ST. JUDE MEDICAL
MORE CONTROL. LESS RISK.

Submission by **St Jude Medical Australia Pty Ltd** to the Senate Standing Committee on Community Affairs Inquiry into the Regulatory Standards for the Approval of Medical Devices

This submission addresses Term of Reference (b)

'the cost effectiveness of subsidised devices'

Executive Summary

St Jude Medical believes that the criteria to include a device on the Prostheses List are out-dated and unreasonably restrictive. This results in the delivery of care that is more expensive, but yet delivers poorer outcomes.

We recommend that the Prostheses List Rules be revised to enable the clinical effectiveness and cost effectiveness of devices that do not meet the present narrow criteria to be taken into account. In the short term we recommend the Minister of Health and Ageing exercise her discretion to list appropriate products as is currently the case with cardiac loop recorders and insulin pumps.

Introduction

St Jude Medical Australia has long had concerns that the rules surrounding the Prostheses List are unreasonably restrictive and result in perverse economic incentives. These economic incentives work against best practice and are not in the best interests of Australians who purchase private health insurance.

These concerns have been brought to the attention of the House of Representatives Standing Committee on Health and Ageing on a number of occasions. St Jude Medical Australia welcomes the opportunity to bring this matter to the Senate's attention.

We would like to use the example of the St Jude Medical Pressure Wire to illustrate where the most cost saving and effective clinical treatment is not delivered to patients as a direct result of the rigid and anachronistic Prostheses List Rules.

The Prostheses List Rules

The Prostheses List rules require the following:

The product should:

(a) Be surgically implanted in the patient and be purposely designed in order to:

(i) replace an anatomical body part; or

(ii) combat a pathological process; or

(iii) modulate a physiological process; or

(b) be essential to and specifically designed as an integral single-use aid for implanting a product, described in (a) (i), (ii) or (iii) above, which is only suitable for use with the patient in whom that product is implanted; or

(c) be critical to the continuing function of the surgically implanted product to achieve (i), (ii) or (iii) above and which is only suitable for use by the patient in whom that product is implanted; and

5. The product has been compared to alternate products on the Prostheses List or alternate treatments and:

(ii) assessed as being, at least, of similar clinical effectiveness; and

(ii) the cost of the product is relative to its clinical effectiveness

The requirement that a device ***be surgically implanted*** is problematic in some cases. This criterion is very dated and does not take into account the technological advances that have come about since this criterion was written. In some cases a less effective and more costly treatment will be delivered because the device involved is implantable and therefore included on the Prostheses List and the alternative, but superior treatment path involves a device that is not implantable.

Economic Consequences of the Prostheses List

In general the Prostheses List is a useful tool that gives certainty to hospitals, insurers and suppliers of medical technology. When a device that is included on the Prostheses List is implanted in a private patient, the hospital will receive a benefit from the insurer which in most cases will cover the cost of the device. A device that is not included on the list will be paid for by the hospital. Even though arrangements between hospitals and health funds are often based on a case fee where all services and products other than prostheses are included, there is a strong incentive for hospitals not to use a non-listed device, regardless of its effectiveness, when it results in a procedure becoming financially unviable.

We would like to use the example of the measurement of Fractional Flow Reserve (FFR) during coronary angiography to demonstrate the consequences of this perverse incentive.

Fractional Flow Reserve (FFR) guided Coronary Interventions

Product/Procedure

When a patient has a heart attack or is diagnosed with angina, a coronary angiogram is usually performed. A coronary angiogram is a procedure that uses X-ray imaging to see the heart's blood vessels. During cardiac angiography blood pressures are recorded and X-ray motion picture shadow-grams of the blood inside the coronary arteries are recorded. These recordings can reveal the cause of a heart attack or angina which is generally the narrowing of the coronary arteries through fatty deposits or plaque known as coronary stenosis (blockage).

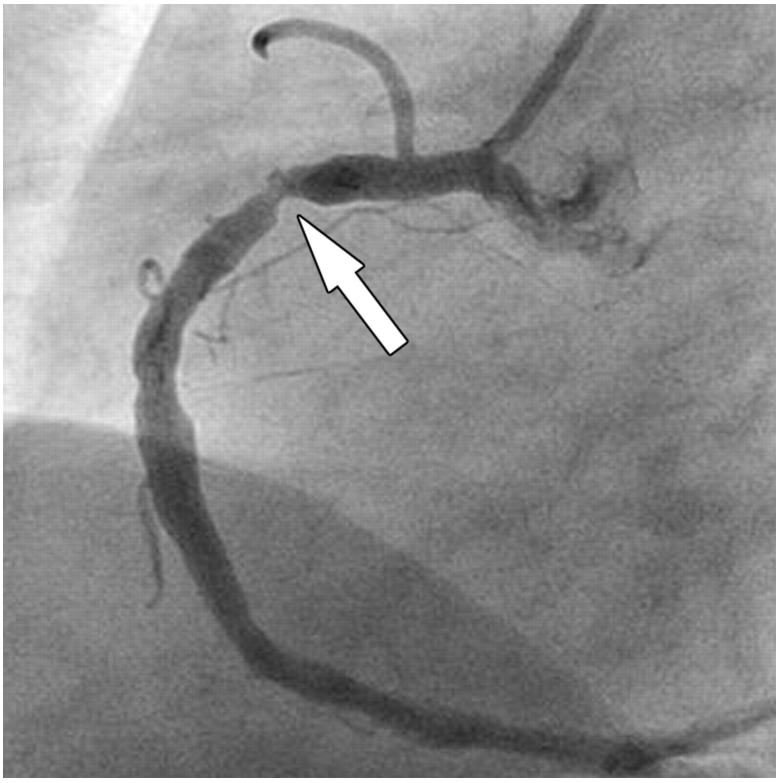

Diagram 1 – Right Coronary Artery narrowing

Coronary Angiography shows the exact site of the narrowing or occlusion of the coronary arteries. It can also show the severity. This is generally done through the physician determining the size of the occlusion via visual images (eyeballing) on cardiac monitors. This however can be inaccurate[1].

FFR is measure of the actual severity of a blockage that is calculated from pressure measurements taken from inside the artery with a St Jude Medical Pressure Wire. This approach allows for immediate diagnosis as to the extent a particular blockage contributes to the patient's angina and the decision of whether treatment (usually a stent) of the blockage is warranted.

Imaging such as Angiography, CT and IVUS (Intravascular ultrasound) cannot identify which individual lesion/lesions are the causes of patients' angina. Imaging can both over and under estimate lesion severity, either leaving significant lesions untreated or causing excess treatment. Imaging cannot take into account any other factors other than what the lesion looks like.

Pressure Wire features a miniaturised, high fidelity pressure sensor for measurement of pressure inside the coronary artery for accurate FFR measurement. When integrated into routine practice, measurement of fractional flow reserve (FFR) has been shown to reduce the incidence of heart attack and death by 34% by more accurately placing stents only where they are needed and placing stents in lesions that would have otherwise been thought insignificant. It also reduces death, heart attack, repeat procedures, and coronary artery bypasses by 28 percent combined [2]

The average number of stents used is reduced by 30 percent.

The evidence supporting these findings is of the highest order and has recently been recognised as such by the European Society of Cardiologists.

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[1] Pim A.L Angiographic Versus Functional Severity of Coronary Artery Stenoses in the FAME Study: Fractional Flow Reserve Versus Angiography in Multivessel Evaluation. JACC. 2010:2816-2821

[2] Tonino PA, De Bruyne B, Pijls NH, et al. Fractional Flow reserve versus angiography for guiding percutaneous coronary intervention. N Engl J Med. 2009; 360(3):213-224.

European Society of Cardiology (ESC) Guidelines

FFR-guided coronary angiography is recommended for detection of ischemia-related lesion(s) when objective evidence of vessel-related ischemia is not available. The evidence supporting FFR has been placed in highest possible level of evidence category in the new ESC guidelines.

Evidence Level 1A

'1' – Evidence that a given treatment or procedure is beneficial, useful, effective

'A' - Data derived from multiple randomised clinical trials or meta-analyses

Economic Considerations

- **The benefit paid by health funds for drug eluting stents is $3450.**
- **The St Jude Medical Pressure Wire costs $1360.**
- Evidence shows that an average of **2.74** coronary stents is used per case.[3]
- This is reduced to an average of **1.93** coronary stents per case if FFR is measured first with a pressure wire.
- Hospitals will receive a benefit of **$3450** for each stent used so the number of stents used will not impact them financially
- They do not receive any additional benefit for using a pressure wire
- There is a financial disincentive to using this device in private hospitals despite the significant decrease in heart attacks, death and overall cost.
- The uptake of this technology is much greater in the public sector than in the private sector as there are different financial drivers.

[3] Tonino PA, De Bruyne B, Pijls NH, et al. Fractional Flow reserve versus angiography for guiding percutaneous coronary intervention. N Engl J Med. 2009; 360(3):213-224.

Health Insurers

Most health funds are supportive of this technology, and some will intermittently pay a benefit- primarily on request several days prior to the procedure. However this is very inconsistent, impractical in the real world and varies between insurers and even between patients admitted to different hospitals who are covered by the same health insurer. It is also an ineffective mechanism in emergent cases. It creates inequities where some private patients have access to a technology that greatly reduces their risk of myocardial infarction or death and others do not.

Patients are likely to be quite unaware as to whether they have had the benefit of this technology or not.

Financial analysis shows that health funds are likely to save $1200 on average per case if a benefit is paid for Pressure Wire in the same manner that a benefit is paid for stents.[4]

Health funds are understandably reluctant to pay an additional benefit for a product when they are not obliged to. In our experience this holds true for many insurers even when the benefits to their members is not in doubt, it is likely they will save money themselves and they acknowledge that this is indeed the case. We can only surmise that this is due to a reluctance to set a precedent.

St Jude Medical Pressure Wire and the Prostheses List

An application to include this device on the Prostheses List was recently declined on the basis that:

'These devices are not a prostheses and do not meet the criteria for listing. They are not implanted, nor left in the body.'

It is our understanding that the clinical superiority and cost saving nature of the device was not in question - merely that it did not remain in the body. It is difficult to understand why regulation is

[4] O'Malley. S 'The financial advantage of using the Radi coronary pressure wire in patients with multi-vessel CAD' Feb 2010

limiting access to this device when government policy is to support procedures which improve outcomes and save money, nevertheless this is the case at present.

Minister Roxon's stated and very reasonable rationale behind listing cardiac loop recorders and insulin pumps despite not meeting the criteria is the following:

'***Products will only be listed where they are clinically effective, cost effective, provide significant health benefits to patients and prevent the need for expensive downstream medical costs'***[5]

The St Jude Medical Pressure Wire exceeds these criteria in that it is not only cost-effective but cost saving. Savings are made not only in downstream medical costs by a reduction in heart attacks, repeat procedures and death but are also accrued immediately due to the reduction in use of unnecessary coronary stents.

To address this issue, the government has a simple policy solution

1. ***The Prostheses List Rules could be amended as in the case of Insulin Pumps and Cardiac Loop Recorders***

This would be a sensible policy decision which would save money and improve patient outcomes in the short term.

To prevent further instances where the Prostheses Rules limit access unreasonably to clinically superior and cost saving devices, the criteria for Part C of the Prostheses List which includes Insulin Pumps and Cardiac Loop Recorders should be revised as a matter of urgency.

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[5] Second Reading Speech - *Private Health Insurance Legislation Amendment Bill (No.2) 2009*

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Submission by **St Jude Medical Australia Pty Ltd** to the Senate Standing Committee on Community Affairs Inquiry into the Regulatory Standards for the Approval of Medical Devices

This submission addresses Terms of Reference

(a) 'the role of the TGA in regulating the quality of devices in Australia

(d) 'the processes in place to ensure that approved products continue to meet Australian standards

(e) the safety standards and approval processes for devices that are remanufactured for multiple use

Executive Summary

St Jude Medical Australia believes that the TGA is the appropriate body to assess the safety, quality and performance of medical devices supplied in Australia. However we regard the proposed regulatory reforms to increase the level of evaluation of Class III and AIMD medical devices to full conformity assessment by the TGA to be a costly and inefficient duplication. The TGA has failed to demonstrate how this duplication of regulatory evaluation will provide additional protection to support TGA's stated mission of safeguarding the health and safety of the Australian public.

St Jude Medical Australia believes that the proposed regulatory reforms will do little to improve protection to Australian consumers and will create a barrier to timely access for Australians to advanced technologies.

We would ask the Senate to consider the appropriateness of the proposed duplication of quality system and product evaluations of Class III and AIMD medical devices that have already been completed to an appropriate standard by an overseas Notified Body.

St Jude Medical Australia supports the use of registries to monitor the use of high risk devices. However costs and governance should be shared by all stakeholders. In addition there should be appropriate access to registry clinical data for all stake holders, including manufacturers, consumers and clinicians.

St Jude Medical has serious concerns regarding the approval processes for 'remanufacturing' of single use devices. It is difficult to understand why remanufactured single use devices with questionable supporting evidence are even being considered for supply in Australia while in parallel the proposed level of regulatory burden for Class III and AIMD single use medical devices is increasing.

We fail to understand the rationale behind this TGA process or how this is in the interest of the health of Australians.

Term of Reference (a)

'the role of the TGA in regulating the quality of devices available in Australia'

SJM considers that the TGA is the appropriate body to assess the safety, quality and performance of medical devices supplied in Australia.

New medical device regulations came into effect in Australia in 2002 which provided a risk-based approach harmonized with the European Medical Device Directives. Given that 98% of medical devices in Australia are imported and the Australian market represents a miniscule 2% of the global medical device market, it is entirely appropriate that the TGA leverage benefit from both the recognition and acceptance of quality system audits and product evaluations that have been conducted by competent organisations overseas. Over the past nine years, significant confidence building activities have been undertaken between the TGA and Notified Bodies to assess and establish common, mutually acceptable competency standards to ensure that, where reliance on overseas evaluations is appropriate, the assessments are conducted to an equivalent standard of the TGA.

In response to significant consumer input as part of the HTA Review, the TGA has proposed a range of extreme regulatory reforms which will require full conformity assessment of all Class III and AIMD products by the TGA. This represents a costly and inefficient duplication of quality system and product evaluations that have previously been completed by a competent overseas Notified Body.

Furthermore, the delays caused for an already resource-strained government agency by an unnecessary duplication in quality system audits and product evaluations, has the potential to create significant delays in patient access to leading/cutting edge/new and improved medical devices and therapies within Australia.

St. Jude Medical supports the change of classification of hip, knee and shoulder implants to the higher level of Class III in line with Europe. However, the TGA has failed to provide evidence to demonstrate how the current process of reliance on overseas evaluations for

Class III and AIMD medical devices does not provide an appropriate level of protection for the Australian public or how duplicating this process in Australia will provide any additional level of assurance.

In this regard, St. Jude Medical supports Recommendation 10 of the Transparency Review which proposes that Performance Indicators be used to provide quantitative and qualitative information on the TGA's organisational effectiveness and operational efficiency

The recently released Transparency Review Report makes twenty-one recommendations which the Panel believes will enable the TGA to better communicate its regulatory processes and decisions to the community and describes the means by which TGA can provide increased transparency in the understanding by the public of its roles and functions.

This will hopefully address community concerns about the lack of information made available to the public.

Term of Reference (d)

'the processes in place to ensure that approved products continue to meet Australian standards'

Medical device companies and the TGA have strict post-market surveillance procedures in place to report adverse events that occur with approved products. This enables the performance of medical devices in the field to be monitored and the identification of any trends that might indicate a deficiency in the quality, design or performance of a product.

Product registries are a useful mechanism to monitor the performance of high risk devices, however input and involvement of all stakeholders is required to establish appropriate governance. This is not currently the situation with the National Joint Replacement Registry.

A collaborative approach to funding registries is required to ensure that one stakeholder is not unduly penalised as is currently the case with the National Joint Replacement Registry (NJRR). The NJRR is 100% funded by industry.

In addition all causes of revision which may be unrelated to the design, quality or performance of the device need to be considered. These may include infection, surgical method and skill or appropriate choice of prostheses.

Appropriate access to clinical data for manufacturers, consumers and clinicians is required so that early trends can be investigated to limit the ongoing use of devices with demonstrated deficiencies in quality, safety or performance.

Term of Reference (e)

'the safety standards and approval processes for devices that are remanufactured for multiple use'

St Jude Medical Australia has ongoing concerns about significant gaps in the Australian Regulatory Guidelines for Medical Devices (ARGMD) on the Reuse of Single Use Devices.

Australia has a regulatory system for medical devices that is harmonised with the European Medical Device Directives. St Jude Medical Australia fully endorses this approach. Remanufactured devices are not considered suitable for CE marking in Europe.

Under the Australian regulatory system for medical devices, it is the responsibility of the designing manufacturer to determine the intended use of a device based on a thorough understanding of the design, materials, manufacturing processes and risk analysis. If the device cannot be guaranteed by the manufacturer to perform according to specification more than once,

then it must be labeled as **"Single Use Only".** It is incongruous that TGA is currently considering an application to 'remanufacture' products that the original manufacturer has designed to be used only once. It appears that the TGA is contemplating condoning 'off label' use.

Traceability and Post Market Surveillance

In many cases the original manufacturer's name is indelibly marked on the device. We object to a remanufacturer supplying a device that is not being used as intended by St. Jude Medical Australia but which will still bear the company's branding. Any performance issues will likely to be referred to the original manufacturer rather than the 're'-manufacturer.

Batch/lot/serial number information is frequently only provided on labeling which is discarded at the first use and recorded in the patient's medical records, however any subsequent remanufacture and supply will not be traceable by the original manufacturer.

We believe remanufacturing of single use devices will negatively impact on post market surveillance procedures which require the manufacturer to maintain distribution records so that devices can be traced in the event of a deficiency in quality, safety or performance. St Jude Medical Australia has serious concerns that in the event of a field action or recall the company's products will be impossible to trace if they have been remanufactured by a third party.

Informed Patient Consent

The Eucomed White Paper released in December 2009 (http://www.eucomed.org/uploads/Press%20Releases/Eucomed%20White%20Paper%20on%20the%20reuse%20of%20single-use%20devices.pdf) makes compelling reading and cites several ways in which the remanufacturing of single use devices may elevate the risk to the patient to an extent where the overall risk outweighs the benefit and these include:

- Potential risk of cross infection where the remanufacturing process is unable to completely remove micro-organisms particularly prions because of the design of the device or the materials used
- The accumulation of chemicals used for sterilization to unsafe levels
- Damage to the integrity of the materials due to repeated processing
- Potential for mechanical failure because single use devices are not designed or validated to withstand the unpredictable fatigue that is associated with reuse

Patients need to be fully informed that a reprocessed medical device may be used during their procedure. Medical ethics require that patients are fully informed of any risks associated with a medical procedure and this requires full disclosure of the potential risk associated with the use of a reprocessed medical device and this should be documented as part of signed informed patient consent.

The TGA has stated in Senate Estimates that the TGA would 'only control labeling requirements but would not usually go so far as to dictate what the physician should say to a patient'[i]. However a physician may be unaware that he or she is using a remanufactured device. Therefore, with TGA's current approach there is no assurance that the patient will be informed of the use of a remanufactured device inside their body.

This issue is of great concern to St. Jude Medical as we are committed to supplying safe and effective products in support of positive patient outcomes consistent with TGAs stated mission of safeguarding public health and safety.

Term of Reference (f)

'the processes in place to notify the relevant authorities and the general public of high revision rates or possible faulty devices'

SJM supports the recommendations of the Transparency Review report which recommends processes for ensuring that information related to deficiencies in the quality, safety or

performance of medical devices will be made available to health care professionals and the public as early as possible. However, this must be done with extreme caution so as not to cause unnecessary anxiety and concern to patients or to disclose commercially confidential information where there is no clearly demonstrable benefit to health care professionals or consumers.

[i] Community Affairs Senate Estimates June 2010