Community Affairs
Senate [redacted] Committee
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Inquiry: Medical Devices
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Medical Technology Association of Australia

Senate Community Affairs References Committee
Inquiry into Reforms to Medical Devices Regulatory Framework
26 September 2011

Thank you for the opportunity to appear before the Committee.

MTAA represents the manufacturers and suppliers of a wide variety of medical devices which provide life-sustaining assistance to patients in need, deliver long-term improvements in quality of life, and aid the day-to-day comfort of patients.

Without medical devices patients would not be able to hear, to walk, to see, or in some cases, to survive.

Tragically from time to time there can be a catastrophic failure of a device. The challenge for us all (law-makers, the regulator, doctors and industry) is to learn from failures to ensure that the systems are as robust as possible, consistent with global best practices, so that Australian patients are assured of the safety and efficacy of the medical devices that deliver life-enhancing benefits.

I would like to address key issues raised in our written submission

Australian regulatory system for medical devices

- Australia has a risk-based system of assessment for the approval and registration of medical devices – the greater the risk in terms of how invasive within the human body the product is, the duration of use and the risk it poses to the patient, user or other person, the greater the evidence required to support registration
- Australian system applied by TGA is similar in concept to that used in Europe – it requires a manufacturer to comply with a comprehensive set of essential principles of safety and efficacy based on internationally agreed standards
- System combines an assessment of manufacturer's documentation (technical dossier) prior to registration with ongoing obligations on the company to monitor & report on performance of the approved device

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Explaining the differences between drugs and devices to understand different regulatory treatment

- Regulation of safety and efficacy of medicines is based on pharmacology and chemistry where the properties and action of active ingredients are determined in pre-clinical and clinical studies. Clinical evidence is obtained mostly pre-market from large double-blind randomized controlled trials
- In contrast, randomized, double-blind, placebo-controlled trail designs are very difficult, and often unethical, to implement the evaluation of a device and/or surgical procedure
- Ongoing assessment of a medical device, after the device has been used with a patient, becomes more critical with the patient experience becoming part of the assessment process
- Another key difference between drugs and devices lies in the development cycle. Medical devices are developed in a framework of continuous innovation and iterative improvements based on advances in science, technology and materials
- In comparison pharmaceuticals are developed following extensive research and development of a specific molecule or compound with the result that it can take many years for a new drug to enter the pipeline.

Assessment of medical devices for reimbursement

- All high risk implantable devices are assessed by the relevant clinical group before listing on the Prostheses List for reimbursement
- Products are assessed on the basis od clinical effectiveness
- Clinical effectiveness is assessed on 2 years' clinical evidence of the device in use with patients.

Key themes from reviews

Over the past 2 years there have been several reviews which have looked at the regulation and/or the reimbursement of higher risk medical devices, and more recently the transparency of TGA and its processes. There are some key themes which emerge from these reviews:

- Increased rigour of assessment of higher risk medical devices
- Improved alignment of assessment processes through the health technology assessment pathway – from regulatory to reimbursement
- Improved transparency of information about medical devices available to consumers
- Improved post market surveillance (recognizing key differences in pre-registration assessment between drugs and medical devices).

Background to HTA Review

Of these the Review of Health Technology Assessment was the most wide-ranging.

HTA Review:

- Supported by both sides of Parliament – initial work undertaken under Howard Government with Tony Abbott as Health Minister
- Review initiated by Rudd Government under Nicola Roxon as Health Minister
- Followed several reports from the Productivity Commission and a review by Robert Doyle

HTA Review

- Relevant recommendations for reform:
    - That TGA increase the rigour of regulatory assessment of higher risk medical devices
    - That the processes for assessment and listing of implantable devices for reimbursement by private health insurers be improved with increased transparency and consistency in decision-making
- Very significant series of reform proposals which are currently at varying stages of implementation
- Reform has been undertaken in a consultative manner with regular engagement with clinicians, hospitals, consumers, private health funds, industry

Current status of reforms

- Regulatory:
    - phase 1 of TGA response to HTA Review was released last week and addresses:
        - upclassification of orthopaedic joints (earlier paper circulated in 2009)
        - identification of products registered on the ARTG
        - responses to recent Transparency Review as they concern medical devices (provision of product registration material; provision of consumer information)
- Reimbursement of implantable medical devices listed on the Prostheses List:
    - Improved processes for assessment of devices
    - Grouping of like products with allocation of a benchmark benefit (rather than the previous negotiated position)

- Cost effectiveness emerging as an additional consideration.

Areas for further reform

- Post-market surveillance – 3 recommendations from HTA Review deferred by Government:
  - Reporting of adverse events has been addressed in part by Transparency Review by proposing better methods to ensure patients and doctors are aware of reporting lines into TGA
  - Clinical registries to monitor medical devices once used with a patient

Single use devices

- Standalone term of reference
- As with all regulated products the overriding concern is for patient safety
- Need to ensure that the standards to assess a remanufactured medical device are at least as rigorous as for any originally manufactured device and are able to identify and track remanufactured devices
- TGA guidelines as published in the ARGMD set additional requirements for remanufactured products - would like more transparency on what assessment is undertaken
- Under an agreement between States and Commonwealth, States have agreed that any remanufacturing by public hospitals will also meet these standards – would like reassurance that public hospitals comply with this requirement
- Patient awareness of remanufactured single use devices and informed consent to use

MTAA perspectives on key themes from numerous reviews

- Support an increase in the regulatory assessment of higher risk implantable risk devices – as evidence in the recently announced reforms to upclassify class IIb orthopaedic joints to class III

- BUT Australia is a small market and therefore changes to requirements in Australia can't exceed the regulatory requirements in comparable markets because the result will be that Australian patients will not have access to newer beneficial technology

- Support expansion of clinical registries for PMS BUT these need to meet ACQSQHC guidelines (shared funding, accountable governance, appropriate data management) and preferably meet Australia's health priorities (eg. based on cost of device/procedure, patient numbers, risk to patient).

- Support increased education on, & awareness of, processes to report adverse events by doctors & patients.