Senate Community Affairs Committees for inquiry into the Regulatory Standards for Medical Devices in Australia

Submission from Boston Scientific Australia New Zealand

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Executive Summary

The Senate Inquiry into the Regulatory Standards provides an opportunity to consider the progress being made in reforming of wider Health Technology Assessment as well as the regulatory processes in Australia, and whether these reforms have improved access to technologies while mitigating the risks to patients.

Boston Scientific was active in the creation and therefore supports the MTAA Submission on behalf of industry. Boston Scientific own Submission is designed to illustrate and reinforce the views outlined in the MTAA Industry Submission.

Boston Scientific does not supply orthopaedic products, but is a significant manufacturer and supplier of highly complex and sophisticated medical devices, such as defibrillator and drug eluting cardiac stents.

The key recommendations of this Submission are:

1. Clear separation of regulatory; clinical and cost effectiveness assessment; and reimbursement functions.

2. Continued international harmonisation, including working with, and recognising the work of other regulators and notified bodies. In addition, working with other regulators and countries to strengthen the use of clinical evidence and methodologies for assessment and review.

4. Addressing the perverse incentives created by the Prostheses List only covering implantable devices, when a non-implantable device maybe more clinical appropriate and/or more cost effective.

Boston Scientific Australia

Boston Scientific is a worldwide developer, manufacturer and marketer of medical devices for over 25 years. Boston Scientific employs over 25,000 employees with revenue of $US9 billion in 2010. Australia is important to Boston Scientific; we employ 160 people, with offices in most states. Australian expertise is also recognised, with BSC using Australian hospitals in its next generation drug eluting stent trials, and hosting international training for New Zealand and Asia based physicians.

Boston Scientific's mission

To improve the quality of patient care and the productivity of health care delivery through the development and advocacy of less-invasive medical devices and procedures.

This is accomplished through the continuing refinement of existing products and procedures and the investigation and development of new technologies that can reduce risk, trauma, cost, procedure time and the need for aftercare.

Boston Scientific provides products in the following medical areas

Interventional Cardiology

Boston Scientific is the worlds largest supplier of drug eluting stents, and the only sponsor in Australia with two stent platforms – TAXUS® Liberté® Paclitaxel-Eluting Stent and PROMUS Everolimus Eluting Stent. BSC also provides balloon angioplasty catheters and bare metal stent systems, embolic protection devices, the Cutting Balloon® Device, and ultrasound imaging systems.

Boston Scientific is also the sponsor of several large international and Australian interventional cardiology trails, and registries. These include the ground breaking SYNTAX Trial that compared drug eluting stents with CABG in complex patients, Horizon AMI Trial, ATLAS Trial, and registries at Monash University and Melbourne Interventional Group.

In addition, Boston Scientific is recognizing the talent of Australian researchers with its appointment of Ian Meredith (Monash University) to be the principle investigator for its new generation of drug eluting stents.

Cardiac Rhythm Management (CRM)

Boston Scientific's Cardiac Rhythm Management (CRM) Group is a leading developer of implantable devices used to treat cardiac arrhythmias, sudden cardiac arrest and heart failure.

Implantable cardiac devices are often used in conjunction with other therapies, such as medications, to manage cardiac arrhythmias and heart failure. They include:

- **Pacemakers** treat bradycardia by serving as a sophisticated timer that monitors the heart's intrinsic rhythm for any delayed or missing beats and helping the heart beat when necessary.

- **Implantable cardioverter defibrillators** (ICDs) treat tachycardia by monitoring heart activity and either pacing or shocking when the heart's rhythm is dysfunctional. In the event of lethal arrhythmias, the device delivers a shock to cardiovert the heart back to normal sinus rhythm.

- **Cardiac resynchronization therapy** (CRT) devices treat heart failure by helping to restore synchrony to the heartbeat and thereby improving pumping efficiency. A patient may receive a CRT system that also offers defibrillation capability in case the patient's heart exhibits life-threatening ventricular arrhythmias—which can lead to sudden cardiac arrest and death.

Endoscopy/Gynaecology

Boston Scientific's Endoscopy business is a market leader in the field of endoscopic (pertaining to the digestive tract) and pulmonary medical device technologies.

Less-invasive treatment options for diseases of the digestive and pulmonary systems include products and procedures designed to help perform biopsies, retrieve gallstones, retrieve foreign bodies in the airway, remove polyps, open strictures of the digestive tract and airway (narrowing of a bodily passage), stop internal bleeding (due to ulcers or ruptured blood vessels), palliate (ease) symptoms of some types of digestive tract and airway cancers.

Today, Boston Scientific is investigating and introducing a number of innovative technologies, such as the Spyglass™ Direct Visualization System designed to offer an endoscopic option for the diagnosis and treatment of biliary diseases.

Urology

Boston Scientific's Urology business is a leading developer of medical technologies used to diagnose and treat urological disorders.

Less-invasive treatment options for urological disorders include devices for the diagnosis and treatment of conditions such as: kidney stones; female urinary incontinence; pelvic floor reconstruction; urethral strictures; BPH; and urinary retention. Boston Scientific's devices are used by urologists to treat diseases of the genitourinary tract (kidney, ureter, bladder, urethra, prostate and pelvic floor) and by urologists, urogynecologists and gynecologists to treat incontinence and pelvic floor reconstruction.

Today Boston Scientific is investigating a number of technologies for the treatment of prostate cancer, bladder cancer and urinary retention.

Peripheral Intervention

Boston Scientific's Peripheral Intervention business is a leading developer of medical technologies used to diagnose and treat peripheral vascular disease. Boston Scientific's peripheral products provide a broad range of options to meet the needs of peripheral interventionalists. Product lines include stents, balloon catheters, sheaths, wires and vena cava filters.

Today, Boston Scientific is investigating a number of innovative technologies; in particular, drug coated stents leveraging Boston Scientific's TAXUS program and carotid artery stenting taking advantage of the Company's core competencies in vascular intervention.

Neuromodulation

Boston Scientific's Neuromodulation business is the innovation leader in less-invasive microelectronic implantable technologies used to treat chronic neuropathic pain. The use of minute pulses of electricity delivered directly to nerves, known as spinal cord stimulation, BSC has improved this technology with re-chargeable pulse generators, individually programmable 16 point leads that reduce unwanted side effects and long-term costs associated with pain medications.

Introduction

The Senate Inquiry into Regulatory Standards of Medical Technologies provides us with a timely opportunity to reflect on the current processes for meeting the two aims of:

1. Ensuring that all medical technologies available in Australia are intrinsically safe and effective; and

2. That patients and health professionals have access to these technologies

This Inquiry seeks to look at a wide range of issues. To simplify our response, BSC would like to address the following questions.

1. Regulatory Framework to improve the quality and safety of technology

2. Ensuring affordable access to technologies

Boston Scientific worked with other sponsors on the MTAA Submission that provides an industry wide view. BSC's Submission compliments the MTAA work, and as such does not attempt to comprehensively respond to the full range of issues. Instead it is designed to highlight key issues that are also covered in the MTAA Submission.

Background

In December 2008, the Government announced a review of the HTA processes including the regulatory and reimbursement processes for medical devices. We are less than 18 months into the implementation, so this inquiry provides an opportunity for a mid-implementation review.

The overriding objective of public policy must be to ensure that patients have access to the best available technology in a timely fashion.

1. Regulatory Framework to improve the quality and safety of technology

There are three important ways to ensure only high quality and safe medical devices are available in Australia:

- Regulation of individual devices
- Quality management systems
- International harmonisation

Regulation of individual devices

Australia uses the internationally recognised risk methodology for determining the type of review to be performed on each device prior to market approval. This risk-based approach means that the more risk the more requirements.

Depending on the level of risk, the onus is on the manufacturer to demonstrate that they have met the essential principles required for approval. Included in this, the manufacturer must demonstrate that they have considered all risks associated with their device. The manufacturer must identify

and detail how they have managed the risk. This is achieved via product testing, clinical trials and via their quality management system.

The TGA has wide powers to investigate and inquire into all aspects medical devices sponsored in Australia. The TGA can increase the burden of evidence required to support a medical device approval by up-classifying the device as has recently happened with orthopaedic hips and knees and occurred previously with devices that pass through the iliac arteries.

Critically in this process, is that the manufacturer must list all tests undertaken, and also why other possible tests were not undertaken. The TGA and other regulatory agencies consider whether the manufacturer has demonstrated that the benefits outweigh the risks.

This also impacts the current debate about re-manufacturing devices designed and validated for a single use. The manufacturer designed and tested the product to meet its requirement to be used once only. As such, the product testing and design information does not provide any evidence to support continued use, reprocessing and multiple-patient treatments. In short, if the principle is that a manufacturer must assess and manage the risk, there has been no assessment, and therefore no explicit management of the risks associated with the device, which is being re-used. The manufacturer only validated it for a single use, and there will not be a validation or worse case scenario testing of the device. Without this, patients are placed at increased risk due to the off-label use and potential device failure.

Quality Management Systems

The second aspect of the TGA is approving the quality management system of the sponsor and manufacturer of a medical technology. This process helps determine whether or not the claims made by the manufacturer in the relation to their products are true. It also determines whether the sponsor has systems that would ensure that if there is a problem, they could identify it, and address it.

By separately approving the device, and then approving the quality system the TGA has the power to see whether not only the initial device is safe and fit for intended purpose, they can also see whether the manufacturer and sponsor meets the requirements of on-going supply.

Furthermore, the sponsor is required to report adverse events, and provide an annual (after initial approval) and bi-annual report on market experience of the product to the TGA.

Re-manufacture of single use devices undermine the Quality Management Systems of the original manufacturer. The sponsor and manufacturer are required to capture all product experience, and adverse event reporting. This information is trended to determine if there is a risk. Without stringent tracking of re-manufactured devices, the original manufacture maybe advised of a product problem or failure related not to their single use device, but to the device once it has been re-manufactured. This could result in product holds or recalls while the issue is investigated, resulting in surgeries being postponed.

Furthermore, the sponsor is required to be able to track all devices to the hospital level. It would be increasingly difficult for hospitals to confirm they have remove all such products in the event of a recall, as it would be unclear what products relate to the recall.

International Harmonisation

Australia is a large country with a small population, and represents 2.6% of the global medical device industry sales. The Australia market is actually smaller than the city of Los Angeles, let alone California. Given this there is a balancing act between ensuring safety and quality requirements and ensuring access. Put simply, if the regulatory requirements are too difficult to meet, then sponsors may opt not to seek registration. This would mean the policy settings, whilst theoretically protecting patients, actually denies them treatment options.

The way to address this is by linking with larger markets to ensure that as many countries as possible are lifting the regulatory standards in unison. Australia is well aware of this and hence was one of the founding members of the Global Harmonisation Taskforce.

The GHTF allows smaller markets like Australia to influence the global requirements of medical devices. Explicitly, it recognises that suppliers will have difficulty meeting unique requirements of smaller markets.

The GHTF provides an avenue to improve the standards of medical devices the world over. The more countries that work within the GHTF framework, the strong the incentives for manufacturers to meet increasingly high standards

The work of the GHTF and the newly announced alliance with New Zealand do provide an opportunity to progressively modify the requirements for devices overtime. In fact, most reputable manufacturers are activity involved in this process recognises the concerns of the public and health care professionals in continuously improving medical practice.

2. Ensuring affordable access to technologies

The second aspect the Senate is examining relates to the mechanisms used to ensure medical devices are affordable to the patient.

In February 2010 the Government accepted13 of the 16 recommendations from the HTA Review. The recommendations set to one side had budget implications that required further consideration.

Since February 2010 the Department of Health and Ageing has been gradually implementing the recommendations against a rather aggressive timeline. In general the implementation has been well handled, properly consultative, and respectful of the different interests of the stakeholders. The MTAA Submission provides an overview of the progress being made.

While we are largely satisfied with the progress, there is one area where Australia does need to consider adjustments to its funding processes. The Prostheses List was designed to provide certainty to patients and health professionals, as well as hospitals and health funds, on what surgically implanted devices would be covered by health funds. The Prostheses List was created to resolve a long-standing and on-going point of tension. However, as technology changes, it in itself is creating perverse incentives.

The definition of prostheses restricts the range of medical technologies to be covered to only those surgically implanted. If the device is not surgically implanted it is not covered. Increasingly technologies are being designed such as radiofrequency ablation, which if used, prevents the need for implantable devices, such as a defibrillator. However, because of the funding definition, patients are receiving a more expensive defibrillator rather than undergoing a less invasive first line treatment.

BSC shares the concerns of health funds that we do not want to address these perverse incentives by listing every possible device. However, there is an opportunity to create an alternative list of surgical treatments requiring non-implantable devices to provide patients and doctors with the same certainty they enjoy from the Prostheses List.

BSC is working with the MTAA on a principled-based approach to creating a "Schedule C" for non-prostheses device treatments. As technologies evolve, there will be increasing need for a explicit list that enable doctors to provide the most appropriate treatment option for their patients. To do this, Australia will have to eliminate the perverse incentives inherit in the Prostheses List definition.