangements**

| Page Reference | TGA Statement | Medtronic Comment and recommendation |
|---|---|---|
| Page 20 | In addition to any feedback on specific aspects of the proposed approach to designation of Australian conformity assessment bodies, we are also interested in broader comments on the proposal | There is a growing consensus towards harmonisation of regulatory requirements as it is not possible for either the regulators or the industry to keep adding resources to meet the growing demand.<br><br>Therefore, we welcome the proposal of Australian CABs which would reduce the burden on the regulator.<br><br>We also think that European Notified Bodies (who are approved as per the revised EU MDR) should be given some additional weightage (or reduced assessment from Designated Authority) should they choose to apply to be an Australian CAB.<br><br>It is noted that the comparable overseas regulators such as US FDA, PMDA (Japan), and HC have moved to establish a more open approach for device reviews. While it is acknowledged that the TGA assessors have to act within their limitations as per the TG Regulations, a much more open and flexible approach would benefit the industry as well as patients.<br><br>We believe that introduction of Australian CABs will bring this open approach to the Australian regulatory landscape which ultimately will benefit the Australian patients. |
| | Comments might take into consideration the context for change and issues to consider outlined in the introduction, and consider the risks and benefits of this proposal and how these might be managed. | We highly recommend that the Designating Authority to be a separate function from the TGA in order to achieve competitive neutrality. |