Medtronic

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Comments on TGA Consultation

Accelerated assessment of Medical Devices Priority Review Pathway

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1. Executive Summary.

Medtronic welcomes the opportunity to respond to the: *Priority Review pathway – 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 is a leader in innovative medical devices and supports the option of introducing priority review pathways.

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: Current Environment

Page Reference	TGA Question	Medtronic Comment and recommendation
9	Are there any other environmental issues that would inform or benefit the development of the proposal?	With the shrinkage of international boundaries and growing availability of information, currently patients and HCPs are accessing information from overseas websites / seminars / conferences and making decisions based on the availability of device in overseas markets (which are still not approved in Australia). Having an expedited pathway will provide further confidence and will benefit **all** population in Australia instead of a select few.
	Are there other issues to be considered in developing this proposal?	N/A

Section: Principles and Criteria

Page Reference	TGA Question	Medtronic Comment and recommendation
	Are the criteria appropriate to restrict acceptance for Priority Review to the truly new and novel devices for patients in immediate need? Noting that acceptance of a large number of applications would undermine the viability of Priority Review.	The criteria will not be useful for many of the overseas manufacturers as they will be using their own regulators to access the priority pathway. The TGA's expectation of "clinical evidence" will mean that the devices will have to wait until such time that the "clinical evidence" is satisfactory as per the current TGA draft guidance on clinical expectations. The TGA should accept the device for review if the comparable overseas regulator such as USFDA has already accepted the device under their scheme.
	Do the proposed criteria cover all issues which should be considered in assessing a medical device for Priority Review designation?	Yes.
	What is your estimated likelihood of making an application for a medical device to have Priority Review designation?	Highly unlikely as the requirements for "novel" device are the same as current TGA's requirement of "clinical evidence". In our experience, the comparable overseas regulators have discussions in advance in terms of expectation of "clinical evidence"; and then the application is assessed based on the agreed evidence, however, there is no such avenue available with the TGA.

Section: Implementation of priority review

Page Reference	TGA Statement	Medtronic Comment and recommendation
	Is the proposed sponsor alert timeframe adequate for industry?	4 weeks is a reasonable timeframe for sponsor alert.
	Decisions will need to be made promptly, within six (6) weeks. Large submissions will undermine this, as will applications that are incomplete in meeting the criteria. Will applicants be able to present a succinct and compelling argument for Priority Review designation, independent of the full application process?	Yes, however, 6 weeks is a long timeframe for review of a proposal. The ideal timeframe should be 4 weeks.
	In the proposed implementation it is expected that sponsors on receipt of designation advice will promptly submit their full application for conformity assessment or inclusion. Is this a reasonable expectation?	The proposal is acceptable.
	It is proposed that priority review status will be revoked if timeframes for reply to request for information are not met. Is the existing practice of a twenty (20) working day timeframe appropriate?	The proposal is acceptable.
	Is the proposed approach to publication of Priority Review applications and decisions appropriate?	The proposal is not acceptable.
	Is the proposal to publish medical device product information for consumers supported, and what extent of detail would consumers seek?	The proposal is not acceptable.
	Is the Priority Review pathway for designated applications adequately detailed? If not, which areas are unclear or require more detail?	• Further clarity on costs is required. • The TGA needs to commit to a timeframe for review for such applications (60 days for level 2 audit and 180 days for CA audits, excluding queries). • Also the document provides a comment that the TGA resources will be re-assigned and there needs to be adequate resourcing for the rest of the applications.

Section: TGA Operational Impacts

Page Reference	TGA Statement	Medtronic Comment and recommendation
	Are there any gaps in the proposed implementation plan?	The document provides a comment that the TGA resources will be re-assigned and therefore it is important to have adequate resourcing available for the rest of the applications. In addition, if the "experts" for the review are not available in Australia, how would the TGA address the gap?
	What aspects of the proposed implementation would you suggest for inclusion in a post-implementation review?	The review should include: • Statistics on the number of applications received verses accepted by the TGA so that the effectiveness of the "criteria for the priority review" are validated. • The TGA should publish the review timeframes.
	What timeframe would you suggest for the review – 1 year, 2 years or 3 years after commencement?	3 years as the first two years would be too early to collect sufficient and valid data.