Medical Technology Association of Australia

Senate Community Affairs Reference Committee
Inquiry into Regulatory Standards for the Approval of Medical Devices
29 July 2011

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MEDICAL TECHNOLOGY FOR A HEALTHIER AUSTRALIA

1. Executive summary

The Medical Technology Association of Australia (MTAA) notes the diversity of issues raised within the terms of reference of the referral to the Senate Community Affairs References Committee for an inquiry into the regulatory standards for the approval of medical devices. While directed primarily to a consideration of the regulation of higher risk medical devices, the terms of reference also address issues of reimbursement, and an assessment of the implementation of the Health Technology Assessment Review.

MTAA is pleased to have the opportunity to address the range of issues which have been raised. Medical technologies provide life-saving assistance to patients in need, deliver long-term sustaining quality of life, and provide aid to improve the day-to-day comfort of patients. Without medical technologies patients would not be able to walk (implantable hips and knees), to hear (cochlear implants and hearing aids), to see (intraocular lenses), or to survive (cardiac pacemakers and implantable defibrillators). Each of these advances has significantly changed the way people with life-threatening or life-challenging conditions are cared for.

Australia has a risk-based system of assessment to manage the approval and registration of medical devices. The greater the risk carried by the product 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. The system used by the regulator in Australia, the Therapeutic Goods Administration (TGA) is similar in concept to that used in the European Union. Both regulatory systems require manufacturers to comply with a comprehensive set of essential principles of safety and efficacy. Manufacturers usually adopt internationally agreed standards to achieve this. The international quality management system standard, ISO13485: 2003, which requires manufacturers of medical technology to establish and maintain the high quality of design, manufacturing and postmarket monitoring necessary for medical technology, is a pre-requisite for either TGA or European Notified Body certification. Assessment and certification of these quality management systems occurs before manufacturers are approved to supply their products. Continued adherence to the quality management system requirements is also assessed through regular surveillance audits.

With the rapid evolution of medical devices, the regulatory systems in advanced economies have had to also evolve to ensure that they remain appropriate. It is in this context that the Review of Health Technology Assessment (HTA) in Australia included recommendations that TGA increase the rigour of regulatory assessment of higher risk medical devices. The implementation of recommendations from the HTA Review is currently underway. Proposals for additional regulatory requirements are premature, pending consideration by the Government of a range of proposed reforms.

The HTA Review also made recommendations to improve the processes for the reimbursement of implantable medical technologies listed on the Prostheses List for reimbursement by private health insurers for patients with private health insurance. The tenor of these recommendations is to increase the transparency and consistency of decision-making, but also to require more sophisticated assessment of cost benefit and clinical benefit.

It should also be noted that medical technologies have evolved more recently than pharmaceuticals and that many of the processes for evaluation and assessment of medical technologies have been developed more recently. While they have been developed with awareness of the requirements for pharmaceuticals, there is recognition that medicines and medical devices are very different and that the requirements for evaluation of safety, effectiveness, and cost-effectiveness are necessarily different.

MTAA encourages the Senate Committee to have regard to the recommendations of the HTA Review and their implementation by the Government. Many of the issues raised in the terms of reference to the Committee are well-addressed in the Government's acceptance of the recommendations of the HTA Review and their gradual implementation. MTAA continues to work proactively with the Government to ensure that the benefits of medical technologies can be accessed by patients when needed, with confidence that the regulatory processes are rigorous and that reimbursement to the supplier is equitable.

2. About the medical technology industry

MTAA represents the manufacturers, exporters and suppliers of medical technology products in Australia. Medical technologies are products used in the diagnosis, prevention, treatment and management of disease and disability. Products range from commonplace, everyday consumable items such as bandages and syringes, to high technology implantable devices such as cochlear implants, cardiac defibrillators and orthopaedic joints, diagnostic imaging equipment, and products which use biological materials.

The medical technology industry had sales in Australia of more than $7.5 billion in 2009-10 and employs more than 17,500 people. It is strongly research-based with clinical input from healthcare professionals to design and develop products for improved patient benefit. MTAA represents companies supplying approximately 70% of all non-pharmaceutical medical products on the Australian market.

3. Terms of reference

Given the range of subjects addressed by the terms of reference, MTAA has identified four main themes and deals with each term of reference under these broad headings.

(a) Regulation of higher risk medical devices – paragraphs (a), (d), (f) and (g)

(b) Reimbursement of implantable medical devices listed on the Prostheses List – paragraphs (b) and (c)

(c) Approval of remanufactured single use devices

(d) Effectiveness of the implemented recommendations of the HTA Review.

This submission addresses each of the identified themes.

4. Differences between medicines and medical devices

There are fundamental differences between medical devices and pharmaceuticals which explain the differences in approach to regulation and to reimbursement of the

different product segments. Randomised, double-blind, placebo-controlled trial designs are very difficult, and often unethical, to implement for the evaluation of a device and/or surgical procedure, and therefore not routine.

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 premarket from large double-blind randomised controlled trials.

Medical devices act through physical interaction with the patient, and safety and performance is assessed in terms of mechanical, electrical and materials engineering. Clinical evaluations of medical devices are more challenging (it is rarely possible to double blind a medical device trial) and flexibility of approach is essential, including non-blinded trials (which may still be randomised), reference to comparative data from external sources such as peer reviewed literature and well constructed registries, and a greater reliance on postmarket follow up.

Medical technology covers a wide variety of products and applications – from thermometers and bandages to pacemakers and MRI scanners. Each is designed to perform specific functions and is approved on the basis of safety and performance. Medical technologies are developed in a framework of continuous innovation and iterative improvements based on developments in science, technology, and materials. They generally have a short product life cycle and investment recovery period (typically 18 months on the market). The majority of new products bring added functions and clinical value based on incremental improvements. Manufacturers make a large investment in manufacturing, distribution, and user training and education. In addition, the company will provide service and maintenance for the lifetime of many high technology devices.

In comparison, pharmaceuticals are developed following extensive research and development of a specific compound or molecule with the result that it can take many years for a new drug to enter the product pipeline. Pharmaceutical companies operate with intensive patent protection, including data exclusivity and patent linkage, because of the extensive product life cycle and long investment recovery period. Manufacturers have relatively low manufacturing and distribution costs, and in most cases little training and no service or maintenance costs for products and equipment.

5. Regulation of higher risk medical devices

The terms of reference require the Senate Committee to report on:

(a) The role of the Therapeutic Goods Administration in regulating the quality of devices available in Australia

(b) The processes in place to ensure that approved products continue to meet Australian standards

(c) The processes in place to notify the relevant authorities and the general public of high revision rates or possibly faulty devices

(d) The effectiveness of current regimes in place to ensure prostheses with high revision rates are identified and the action taken once these devices are identified.

While ensuring the safety and efficacy of medical technology products brought into the Australian market, it is also critical to ensure that regulatory requirements in Australia are consistent with, and do not exceed those of, equivalent overseas markets to ensure that Australian patients can have access to the benefits of innovative medical technology.

The Australian regulatory system requires products to meet the requirements for registration (pre-market approval) and ongoing compliance (post-market surveillance). The exact requirements vary depending on the determined risk classification of the product.

Under TGA's risk-based classification system, higher risk medical devices are those which are classified as Class IIb, Class III, and AIMD (active implantable medical devices). Examples of medical devices in each category include:

(a) Class IIb – cardiac monitors, blood bags, dressings providing a temporary skin substitute

(b) Class III – heart valves, medical devices containing a medicine, breast implants

(c) AIMD – pacemakers, RC implantable defibrillators, cochlear implants.

The TGA released a Consultation Paper in 2010[1] proposing a wide range of reforms the regulation of higher risk medical devices. This followed an earlier Consultation Paper in 2009[2] proposing reforms to the classification of implantable hip, knee and shoulder joints. The effect of the proposed reforms on the classification of implantable hip, knee and shoulder joints will be to upclassify these devices from Class IIb to Class III. The major differences between the regulatory assessment of a Class IIb device and one classified as Class III stem from the requirement to submit a more extensive technical dossier prepared by the manufacturer. With a Class IIb device manufactured overseas, the clinical evidence is not routinely submitted to the TGA for review as approval is based on the submission of prior EC certification. However, the TGA could request it if further review was required. Clinical evaluation reports and risk management reports are submitted and reviewed by the TGA for Class III and AIMD devices along with EC certification. In other words, the higher the risk classification, the higher the level of examination of the evidence provided by the manufacturer to demonstrate that the product is safe and effective.

One other ramification of Class IIb devices compared with Class III devices is that systems that have the same intended purpose can reside under the same Australian Register of Therapeutic Goods (ARTG) listing and are not required to be named individually. This should not insinuate that such products are not assessed. They must still meet the Essential Principles under an audited quality management system and are usually assessed by a validated Notified Body in order to achieve EC certification. With the up-classification of hips, knees and shoulder joints in the European Union since 2009, many of these systems have already been fully assessed.

A requirement inherent in the quality management system adopted by medical device manufacturers is the need to continually ensure the design and manufacturing

[1] http://tga.gov.au/newsroom/consult-devices-reforms-101130.htm
[2] http://tga.gov.au/pdf/consult/consult-devices-joint-replacements-091023.pdf

processes produce devices that perform as required. If changes to the design or manufacturing processes are contemplated, either directly by the manufacturer or resulting from postmarket monitoring, the quality management system requires those changes be assessed, tested, reviewed and approved before the changes are implemented. If those changes could affect the safety or performance of the medical device, the TGA or the EU Notified Body that issued the certification also has to approve those changes before it can be implemented by the manufacturer.

In addition to the evidence supplied by a company when applying for registration, there are ongoing obligations on a company to monitor and report on performance of approved medical devices. These requirements apply to all medical devices irrespective of risk classification.

A manufacturer is required[3] to notify the TGA, or the sponsor, as soon as practicable after becoming aware of any serious adverse event. These are events which might have caused (or may cause) serious injury or death of a patient and which may have been associated with the medical device. These include events which may be related to malfunction or deterioration in the characteristics or performance of a medical device, and any inadequacy in the design, production, labelling or *Instructions for Use* of the device. These requirements also extend to "near misses" where the event did not result in patient harm but may do if it happens again.

If the event represents a serious threat to public health a sponsor is required to report that information to the TGA within 48 hours after they become aware of it.

There is a requirement for a thorough manufacturer investigation of the event to identify the root cause. Such investigations often are conducted with the active involvement of TGA or other regulators. The manufacturer is required to implement corrective actions which may include changes to product design, labelling or production process, issue of advisory notices to users or product recall.

A manufacturer is also required to notify the TGA or the sponsor with information relating to any technical or medical reason for a malfunction or deterioration that has led the manufacturer to recall a product. Recalls conducted in Australia must be notified to TGA and are required to be supervised and audited by TGA.

In addition, a manufacturer is required to "systematically review information gained after the device was supplied in Australia"[4]. This information can come from expert user groups, customer surveys, customer complaints and warranty claims, service and repair information, literature reviews, user feedback other than complaints, device tracking and registration registers, user reactions during training programs or adverse event reports from users.

The TGA has a voluntary reporting system for users of medical devices to report faults or issues with the products they use. The users range from medical practitioners and nursing staff to individuals who have purchased a medical device. These reports are investigated by the TGA and can involve the manufacturers assisting the TGA to determine the cause of any reported issues.

A company may voluntarily withdraw a product from the market for a range of reasons, including awareness of a deficiency in the product which has been reported to the TGA. One of the tools which has assisted companies to monitor the

[3] Schedule 3 of the *Therapeutic Goods Regulations (Medical Devices) 2002*
[4] Therapeutic Goods Administration, *Australian Regulatory Guidelines for Medical Devices* (Version 1.1)

performance of a product has been the use of registries. The National Joint Replacement Registry (NJRR) has been collecting data on the revision of orthopaedic procedures since 1 September 1999 and provides a good source of information in identifying products which have outlier results once adjusted for surgeon technique and hospital infection or other causes of revision unrelated to the device.

MTAA supports the development of other registries for higher risk medical devices but on a planned and informed basis. MTAA would like to see registries developed in accordance with public health priority areas to ensure that the cost of the registry delivers maximum benefit to the healthcare system.

In November 2010 the Australian Health Ministers' Conference (AHMC)[5] endorsed the *Strategic and Operating Principles for Australian Clinical Quality Registries* which had been prepared by the Centre of Research Excellence in Patient Safety (CREPS) at Monash University. MTAA supports the formalisation of guidance for registries and in particular, the following areas:

- Australian Clinical Quality Registries must be able to demonstrate well-organised and well-documented governance structures incorporating representation from stakeholders including funders and policy developers

- Registries must have processes for demonstrating the engagement and commitment of all relevant stakeholders.

MTAA also supports the position[6] that responsibility for registry funding should not rest solely with one stakeholder group when others clearly will benefit. This contrasts with the NJRR which is funded by the medical technology industry alone, notwithstanding that multiple stakeholders benefit from its data.

6. Reimbursement of implantable medical devices

The terms of reference ask the Senate Committee to report on:

(a) The cost effectiveness of subsidised devices

(b) The effectiveness and accuracy of the billing code and Prostheses List.

Australia does not have a system of publicly funded medical devices as there is for pharmaceuticals through the Pharmaceutical Benefits Scheme (PBS). For privately-insured patients, after purchasing the prosthesis from its supplier, the patient's hospital is reimbursed by the patient's health insurance fund an amount determined by the Australian Government based on a benchmark amount applicable to each group of like products. In most cases this should be sufficient to cover the purchase price without imposition of a patient co-payment.

For public patients who do not have private health insurance, medical devices form part of the hospital care delivered in the public health system and are purchased by the relevant health authority.

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[5] http://www.safetyandquality.gov.au/internet/safety/publishing.nsf/Content/PriorityProgram-08_clinical1

[6] Monash University Department of Epidemiology and Preventive Medicine *Funding for clinical quality registries - the Australian Cardiac Procedures Registry* http://www.crepatientsafety.org.au/registries/funding_for_clinical_registries_acpr_experience.pdf

The criteria for listing on the Prostheses List require that a device must be implantable. This requirement is unnecessarily restrictive and does not take into account advances in technology. As a result private patients do not always receive the benefits of technologies which are otherwise available on the Australian market.

There can also be cost implications for the health system. A treatment path that is more costly and less effective may be followed because the device involved is implanted compared with the device involved in the alternative pathway which is not. The implantable device will attract a benefit from a private health fund where the alternative device does not. MTAA acknowledges that the Government's HTA Consultative Committee has terms of reference which will include examination of funding for cost-effective technologies that are not eligible for listing on the Prostheses List.

Until the recent HTA Review, cost-effectiveness of implantable prostheses was assessed relative to comparator devices already on the Prostheses List. This was an imprecise process which at times produced anomalies and inequities. As a result of the HTA Review, the process for grouping of products and the application of a benchmark benefit for each group of like products has been gradually implemented. While it is recognised that there are challenges in performing cost-effectiveness analyses of a medical device or component, the product grouping scheme was set up to enable comparisons – a simpler and more appropriate approach than evidence-based assessments for reimbursement of products on the Prostheses List.

Notwithstanding this development, the previous arrangements served to significantly cap the level of benefits reimbursable to a supplier. If effectiveness of the Prostheses List can be measured by the cap on benefit increases then it has been very effective. The average minimum benefit for products on the Prostheses List has not increased for some time. There are approximately 3,000 items listed on both the 2005 and 2011 Prostheses Lists under the same billing code and product category. An analysis of these items shows that average minimum benefits have decreased by 3.95% since 2005. This is well below the percent change expected with CPI which is an increase of 19.79%. The decrease in minimum benefits is most marked for the general miscellaneous category where the minimum benefit has decreased by 21%.

As a result of the implementation of recommendations of the HTA Review, the recently-established body which makes recommendations to the Government on the level of benefits, the Prostheses List Advisory Committee, now has broader stakeholder representation. This body is expected to contribute to the iterative development of assessment processes appropriate to determining comparative value.

With regard to the effectiveness and accuracy of the Billing Code and the Prostheses List, MTAA has observed ongoing efforts by the Department of Health and Ageing to ensure that product descriptions contained in individual Billing Codes are appropriately descriptive of the approved listing and that all entries continue to have current registration on the ARTG. This is a burdensome task in respect to a list with over 9,000 entries but a necessary task which MTAA supports.

7. Safety standards and approval processes for remanufactured single use devices

The term of reference requires the Senate Committee to report on:

(a) The safety standards and approval processes for devices that are remanufactured for multiple use.

The process of "remanufacturing" is one of disassembling, cleaning, re-testing each disassembled component, constructing a device from validated components, resterilising, re-validating, and repackaging a device which the original manufacturer validated for a single use, to render that device fit for the original intended purpose. A remanufactured single use device is not approved to be used more than once; it is sent back after each use to be remanufactured

The TGA applies the same regulatory standard to the remanufacture of a device as it does to the original manufacture. Remanufactured devices are subject to TGA regulatory requirements identical to those which apply to the original device. Such requirements may range from direct TGA audit and certification for higher risk devices, to acceptance by TGA on the basis of overseas certifications for devices already subjected to established assessment requirements or by manufacturer self declaration of low risk (class I devices). The manufacturer of a non-low risk remanufactured medical device is required to be audited and certified by the TGA before it can submit an application to supply that product in Australia.

While there is a diversity of views among MTAA member companies about the appropriateness of remanufactured devices, all MTAA member companies expect the application of the same standards and high thresholds of quality and safety, regardless of original manufacture or remanufacture.

8. Effectiveness of the implementation of the recommendations of the HTA Review

The HTA Review provided a long-awaited opportunity for a whole of system consideration of the assessment of non-pharmaceutical medical technologies. The need for a review had been identified over several years by the Productivity Commission[7]. It was also supported by both political parties during their time in government.

The HTA Review was conducted by the Department of Health and Ageing with input from a stakeholder working group with representation from all the relevant stakeholder groups – clinicians, consumers, private health insurers, private hospitals, and the medical technology industry. The report was delivered in December 2009 to the Ministers for Health, Nicola Roxon, and Finance, Lindsay Tanner, who had jointly commissioned the report. In February 2010 they accepted 13 of the 16

[7] Productivity Commission, 2005 *Impacts of Advances in Medical Technology in Australia*, Research Report; Regulation Taskforce, 2006 *Rethinking Regulation: Report on the Taskforce on Reducing Regulatory Burdens on Business*, Report to the Prime Minister and Treasurer; Productivity Commission 2008, *Regulatory Burdens: Manufacturing and Distributive Trades*, Research Report

recommendations. The recommendations set to one side had budget implications which 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. At Attachment A is a short analysis by MTAA of the effectiveness of implementation of each recommendation.

One recommendation which has not been implemented to date for budgetary reasons is the development of further medical device registries. MTAA supports this initiative but as outlined earlier in this submission, registries need to be well-designed with clear objectives, equitable governance and funding, with the data available to all stakeholders. MTAA has sought guidance from the Minister for Health and Ageing on the Government's health priorities to better inform industry investment in further registries beyond the NJRR.

9. Conclusion

MTAA urges the Senate Committee to have regard to the considerable effort which is being applied by policy-makers to modernise the requirements for assessment of medical technologies, both for regulatory purposes and reimbursement purposes. Similar developments are occurring in other advanced economies and it is critical for Australian patients that these local changes occur in step with them. Australia is a small market (2.6% of the global market) with over 80% of all medical technologies imported. While MTAA recognises and supports the legitimate interest in ensuring that Australians are cared for and not put at risk, the Australian system is already robust, world class and continuing to evolve. To create unique requirements for Australia that put us out of step with other major economies will result in Australians no longer having access to innovative technologies and becoming dependent on ageing technology.

Attachment A

MTAA assessment of implementation of HTA Review

Following is a summary of activity against each recommendation and MTAA's view on the effectiveness of implementation.

Recommendation 1

That the impact of the proposed changes to the Commonwealth Health Technology Assessment (HTA) system approved by the Australian Government be evaluated within three years of the government response to this review.

Noted. We are now 17 months into the three year time frame for the initial implementation period.

Recommendation 2

That the rigorous consideration of evidence be consistently applied across all Commonwealth HTA processes to ensure sustainability of the Australian Government's health financing arrangements.

While there is not yet clear complete consistency of evidence requirements across all Commonwealth HTA processes (and there is unlikely to be total consistency because of different requirements for different product types), the level of evidence now required for medical technologies has significantly increased. This is consistent with developments in many other jurisdictions around the world. In MTAA's assessment the requirements to date do not exceed those of comparable countries but are at least equivalent to the more demanding countries. The Department of Health and Ageing (DoHA) is currently producing a draft clinical evidence paper detailing requirements for listing on the Prostheses List. Finalisation of this document should cover existing gaps and clarify issues of contention for stakeholders.

Recommendation 3

That the Commonwealth HTA system be guided by the vision, goal, objectives and principles articulated in this Report.

Implementation of the broad outline for the Commonwealth HTA system set out under recommendation 3 remains a work in progress. However there is evidence of improving transparency and efforts to introduce greater flexibility to accommodate the concept of 'fit for purpose' in the development of some areas of HTA activity.

Recommendation 4

That DoHA establish a website for Commonwealth HTA processes by July 2010 which:

a. describes the roles, responsibilities and relationships between the different HTA processes;

b. facilitates access to all related Australian Government HTA websites to ensure that policy and guidance for all Commonwealth HTA processes are easily accessible; and

c. *regularly publishes reports on agreed performance and activity data to clearly demonstrate the performance of the system and focus attention on areas requiring performance improvement.*

The website has been established (see http://www.health.gov.au/hta) and does bring together the various Commonwealth HTA activities on one site. This is a good initiative. The requirement to report on key performance indicators has yet to be implemented.

Recommendation 5

That the procedural fairness and consistency of Commonwealth HTA processes be improved by 2011, by:

a. *establishing independent review mechanisms and opportunities for re-submissions in a consistent manner for Commonwealth HTA processes (where they are currently not available);*
b. *updating operating procedures for administering Commonwealth HTA processes including by publishing specific milestones and timeframe targets for each individual HTA process;*
c. *improving public disclosure of Commonwealth HTA processes including advisory committee membership, performance and activity data, and assessment and appraisal outcomes (including the rationale for those outcomes);*
d. *establishing and publicising specified communication points with applicants throughout each process, including providing opportunities for pre-lodgement meetings; and*
e. *adopting and implementing transparent and consistent policies and procedures for the management of conflict of interest for all external parties involved in Commonwealth HTA processes.*

This is a work in progress. Formal review procedures have not been established but are needed. There has been some improvement in disclosure. For example, there is now disclosure of Clinical Advisory Group meeting dates with submission cut-off times; and reasons for rejection of Prostheses List applications, although publication of the clinical evidence paper will take this to a higher level. Policies have been introduced to improve the management of conflicts of interest. Communication points have improved as a result of the establishment of the portal.

Recommendation 6

That in order to improve the efficiency of HTA, DoHA establish a single entry point (SEP) by July 2010 to receive applications for subsidy under the MBS, Pharmaceutical Benefits Schedule (PBS) and Prostheses List. The role of the SEP will be to:

a. *provide a single point of contact to help applicants throughout the HTA process;*
b. *determine the most appropriate advisory committee(s) to appraise the technology;*
c. *identify the most appropriate assessment pathway for an application, including by maintaining and reinforcing current processes where these are the most efficient for the technologies submitted to a particular process;*
d. *conduct an initial risk and impact assessment and determine the most appropriate methodology to be used in assessing the technology;*
e. *ensure the timely assessment and appraisal of co-dependent and hybrid technologies, or technologies being assessed concurrently for both public and*

private reimbursement and coordinate the provision of comprehensive advice to the Minister for Health and Ageing (the Minister);

f. *achieve synergies through sharing and sustaining HTA expertise across the advisory committee secretariats; and*

g. *develop and report on the achievement of performance targets for HTA for reimbursement.*

The single entry point has been established. MTAA understands however that the processes for initial assessment and direction of an application are not yet running smoothly, particularly for co-dependent technologies. There does appear to be a degree of collaboration across the various HTA secretariats within DoHA. There is no reporting as yet on performance targets. DoHA has experienced slippage in the implementation of some elements of the reform.

Recommendation 7

That applicants have the option of applying to different HTA processes concurrently. Finalisation of each HTA process may be subject to the completion of a critical antecedent process (such as inclusion on the Australian Register of Therapeutic Goods (ARTG) prior to MBS or Prostheses List listing). This will require procedures to be put in place by July 2010 to allow the efficient flow of information between HTA processes (including from the TGA to other HTA agencies, subject to confidentiality constraints).

Applicants now have the opportunity to lodge applications and have them assessed concurrently. While this may offer some reductions in processing times, the listing of medical technology on the Prostheses List can only be as fast as the slowest critical antecedent process. See comments regarding continuous applications at Recommendation 12.

Recommendation 8

That the Therapeutic Goods Administration (TGA), in the context of international harmonisation:

a. *continue its role as the independent national regulator solely responsible for assessing the safety, quality and efficacy of therapeutic goods for entry on the ARTG and marketing in Australia;*

b. *respond to the issues raised in consultations regarding third party conformity assessment by July 2010, with a view to implementing changes agreed by government by 2011;*

c. *increase the rigour of regulatory assessment of higher risk medical devices by 2011, to ensure an appropriate level of evidential review is undertaken to ensure safety, quality and efficacy of these devices prior to entry on the ARTG and to provide a sound evidence basis for Commonwealth HTA processes; and*

d. *develop protocols by July 2010 for sharing information with other HTA agencies through the SEP (subject to commercial-in-confidence constraints) on the outcomes of its safety assessments.*

While the timeline has slipped, TGA released a consultation paper in late 2010 which outlined significant proposed reforms to the regulation of higher risk medical devices. MTAA understands that TGA has recently presented to Government options for reform, taking into account the submissions received and in particular the cost implications of some of the proposed reforms. The proposed reforms include options for third party conformity assessment but these carry with them a higher standard of

product review with compulsory conformity assessment by TGA of all higher risk devices, whether manufactured in Australia or elsewhere. This removes the inequity between Australian and overseas manufacturers but subjects all to a much more expensive assessment process which in almost all cases will duplicate very rigorous assessments already undertaken by a European Notified Body.

Until MTAA sees the outcome of the Government's consideration of the options which have been put it is not clear whether the reforms will increase the barriers for market entry for medical devices.

Recommendation 9

That by July 2010, MSAC strengthen and streamline its operations and improve the flexibility of its regulatory processes by:

a. providing advice to the Minister based on a critique of an applicant's comparative clinical and economic evaluations , as an alternative to the current process and in the context of agreeing specific timeframes for assessment with the applicant;

b. ensuring that data collection requirements supporting a recommendation for interim funding for a professional service for listing on the MBS are sufficiently rigorous and reliable to provide a sound basis for a final decision on funding;

c. ensuring that its advice to the Minister addresses all aspects of the proposed change to the MBS, especially in regard to the proposed MBS item descriptor and fee; and

d. streamlining current processes for accessing expert advice to improve timeliness of assessment processes and set a target of all advisory panels being established within six weeks of accepting an application.

MSAC had commenced reforms to its processes during the HTA Review. It rolled out further changes to its processes in late 2010 before consulting about the changes. MTAA and others made submissions on the proposed changes but it is not clear that DoHA has in fact taken any account of these submissions. Final guidance material has not been published by MSAC which is leaving companies in the dark about the processes.

There are several issues of concern. The first is that MSAC had indicated an intention to take into account policy considerations before undertaking a health technology assessment of a new procedure (and related technology) which is a divergence from HTA best practice.

There are also issues with the processes which MSAC has deployed. These include unrealistic evidence expectations, and growing delays in the timeline for review and finalisation of applications. Guidance is not transparent to applicants and it is a major issue that there is still no appeal or review process.

Recommendation 10

That in order to reduce regulatory costs:

a. the terms of reference for the PDC and its subcommittees be revised by July 2010 so that it is clear that its assessments of prostheses only consider clinical effectiveness (including comparative cost and comparative safety); and

b. channels of communication between the TGA and PDC should be formalised to ensure that any concerns the PDC encounters regarding the intrinsic safety

of prostheses are immediately referred to the TGA and dealt with appropriately.

The terms of reference have been revised. Channels of communication between the Prostheses List Advisory Committee (PLAC) (the successor to the PDC) and TGA have improved, with further work underway. Both PLAC and TGA have shown a willingness to work together to align practices which should assist companies to more efficiently develop evidence for both regulatory and reimbursement purposes.

Recommendation 11

That the PDC be restructured by July 2010 to ensure that its membership is balanced and:

a. includes individuals with expertise in current clinical practice, health policy and health economics;
b. includes representation from health consumers, health service providers, and the health insurance and health technology industries; and
c. has an independent chair.

The PDC has been restructured and is now known as the PLAC. It is better constituted and more equitably reflective of the stakeholder interests. It includes individuals with specialist expertise who can contribute to deliberations. It has an independent chair, Prof John Horvath, who brings considerable experience in health policy.

This has been one of the more successful HTA reforms.

Recommendation 12

That the arrangements for the Prostheses List be changed by 2011, with appropriate consultation, to:

a. accept applications on a continuous basis, but still make the Prostheses List every six months;
b. establish and maintain groups of products with similar clinical effectiveness;
c. abolish the negotiation of benefits for individual listed products, and instead establish and maintain a single (benchmark) benefit for the products included in each group, with sponsors being required to accept this benefit in order to be listed;
d. abolish the negotiation, setting or publication of maximum benefits, to eliminate the potential for gap payments for patients who have Private Health Insurance (PHI); and
e. permit the establishment of new product groups (or sub-groups) where a sponsor establishes clear superiority of their product compared to those in an existing group.

Initially this recommendation caused the industry more concern than any other recommendation. However MTAA has found DoHA willing to listen to concerns and to adjust the way it has implemented this recommendation to take account of concerns. As an example, in setting a benchmark benefit DoHA has taken account of reasonable utilization which means that a product that might be rarely used does not drive down the benefit for all other products in the same group. This was a significant concession.

While some companies remain concerned about benchmark benefits, on evidence provided at a recent HTA Consultative Committee meeting, in most cases the benefit

has moved very little in the new groups. There are some limited exceptions which impact on a small number of companies.

The abolition of the negotiation of benefits has been a positive move. MTAA had objected to the conflict of interest inherent in the negotiators' position in that they were directly employed by the payers (the private health insurance industry). The time required for companies to prepare for, and participate in, negotiations was also considerable. This is no longer an impost. However, the sponsor still needs the option to respond to proposed grouping and benefits before listing.

The removal of maximum benefits may also have the result that there is an increase in products which carry a patient co-payment. The new system does not take account of a company's commercial prerogative to charge an amount which is different from the benchmark benefit. This may emerge as an issue for other stakeholders as well once the new benchmark benefits are fully implemented.

One positive outcome to flow in implementation of this recommendation is the establishment of the HTA Consultative Committee referred to above. It has had the initial task of reviewing the new groupings and benefits to 'sanity test' them before they are sent to sponsors. However the Committee is to have an ongoing role in reviewing a range of policy issues relevant to the Prostheses List and future private health insurance funding for medical technology. MTAA regards this as a very significant development in that it provides a stakeholder forum for proper consideration of important policy issues.

While the acceptance of applications on a continuous basis provides some advantages, maintenance of a six-monthly interval between Prostheses Lists still imposes significant listing delays in circumstances where applications just miss submission processing deadlines.

Recommendation 13

That, in order to improve the contribution of post-market surveillance to patient safety, the TGA take steps to increase the rate of reporting of adverse events, including by health service providers and consumers.

The reporting of adverse events is one of the areas of focus which is being addressed in the recent Review of TGA Transparency, chaired by Professor Dennis Pearce. The Panel delivered its report to the Parliamentary Secretary for Health at the end of June 2011[8].

Recommendation 14

That, in order to improve the contribution of post-market surveillance to the sustainability of the health system and the longer-term regulatory efficiency of HTA processes, DoHA explore options for consideration by government in 2011 to facilitate the expansion and use of post-market surveillance data to inform safety, effectiveness and reimbursement decisions for devices and procedures.

It is not clear to MTAA whether further work is underway on this recommendation. The extent of post-market surveillance has been raised in submissions to the TGA Transparency Review, particularly with respect to notification of adverse events.

[8] http://tga.gov.au/pdf/consult/review-tga-transparency-1101-final-report.pdf

However the linkage of data which might provide a more complete understanding does not appear to have been progressed.

Recommendation 15

That registers for high-risk implantable medical devices and/or procedures be established, with:

a. key stakeholders such as clinicians, health consumers and industry to participate in governance of and contribution to registries;

b. establishment of mechanisms to apply data from the register to future HTA;

c. the feasibility, benefits and methodologies for data linkage to be explored in a pilot project in regard to a particular device identified by the high-risk implantable devices register;

d. consideration of how developments in e-health and data linkage could improve the efficiency of the post-market surveillance of medical technology more generally; and

e. the development of criteria, the identification of opportunities and the consideration of strategies for improvements in public investment in medical devices.

This recommendation has been deferred because of budget implications.

Recommendation 16

That the Australian Health Ministers' Conference be asked to consider the need for a national approach to HTA processes, including processes required to evaluate blood and blood products.

This recommendation has been deferred because of budget implications.