Regulation Impact Statement

Review of Health Technology Assessment in Australia

1 Introduction

On 18 December 2008, the Minister for Health and Ageing, the Hon Nicola Roxon MP, and the Minister for Finance and Deregulation, the Hon Lindsay Tanner MP announced the Review of Health Technology Assessment in Australia (HTA Review) including that it would be conducted as a Better Regulation Ministerial Partnership. The HTA Review has been undertaken by the Department of Health and Ageing (DoHA) in consultation with the Department of Finance and Deregulation (DoFD). The HTA Review was required to report to Ministers Roxon and Tanner in late 2009.

Summary Terms of Reference for the HTA Review

The HTA Review is to report against the following terms of reference (as follows:

1. Simplification and better co-ordination between Commonwealth HTA processes (as identified in the Review scope), which includes:

a) consideration of a single entry point and tracking system for applications for market registration and funding;

b) making time to affordable access as short as possible for new technologies while maintaining or improving the rigour of evaluation processes; and

c) examination of the feasibility of conducting concurrent assessments for market registration and funding and coverage purposes, noting current work in this area.

2. Improving role clarity and addressing duplication between processes, where it exists, including consideration of consolidating functions with the Australian HTA system.

3. Reviewing post-marketing surveillance mechanisms to ensure the ongoing safety, and efficacy of medical devices.

4. Strengthening transparency and procedural fairness in the assessment, decision making and fee negotiation arrangements for processes (as outlined in the Review scope) through improved communication with stakeholders about process, methodologies, outcomes and performance against key indicators.

5. Enhanced arrangements for assessment of co-dependent[1] and hybrid[2] technologies.

The full HTA Review terms of reference are on the HTA Review website: www.health.gov.au/htareview

The HTA Review is a part of the Australian Government's response to the Productivity Commission's reviews of regulatory burdens on business, which recommended action to reduce fragmentation, duplication and unnecessary complexity in the regulation of medical devices and technologies. Previous reviews of HTA in Australia have found that sponsors of new medical procedures or devices often must navigate a range of HTA processes in order to secure market entry and reimbursement approval. The HTA Review was required to canvass opportunities for reform within existing funding levels and consistent with government policy objectives.

[1] Where therapy involving the use of one health technology to directly improve health (e.g. a medicine or a medical device or a procedure) is improved by the use of another health technology which might more accurately identify patient subsets most likely to gain from the therapy or monitors therapy response.

[2] Where the characteristics of different health technologies (e.g. a medicine or a medical device or a biologic) are combined in one intervention (e.g. laser activated medicines such as photodynamic therapy, or drug eluting stents)

Defining health technologies

Health technologies can be defined as including all innovations in the provision and arrangement of health care such as pharmaceuticals, diagnostic and therapeutic goods and services (including prostheses, devices, diagnostic tests, and medical and surgical procedures). Technologies do not always fall neatly into single categories. As health care is evolving, an increasing number of co-dependent, hybrid and converging technologies are now also in use. These technologies range from a single product with several components known as 'hybrid technologies'[3], to the use of several types of services that may be linked along the clinical pathway (either sequentially or concurrently), known as 'co-dependent' technologies[4].

Health technologies are developed to address particular health problems and thereby aim to improve the quality of people's lives. The World Health Organisation (WHO) notes that they form an indispensable component of the services health systems can offer in the prevention, diagnosis and treatment of disease and in alleviating disability and functional deficiency.[i]

Innovations in health technologies are believed to have contributed to improvement in both the quality and length of life of millions of Australians. However, the increased use of health technology has coincided with and, in the views of some analysts, contributed to, ever increasing health care costs.[ii] In its analysis of the impacts of advances in health technology, the Productivity Commission estimated that:

- half of the improvement in length and quality of life may be due to medical innovations[iii]; and
- technology has contributed around one-third of the increase in real total health expenditure in the decade from 1992-93 to 2002-03. [iv]

The Medical Technology Sector in Australia

In its submission to the Review of Health Technology Assessment in Australia (HTA Review), the Medical Technology Association of Australia (MTAA) noted that:

> *The Australian market for medical technology is approximately 2% of the global market. Because of its small size, this means that companies developing innovative technologies will always need to consider the potential return on investment in making a decision as to whether to bring a technology into Australia or invest in development of a new technology in Australia.* [v]

Figure 1 lists the key characteristics of the medical technology industry in Australia.

[3] For example, a drug eluting stent for treating cardiovascular disease or photodynamic therapy for treating skin disease.

[4] For example, bone densitometry testing associated with access to alendronate (Fosamax) for the treatment of osteoporosis or in situ hybridisation (ISH) testing related to eligibility for trastuzumab (Herceptin) for the treatment of breast cancer.

Figure 1 Medical technology industry in Australia - key facts

- Total turnover in Australia of $7.4 billion in 2008 (expenditure on aids and appliances, major medical equipment, and medical and surgical supplies including surgically-implanted prostheses and homograft items)
- Export revenue of $1.3 billion in 2007-2008
- Imports expenditure of $2.48 billion in 2007-2008
- Produces more than 250,000 products
- Local manufacturers contributed over $2.6 billion to Australia's gross domestic product in 2007-2008
- Manufacturing research and development is 6% of sales income - six times the manufacturing industry average of 1%
- Employs over 17,500 people, with around 50% in manufacturing companies and 50% in wholesaling
- Invested $160 million in R & D in Australia in 2007-2008

Source: MTAA[vi]

In its submission to the HTA Review, the Department of Innovation, Industry, Science and Research (DIISR) described the structure of the medical devices industry as:

> *composed of local small to medium sized enterprises (SMEs), which excel in niche markets, and importers, including many multinational companies... The medical devices industry is knowledge intensive, highly skilled and regulated, and innovation results from considerable research and development.*[vii] *... Australia exports most of the medical devices it produces and imports most of the medical devices it consumes.*[viii]

As DIISR noted, the Australian medical technology industry is characterised by small companies operating in small markets. In this environment, there is a risk that if regulatory arrangements impede timely market access, niche players may opt to set up overseas and market back to Australia, resulting in lost innovation and economic opportunities.[ix]

It is also significant that, in comparison to pharmaceuticals, devices tend to follow an evolutionary development path consisting of small but frequent innovations. Each particular innovation or phase of a device may therefore have a relatively short commercial life span before a competitor introduces a further innovation. These aspects of the medical technology market have implications for the regulatory system. For example, the timeliness of an HTA is especially important as the time taken to approve a device may take a greater share of the 'market window' than would be the case for a breakthrough pharmaceutical with 15 years' patent protection.

The Role of Health Technology Assessment in Ensuring a Sustainable and Effective Health System

In recent years most countries have experienced exponential growth in the use of health technologies such as new pharmaceuticals and diagnostic tools, tele-medicine, and surgical equipment in the treatment of patients. These innovations provide a major opportunity for governments, health care providers and patients to improve health care services and outcomes.

As a result of the rapid spread of these technologies, governments have faced unprecedented challenges in providing high quality and innovative care while managing health care budgets and safeguarding the basic principles of equity, access, and choice. Governments are increasingly required to manage scarce resources strategically, by investing in services that deliver the best health outcomes; this means care that is affordable, effective, safe, and patient-centred. They must also make sure that innovation is adequately supported, with sufficient access to new treatments.[x]

The Australian Government assists Australians in accessing necessary health services by subsidising the cost of health-related goods and services through a range of different funding arrangements. Some of the most significant, and most relevant to the HTA Review, are the Pharmaceutical Benefits Scheme (PBS) for pharmaceuticals, the Medical Benefits Schedule (MBS) for medical services, and subsidised private health insurance for hospital in-patient services. These programs involve substantial costs – in 2008-09, total Australian Government expenditure was approximately: PBS - $8.6 billion; MBS - $14.3 billion; and private health insurance - $2.4 billion. [xi]

The costs of these programs has been rising over time, due to a range of factors including population growth, population ageing, development of new technologies and changing expectations of health care. Ensuring that these programs are delivering value for taxpayers and are sustainable in the longer term requires careful assessment to ensure that the medicines, devices, technologies and services they support are as safe, effective and cost-effective as possible.

Efficient and effective HTA processes are crucial to supporting sustainable management in the growth of subsidised health technologies.

Purpose of HTA

The purpose of health technology assessment (HTA) is to provide policy-makers, funders, health professionals and health consumers with the necessary information to understand the benefits and comparative value of health technologies (that have been registered for use in Australia by the Therapeutic Goods Administration, TGA) and procedures to inform policy, funding and clinical decisions, and also patient choices.

HTA provides a means by which new technologies can be assessed and prioritised against existing health care interventions to determine the best value for money for the Australian community. It is therefore a key tool for the Australian Government to achieve its overall objective of delivering a safe, effective and efficient health system that is financially sustainable in the longer term. The Australian Government established the PBAC, the MSAC and the Prostheses and Devices Committee (PDC) to provide HTA advice on applications for benefit or subsidy under the PBS, MBS or Prostheses List.

2 Issues under review

HTA is a key tool for the Australian Government to achieve its overall objective of delivering a safe, effective and efficient health system that is fiscally sustainable in the longer term. HTA processes apply principally to diagnostic tests, medicines, medical devices, prostheses and surgical procedures. They operate with the objective of ensuring that only safe and effective health technologies are permitted to be sold in Australia and that Australian Government funding (in the form of subsidies) is directed to priority technologies that are both clinically and cost effective.

Since 2005, a number of independent and Department of Health and Ageing (DoHA) reviews of Commonwealth HTA arrangements have been undertaken. These reviews included:

- the Regulation Taskforce report, *Rethinking Regulation – Report of the Taskforce on Reducing Regulatory Burdens on Business* (January 2006)[xii] (known as the 'Banks Review'), which specifically recommended that the Australian Government undertake a system-wide, independent and public review of HTA;
- the Productivity Commission report, *Impacts of Advances in Medical Technology in Australia* (August 2005)[xiii] which highlighted the need for better coordinated, more systematic HTA with transparent objectives, underpinned by the principle of overall

community wellbeing;

- the Report of the Review of the Prostheses Listing Arrangements (October 2007)[xiv] (known as the 'Doyle Review') which made a series of recommendations specific to the Prostheses List and the work of the PDC; and
- the Productivity Commission, *Annual Review of Regulatory Burdens on Business: Manufacturing and Distributive Trades* (September 2008)[xv], which made recommendations around the efficiency of the TGA's processes in regulating health technologies.

The following summary of issues identified by these reviews and key stakeholders (including the medical devices industry) relate to both the operation within and between the various Commonwealth HTA agencies within the scope of the HTA Review. The HTA Review provided an opportunity to systematically validate whether these issues raised in earlier reviews represented legitimate or perceived concerns. Issues included:

<u>Whole of system integration challenges</u>

- At the Commonwealth level, multiple, separate HTA assessment agencies results in unnecessary complexity of regulating and approving therapeutic goods and can cause delay in access to new products. In particular:
  - the sequential pathway of assessments (TGA, MSAC, PDC) in a worse case scenario can take up to 40 months from inclusion on the Australian Register of Therapeutic Goods (ARTG) which allows for market entry to reimbursement
  - processes appear to contain duplication
  - sponsors need to supply the same information in different formats to separate agencies which does not comply with principles of good regulatory process.
- There is a perceived lack of transparency in HTA processes.
- HTA effort is not always targeted to the areas of highest potential health benefit or financial risk. It is essentially reactive, responding to submissions from commercial interests without Government priority setting.
- Duplication of effort between Commonwealth and state and territory HTA activity. Many states and territories have instigated their own bodies to advise on the use of new medical technologies in hospital settings, some of which overlap with the work of Commonwealth HTA agencies.
- Siloed processes prevent consideration of health technologies within a holistic model of care that include prevention, diagnosis, treatment and rehabilitation of disease.
- HTA expertise is specialised and separation of activity does not make best use of the scarce knowledge and skills.
- There is no systematic national process for HTA findings to be linked to clinical practice guidelines to assist in closing the gap between research evidence and contemporary clinical practice.
- There is a lack of organised management of outmoded technologies and interventions, some of which may be harmful to patients as well as wasteful of scarce resources.
- The system does not have the flexibility to respond to new knowledge, including revolutionary technologies such as pharmacogenomics and medicine/device combinations. A clear and consistent framework for considering these products that operates across agencies, including the PBAC, is needed.

TGA challenges

- Australian based manufacturers do not have a choice of certification body. Only the TGA is permitted to conduct pre-market assessment (known as conformity assessment) for domestically manufactured goods. Overseas manufacturers can enter the Australian market on the basis of assessments conducted by third party conformity assessment (TPCA) bodies and under mutual recognition agreements between Australia and the European Community. Domestic manufacturers contend that choice of TPCA body would reduce regulation timeframes and costs and create a level playing field with overseas manufacturers.
- Post market surveillance arrangements are fragmented and largely reactive, with a heavy reliance on sponsors' notification of adverse events. A more comprehensive approach that proactively utilises a variety of data sources to inform ongoing marketing is required.

MSAC challenges

- MSAC is considered slower, more cumbersome, less flexible and possibly less consistent in its recommendations than other Commonwealth HTA agencies.
- Responsibility for establishing and then reviewing the evidence base for MSAC applications lies with DoHA rather than the applicant. The general lack of evidence provided coupled with a "one-size fits all" approach to evaluation results in inefficient use of HTA resources.
- The establishment of expert advisory panels is considered unacceptably slow. These panels are an essential part of the MSAC process and develop the evaluation protocol (essentially the clinical parameters for the review) but can take up to six months to be formed.
- There is currently no targeting of assessment effort based on an application's alignment with health priorities and potential for improved clinical outcomes.
- There are concerns about the thoroughness of the MSAC's cost effectiveness evaluations. The link between the MSAC's conclusions and the MBS fees and descriptors agreed by the Medicare Benefits Consultative Committee is less robust than for other HTA agencies.

PDC challenges

- There is considered to be assessment duplication concerning how safety of devices is assessed by the PDC and the TGA.
- The process is considered onerous, overly administrative and lacks transparency. A particular concern is the limited transparency concerning the choice of comparator used in benefit negotiations and reasons for decisions.
- Limited opportunities are provided to sponsors to comment on assessments and the lack of clinical expertise on the Prostheses and Devices Negotiating Group (PDNG) also limits the level of debate that occurs during price negotiations.
- There are inherent conflicts of interest in the composition of the PDNG and sponsors are concerned that the PDNG are employed by insurers and therefore act on their behalf during negotiations. It has also been argued that the PDC itself is fundamentally unbalanced as it is weighted towards insurer representation as against sponsor representation.
- The biannual application process is too infrequent for products that have a lifecycle of only a few years. In particular, as inclusion on the ARTG is required before an application to the

Prostheses List is made, receipt of an ARTG number shortly after the cut off for a listing cycle means there is a six month delay before an application can be lodged.

- Some products already on the Prostheses List do not meet the criteria for listing, while new applications that do not meet the criteria are being declined. The Health Minister agreed to implement recommendation 8 of the Doyle report - that items on the List that do not meet the criteria for listing should be removed by no later than December 2008[5].
- Individual Clinical Advisory Groups (CAG) are considered to have differing views on what constitutes acceptable clinical evidence for the purpose of listing and benefit level.

3 Objective

Ministers Roxon and Tanner asked DoHA to conduct the HTA Review (in consultation with DoFD) to examine Commonwealth HTA processes and make recommendations about options for improving process efficiency and reducing regulatory burden that can act as impediments to medical innovation, without compromising timely and affordable patient access to medical services and devices that: a) are demonstrated to be safe, effective and cost effective; and b) deliver improved health outcomes and value for money.

The Commonwealth Health Technology Assessment (HTA) processes in scope for the HTA Review were:

1. the regulation of therapeutic goods for market entry, currently undertaken by the TGA;
2. the approval of funding under the MBS, currently informed by MSAC and relevant implementation consultative committees;
3. the listing of prostheses for private health insurance coverage, as currently informed by PDC; and
4. the listing of hybrid and co-dependent technologies as currently informed by the MSAC, PBAC and PDC.

Processes specifically out-of-scope for the HTA Review included those: performed by the Pharmaceutical Benefits Advisory Committee (PBAC) (except where there is an interface between the Medical Services Advisory Committee (MSAC) and PBAC, particularly for co-dependent or hybrid products); relating to the HTA performed jointly by the Commonwealth and the states and territories (such as the regulation or subsidy of blood or blood products); and those wholly within the operation of state and territory government HTA. Any HTA processes conducted by Australian Government departments outside the health portfolio were also not considered.

A key objective of the HTA Review was to address the regulatory burden on business that results from HTA processes, to ensure that those processes are efficient, measured and proportionate. The HTA Review sought to identify opportunities for reform of the processes that may be poorly designed, duplicated or unnecessary, imposing unwarranted costs and complexity on business and discouraging innovation. The recommendations from the HTA Review aim to strike an appropriate balance not only by reducing costs to business but also by improving patient access to safe, effective and cost-effective health technologies through better regulation.

[5] Work is ongoing to implement this Doyle Review recommendation and will continue in the August 2010 cycle.

4 Options considered in the HTA Review

Identifying the issues

The HTA Review conducted an initial round of consultations with stakeholders including inviting and receiving 86 submissions, conducting focus groups with stakeholders and bilateral meetings with key peak agencies to identify the issues that needed to be addressed through the HTA Review.

As part of the Review, DoHA also undertook a comprehensive analysis of current Commonwealth HTA processes which is documented in Appendix G of the HTA Review Report. This analysis identified a number of areas requiring change to improve regulatory burden on industry.

Through this analysis and the outcomes for consultation activities, the HTA Review found that there are a number of areas that need to be strengthened to further improve outcomes, regulatory efficiency and stakeholder confidence. Maintaining the status quo would not address these issues and only continue to embed inefficiencies. Issues which need to be addressed include:

- assisting applicants to navigate the system by more clearly defining and communicating roles, responsibilities, functions and linkages of (and boundaries between) the committees and their assessment processes;
- addressing stakeholder concern about the business and consumer impacts of delays in access to public and private funding (often perceived by manufacturers as a delay to market access) for medical technologies, due in part to the sequential nature of HTA processes;
- improving consistency between PBAC, MSAC and PDC processes for the performance of similar HTA functions in assessing the comparative clinical and cost effectiveness of pharmaceuticals, vaccines, medical services and devices;
- implementing more structured communication and coordination between the different secretariats and committees;
- developing assessment and evidence requirements that are appropriate to the assessment of technologies which are either low risk, low cost or have short life-cycles;
- improving the transparency and predictability of MSAC and PDC processes in regard to who assesses an application, how it will be assessed, what evidence will be required and how long the assessment will take;
- establishing consistent independent review mechanisms for MSAC and PDC;
- enabling better use of scarce specialised HTA knowledge and skills across HTA committees and secretariats;
- implementing consistent methodologies, protocols and definitions for the assessment of co-dependent and hybrid technologies;
- streamlining and coordinating processes to address stakeholder concern about the impacts of delays; and
- improving the rigour and efficiency of MSAC by allowing submission based evaluation.

Options considered during second round consultations

This analysis led to the development of a range of options which were published as a series of five options papers for public consultation through focus groups with stakeholders and bilateral discussions between key peak bodies with DoHA and DoFD. The options papers are at Appendix J of the HTA Review Report but in summary, options presented to stakeholders for consideration are listed below. Where options have resulted in recommendations in the HTA Review Report (whether the same as the presented option, or varied as a result of consultations), the relevant recommendation is identified in *italics.*

1. Proposed conceptual framework for Commonwealth HTA processes – including a vision, goal, objectives and principles – *recommendation 3*.
2. Single Entry Point - *two options* for a single entry point were presented including: a) a new single entry point to process and manage all applications; and b) a single entry point manages applications for HTA for market regulation and a single entry point manages applications for HTA for reimbursement – *recommendation 6 supports implementation of option 2b*.
3. Triaging of HTA applications – to determine the most appropriate HTA process(es) and HTA advisory committee(s) to undertake assessment of the technology (or any combination) and the most appropriate assessment level for different types of applications within each HTA process (for example, new products, "me-too" products, and co-dependent and hybrid products) and the likely evidence requirements and time implications – *recommendations 6b, 6c, and 6d*.
4. Allowing submission based evaluation for potential new MBS Items – *recommendation 9a*.
5. Implementation of a risk-based approach to assessment - to ensure the intensity of assessment matched the risk of the technology – *recommendations 6b, c, d, and e*.
6. Improved guidance on methodologies and methodological processes – *recommendations 4 and 5b*.
7. Improved public information on HTA processes - through a single website – *recommendation 4*.
8. Standard approach to HTA program management – through a standard approach to guidelines for all Commonwealth HTA processes (in structure, content, definitions and language - to the extent possible) and strengthened committee management – *recommendations 5b, 5c and 5e*.
9. Specified communication points – to be introduced across HTA processes so that applicants could more easily monitor application progress as well improved internal communications for HTA advisory committees and/or secretariats – *recommendation 5d*.
10. Independent review mechanisms for HTA processes and decisions – *recommendation 5a*.
11. Better information on performance of the HTA system – through the development of key performance indicators (KPIs) for Commonwealth HTA processes and public reporting of results against these KPIs to enable comparisons of results over time and across HTA processes – *recommendations 5c and 6g*.
12. Widening the scope of current post market surveillance activities – to include *comparative* safety, clinical effectiveness and cost effectiveness – *recommendation 14*.
13. Establish a more rigorous coverage with evidence development framework – *not recommended*.

While stakeholders supported this option and the need for a more rigorous framework, it was agreed that it should only be used when the safety and efficacy of the technology or procedure was assured with the only uncertainty around cost effectiveness. The challenges with pre-agreed data collection, especially for medical devices which rely on strong clinician input and support, cannot be easily overcome without appropriate tools for data collection which are the subject of recommendations 13-15 of the Review report and considered to be longer term initiatives. MSAC does provide the capacity for interim funding (which is another form of coverage with evidence) for promising technologies, and *recommendation 9b* seeks to address improved data collection requirements.

14. The expanded use of registries for post-market and post-reimbursement data collection with options including: a) device or procedure specific registers; b) class registers; and c) comparative registers – *recommendation 15*.
15. Enhanced data linkage to support post-market surveillance activities including two options to: a) 'piggy back' on existing national data linkage and e-health initiatives that would then feed information into post market surveillance system; and b) 'pilot' a specific data linkage project for post market surveillance purposes – *recommendations 14 and 15d*.
16. A review process with capacity to recommend disinvestment – through identifying ineffective technologies and recommending reducing or refining or removing the use of technologies from government and insurance funding schedules – *recommendations 13 and 14*.

The options considered by stakeholders represented a package of reforms that were intended to complement each other, but could also be implemented individually. Stakeholders generally supported all of the options, but noted that greater detail was required. It was generally acknowledged by both DoHA and stakeholders that a widespread and comprehensive reform approach is necessary if the Review is to achieve its objectives, and that implementing some options and not others would likely affect the extent and success of the reforms sought. Maintaining the status quo is not supported or recommended.

5 Assessment of impact

HTA Review consultations confirmed that all stakeholders generally want sound, comprehensive Commonwealth market entry and HTA processes to ensure that only safe and effective health technologies that provide value for money are available in Australia. However, the different stakeholder groups have competing interests and tensions in how this is achieved, including:

- government decision-makers – wanting to ensure that HTA processes retain the necessary rigour required to achieve cost-effective gains in health outcomes while addressing regulatory burden on industry in an environment of fiscal responsibility;
- regulators – balancing the time taken for a review prior to granting marketing approval and ensuring the high level of quality and safety the Australian public expects of therapeutic goods available in the market;
- health professionals and hospitals – maintaining the rigour of current HTA processes, utilising post-market surveillance to collect ongoing evidence of clinical effectiveness and identifying additional funding mechanisms for technologies that assist with delivery of treatment while containing expenditure;
- private health insurers – maintaining the emphasis on ensuring patient safety and quality of outcomes, but also, as businesses, controlling the expenditure on medical devices and prostheses;

- manufacturers – seeking simplified HTA processes, speed to market and subsidy, and transparency in government decision-making; and
- consumers – seeking to ensure there is access to safe, high quality health technology which is economically sustainable while at the same time protecting the Australian public through robust event reporting and post-marketing surveillance.

A key challenge for the HTA Review was to balance these competing interests and tensions and recommend options for reform that could be sustained within finite health budgets to ensure Australians have access to safe, effective and cost-effective health technologies with minimal delay and regulatory burden.

The HTA Review Report presents 16 recommendations which provide a strategic way forward for Commonwealth HTA processes into the next decade. The Report presents a feasible, staged reform agenda with recommendations one to 12 (inclusive) and 16 considered to be cost neutral and therefore able to be implemented in the short to medium term (that is, during 2010-2012) within existing departmental resources. While each of these recommendations could be implemented individually and achieve improvements in Commonwealth HTA processes, implementation as a package will ensure stronger and more sustainable reform outcomes.

The remaining recommendations (13 to 15 inclusive) are considered longer term options for reform and while scoping of these proposed activities could commence – because the Review was required to present cost neutral recommendations - have been proposed for consideration within the context of broader health reform.

Review recommendations will not introduce any new significant regulatory reform, and by providing improved administrative arrangements will reduce or neutralise existing regulatory impact as a result of what the Review found to be poorly coordinated Commonwealth HTA processes. The following provides an analysis of the significant costs, benefits and overall net impact on stakeholders as a result of HTA Review recommendations.

Manufacturers

In any year, the TGA is likely to assess 9000 applications from manufacturers to include medical devices on the ARTG, and of these, approximately 1000 applications will subsequently be made to PDC. MSAC considers approximately 14 applications per year and on average, half of these involve direct applications by manufacturers or sponsors of medical devices, while the other half mostly involve applications by specialist medical craft groups. PBAC does not consider medical devices. Currently manufacturers pay for assessments and appraisals conducted by the TGA and PDC under full cost recovery. MSAC assessments and appraisals are funded by DoHA. These arrangements will continue.[6]

The introduction of improved and consistent guidelines across Commonwealth HTA processes, a single Commonwealth website for clearly explaining these processes and a single entry point to assist manufacturers determine which committee(s) and assessment pathway(s) are appropriate and the likely evidentiary requirements before submitting an application, will provide administrative benefits to manufacturers.

Standardisation of information and HTA processes will reduce the time and resources necessary for manufacturers to learn about and engage with and across Commonwealth HTA processes. This will benefit manufacturers in more timely development of applications and their consequent management when HTA commences.

[6] Cost recovery was introduced for PBAC assessment of pharmaceuticals from 1 January 2010.

Most applicants will continue to primarily deal with two assessment processes for: 1) market entry approval through the TGA; and 2) for Commonwealth HTA benefits/subsidies through the HTA advisory committees (MSAC or PDC or PBAC).

For the small number of applications (up to 5 to 10) per year that do not follow a clear-cut pathway, better coordinated processes should reduce manufacturer uncertainty, facilitate speedier assessment and appraisal and consequently, faster access to the Commonwealth subsidised market. These applications will include: 1) hybrid technologies - which present definitional challenges as to which reimbursement scheme is appropriate and thus which assessment process should be used; 2) co-dependent technologies - which need to be assessed by two different committees for two different reimbursement schemes; or 3) where an MBS item number is needed for a medical device.

The introduction and consistent use of performance measures and reporting for all Commonwealth HTA processes will provide greater transparency and accountability, and enable manufacturers to plan business activities around Commonwealth HTA cycles. The introduction of consistent independent review mechanisms will ensure robust HTA outcomes and give increased certainty to manufacturers that their application will be treated fairly.

Manufacturers will benefit from being able to apply to Commonwealth market entry and HTA processes concurrently as a means of achieving earlier access to the subsidised market. However, they will need to weigh carefully the strength of their application and supporting evidence against Commonwealth HTA eligibility criteria before deciding to proceed with concurrent applications in the event that one of the applications is unsuccessful. Applicants seeking MSAC assessment before a therapeutic good is included on the ARTG will be charged a fee to have the assessment conducted concurrently with the TGA to minimize the financial risk to government of conducting an HTA on a therapeutic good not yet approved for use in Australia (MSAC assessments currently cost DoHA $250,000 per assessment). Consideration may be given to refunding the fee if the therapeutic good is subsequently included on the ARTG.

These proposed changes to ensure consistency and integration across Commonwealth HTA processes (with the exception of applications for concurrent assessment by MSAC) will not result in increased regulation or additional costs to manufacturers, but will provide manufacturers with administrative efficiencies and time and cost savings through receiving better information and support from DoHA and/or the TGA, and streamlined management of applications requiring multiple advisory committee assessment and appraisal. It is not possible to quantify potential cost savings or potential market gains as a result of streamlined or more timely applications as applications vary in complexity, level of evidence required and provided across the different HTA processes.

Impact on Manufacturers from proposed TGA changes

The HTA Review made a number of recommendations relating to TGA functions. The TGA is currently consulting on two of these matters which will not be completed until after the HTA Review has reported. It is estimated that approximately 12-15 businesses will be impacted by any changes proposed by the current third party conformity assessment (TPCA) consultations and 10-20 businesses from the outcomes of the Reclassification of Joint Replacement Implants (RJPI) consultations. Both matters may be subject to regulatory change, which will be managed by the TGA as required.

Firstly, manufacturers of high risk medical devices that are subject to more rigorous assessment in the future are likely to be impacted by increased compliance costs, however, they will also benefit from international harmonization of regulatory standards which enables Australian manufacturers to export products based on TGA's reputation as a stringent

regulator and standards consistent with other comparable countries. Secondly, the introduction of TPCA) will allow for more timely assessment for Australian manufacturers of medical devices, resulting in faster access to market. This may result in reduced compliance costs for some manufacturers where TPCA is allowed (most likely for lower risk devices) and no change in compliance costs for higher risk devices which continue to be assessed by the TGA.

It is not possible to quantify the overall costs and benefits of these processes to manufacturers until a final decision is made about which devices will be categorized as high risk, and which categories of devices will be able to be assessed through TPCA. Overall, however, increased regulation in these areas will provide benefits to consumers, health professionals and private hospitals by assuring the safety, quality and effectiveness of medical devices available for use in Australia. Australian manufacturers that also export overseas, will benefit from meeting internationally harmonized standards for medical devices (that are generally implanted in the human body) being marketed for use in Australia.

Impact on Manufacturers from proposed changes to MSAC

Currently it is estimated that approximately 7-10 businesses per annum apply for MBS funding through MSAC (the remainder of applicants to MSAC are referrals from within government, medical colleges and health professionals). It is estimated that the time from application to completion of an MSAC appraisal averages 18 months.

The proposed introduction of submission-based evaluation by MSAC will provide manufacturers with a 'fit-for-purpose' (rather than the current one-size-fits-all) approach to HTA, reducing the impact of current lengthy MSAC assessment and appraisal timeframes on manufacturers, which can delay access to market. It is anticipated that this approach will provide an assessment/appraisal timeframe of 6-9 months, representing a significant time-saving benefit to manufacturers. While manufacturers seeking a submission-based evaluation and consequent MSAC critique will be subject to the financial cost of preparing this type of application and collecting the supporting data, approximately 50% of applications to MSAC (or 7 applications per year) are already providing this level of information. Manufacturers will still have the option of an MSAC funded and conducted assessment. Recommended improvements to sourcing expert HTA advice will ensure that applications are assessed within 12 months, thus minimizing time and resource imposts on manufacturers.

Proposed changes to introduce more stringent data collection requirements for interim funded MBS items (only a small percentage of overall MSAC applications) will provide manufacturers with greater surety about what data is required to support ongoing MBS listing. While collecting the data is likely to impose a cost on the manufacturer, the benefits of earlier receipt of MBS funding (if approved by MSAC and accepted by government), which will assist with establishing the necessary evidence base, will outweigh the likely cost impost. Manufacturers would also have the option of collecting the necessary data before submitting an application to MSAC. Importantly, for government, this will ensure that sound evidence is collected to warrant ongoing government subsidy of an interim funded MBS item.

Health professionals and medical colleges that seek MBS funding through MSAC will also benefit from these proposed changes through speedier HTA and clearer guidance on requirements for HTA processes generally. .

Impact on Manufacturers from proposed changes to PDC

It is estimated that approximately 78 manufacturers will benefit from the proposed changes to Prostheses List arrangements. Manufacturers will benefit from being able to submit applications to the Prostheses List at any time rather than waiting for the current biannual

application window periods, with the potential for earlier listing and consequent access to market.

Prostheses fees may need to increase to allow for the grouping scheme work for the Prostheses List (which was agreed by the previous government and commenced in 2007) to be fast-tracked. This would be a one-off cost which would be counter-balanced by the significant benefits for all stakeholders of completing this work quickly. Currently PDC clinicians (who have limited time available) undertake this work, which is usually followed by months of debate between manufacturers, insurers and clinicians about the appropriateness of the grouping schemes and then benefit offers and negotiations for every product affected by the review.

Completing this work will provide manufacturers with greater certainty about how their application will be treated, assist with business planning and reduce the length of time to listing through providing for a more administratively effective Prostheses List by ensuring that devices are included in the correct group with correct benefits. As well, there may be both costs and benefits to manufacturers once the grouping scheme is finalized as some ungrouped devices may see increased benefits and others may see decreased benefits because they are currently either inappropriately grouped or not grouped at all, and consequently current benefits may be at variance with the correct group benefit.

It is not possible to quantify the cost savings impact on manufacturers of delays in access to market and which devices are used, because data are not collected and/or linked on the number of devices sold and/or used through these different regulatory processes. Recommendation 15 of the HTA Review recommends the need for improved data linkages to inform the efficiency of the post-market surveillance of medical devices generally.

Private health insurers and private hospitals

Private health insurers and private hospitals will benefit significantly from improved administration of the Prostheses List because it will make it more effective and simpler to administer, consequently reducing current time and resource costs. Private health insurers will also achieve savings through DoHA completing the grouping work, and simplifying benefit setting arrangements with the latter work currently being funded by private health insurers. Private hospitals will also achieve savings from the abolition of gap payments where they currently absorb (rather than pass on) uncollected gap payments.

Consumers, health professionals

Overall, consumers and health professionals will benefit from more rigorous and/or improved Commonwealth market entry and HTA processes which provide increased surety about the safety, effectiveness and quality of medical devices being marketed for use in Australia. Streamlined and more timely HTA processes will result in earlier access to new health technologies. Recommended changes to the Prostheses List will provide health professionals with improved accessibility to and use of the List as a reference tool for the selection of prostheses available for reimbursement via private health insurance. While abolishing gap fees may result in less choice of prostheses for consumers, they will benefit from fewer out of pocket expenses (as manufacturers could still negotiate gap payments with hospitals as a commercial arrangement).

Government

The predominant costs associated with implementing HTA Review recommendations will be borne by government as DoHA will implement changes within existing departmental resources. However, this is counter-balanced by the benefits that DoHA will achieve through streamlined, simplified and efficient administrative arrangements with reduced program

complexity across Commonwealth HTA processes, in turn providing improved services to applicants. The introduction of the single entry point and common operating procedures will result in better internal and external coordination of HTA resources, expertise, information and communication.

Summary

The HTA Review recommendations seek to introduce a strategic, holistic and coordinated approach to managing Commonwealth HTA processes. It will enable DoHA to administer these processes to reduce duplication, streamline administrative arrangements, improve role clarity and simplify arrangements for applicants providing for sound public administration. Overall, the proposed recommendations in the HTA Review report are likely to improve the capacity of all stakeholders to interact efficiently and effectively with Commonwealth HTA processes. Any increased or introduced costs are considered minimal, being either an optional (MSAC changes) or one-off cost (PDC changes).

A key outcome of the comprehensive consultations conducted by the HTA Review included that stakeholders were able to identify that changes to current practices may result not only in reduced regulatory burden for them, but also increased regulatory burden for other sectors. For example, while manufacturers were keen to see the current biannual Prostheses List produced more regularly to enable earlier access to private health insurance rebates, they also recognised that this would create an additional resource and administrative impost on private health insurers and hospitals who administer the List,

It is important to note also that while the methodologies used in conducting HTA for reimbursement can involve detailed technical analysis, the final decision about which health technologies should be reimbursed cannot be reduced to a formula. As the decision-maker, the Australian Government must weigh a number of factors against each other when deciding subsidies for health technology, including differing (and sometimes conflicting) community views on the relative importance of a particular technology or intervention, the characteristics and size of the patient group affected, the severity or impact of the disease being treated, and the availability of effective alternative treatments. In addition, government must make judgements about the total amount of funding for health care, taking into account other priorities for the Australian community. In this context, it is appropriate that HTA processes for reimbursement will result in recommendations to the government, but that ultimately decisions about whether and how to fund new technologies, and other health services, rest not with the advisory committees, but with elected representatives.

Where government decides not to reimburse a new technology, it may still be available on the Australian market, but its affordability may be reduced. Decisions by individuals in relation to such technologies should still be subject to informed consent (including informed financial consent).

6 Consultation statement

The HTA Review was conducted by a Task Force within the Health Technology and Medical Services Group in DoHA's Medical Benefits Division and was overseen by an Inter-Departmental Committee (IDC) with representatives from DoHA and DoFD and the departments of DIISR, Veterans' Affairs (DVA), Prime Minister and Cabinet (PM&C) and The Treasury.

The HTA Review canvassed options for reform with all key stakeholders comprehensively throughout the Review including two rounds of bilateral meetings with peak agencies and focus groups with stakeholders.

An Inter-Departmental Committee and a Medical Technology Stakeholder Reference Group (MTSRG), which included the peak agencies for the medical technology industry, representative colleges of health professionals, private health insurers, private hospitals and consumers met on three occasions during the Review.

The MTSRG provided an important forum to allow comprehensive consultation with key stakeholders in identifying issues and developing policy solutions to address the HTA Review terms of reference.

Some stakeholders had expressed concerns about DoHA conducting the HTA Review, in contrast to the Banks Review which recommended the need for a public independent review. DoHA therefore designed the consultation methodology with the aim of ensuring a comprehensive, publicly accessible, transparent process that took account of the views of all stakeholders. Consultation activities included:

a. three meetings of the IDC and MTSRG to: (a) identify and discuss issues to be considered during the HTA Review; (b) consider submission outcomes and policy development; and (c) consider the Draft Final Report of the Review;

b. preparation of a public discussion paper ('Review of Health Technology Assessment in Australia – A Discussion Paper') to inform the preparation of stakeholder submissions;

c. analysis of the 86 public submissions received in response to the discussion paper at b.;

d. internal consultations and analysis within DoHA, including a review of current Commonwealth HTA processes, existing literature and an analysis of previous reviews;

e. establishment of a HTA Review website (http://www.health.gov.au/htareview) as the primary communication medium to keep stakeholders and the public informed about the HTA Review and key activities such as the call for submissions and details about the focus groups. Submissions received , discussion and options papers released and focus group reports developed for the HTA Review were also published on this website;

f. conduct of a first round of public stakeholder focus group consultations consisting of nine sessions involving 102 participants, to seek responses to the discussion paper and contribute to the identification of major issues to be addressed during the HTA Review;

g. conduct of a first round of 15 bilateral meetings between senior DoHA management and key peak stakeholder organisations to identify the issues to be considered in the HTA Review;

h. preparation of a set of five options papers describing proposals to address the HTA Review terms of reference (refer section 4 . The options were developed taking account of stakeholder feedback on issues with Commonwealth HTA processes;

i. conduct of a second round of focus group consultations consisting of 11 sessions involving 113 participants to seek feedback on the proposals; and

j. conduct of a second round of eight bilateral meetings between senior DoHA management and key peak stakeholder organisations to seek feedback on the draft proposals.

In addition, DoHA engaged the Consumers' Health Forum of Australia (CHF) to consult with consumers. This process provided the opportunity for a comprehensive consumer response to policy issues relevant to the HTA Review. CHF and consumer representatives also participated in other consultation activities. The CHF has also been published on the HTA Review website and is Appendix L to the HTA Review Report.

Stakeholder support

Stakeholders commented favourably in every consultation forum (IDC and MTSRG meetings, focus groups and bilateral meeting) about the level and comprehensiveness of consultations. Stakeholders also expressed appreciation at DoHA's willingness to be open and transparent about where existing Commonwealth HTA processes were not operating optimally and were creating regulatory issues for stakeholders.

The HTA Review Report recognises the inherent tensions in the current Commonwealth HTA system between different stakeholders including: manufacturers, private health insurers, private hospitals, regulators, consumers, health professionals and funders. All stakeholders want processes that are streamlined, clearly articulated, and timely, while also ensuring that Australian standards for safe, effective and cost effective health technologies are protected, and provide value for money.

The Report noted that while stakeholders expect changes to current HTA processes, competing tensions may result in some stakeholder expectations not being met. For example: a) manufacturers want speed to market while private health insurers and health professionals want improved rigour around safety of devices; and b) manufacturers want more regular (than twice a year) printing of the Prostheses List (again to enable timely market access), whereas this would increase the work-load on private health insurers and hospitals who administer the List (respectively) for reimbursement of benefits, and costs of devices charged, to patients. The consultation forums provided enabled stakeholders to air and consider competing tensions openly.

The HTA Review Report recognises and provides a comprehensive and balanced response to the concerns and competing tensions raised by stakeholders during consultations, issues arising from other research and analysis undertaken by DoHA and matters raised in previous reviews and reports on HTA in Australia.

7 Recommendations

The HTA Review found that overall the current administration of Commonwealth HTA processes is essentially sound, well constructed and provides a good framework for government decision-making. Each part of the system has a number of strengths. The HTA Review recommends that these strengths be built upon, and in developing recommendations for responding to the current inefficiencies, the Review was conscious of the need to preserve the recognised benefits of current arrangements and avoid undermining current capacity.

The Report presents 16 recommendations which provide a strategic way forward for Commonwealth HTA processes in the next decade. It presents a feasible, staged reform agenda with recommendations one to 12 (inclusive) and 16 considered to be cost neutral and therefore able to be implemented in the short to medium term (that is, during 2010-2012) within existing departmental resources. The remaining recommendations (13 to 15 inclusive) are considered longer term options for reform and while scoping of these proposed activities could commence – because the Review was required to present cost neutral recommendations - have been proposed for consideration within the context of broader health reform.

In making its recommendations to government, the HTA Review was cognisant of the need to propose recommendations that could be sustained within existing funding levels and which are consistent with Australian Government policy objectives, in regard to:

- the regulation of the safety, quality and efficacy of therapeutic goods;
- access to, and financing of, professional services and therapeutic goods, in particular the requirement for demonstrated comparative clinical effectiveness (including comparative

safety) and cost effectiveness to support public[7] and private funding; and

- ensuring that regulatory processes are effective, efficient (minimising the costs of achieving the desired outcomes), proportionate and targeted, addressing key aspects of regulatory reform as required under the Better Regulation Ministerial Partnership.

The final 16 recommendations of the HTA Review are at **Attachment 1**. These recommendations implement all of the options presented to stakeholders during consultations with the exception of option 13 which is discussed in section 4. above. The recommendations sought to address stakeholder concerns about the level of detail in the options and provide for a more prescriptive and detailed outline of intended reforms.

The HTA Review Report has recommended particular sub-options that were presented to stakeholders during the second round of focus groups and bilateral meetings including:

a. Option 2b for the Single Entry Point (separate single entry points for both market regulation and applications for HTA for reimbursement) was recommended *(recommendation 6)* because:
    - The vast majority of devices will go only to the TGA for assessment and interposing an additional step between the TGA and the applicant will add little value and may result in slower service than currently exists.
    - If the SEP takes place before TGA processes, the SEP has to allocate devices between two sharply different pathways (market entry and HTA for reimbursement), alternatively, if the single entry point is after TGA processes, it has only to decide which HTA for reimbursement pathway is appropriate, thereby simplifying the task.
    - There are minimal gains to be made in joining market regulation and the three different HTA for reimbursement processes into a SEP given that there are not strong synergies between them, provided that relevant information is appropriately shared between the market regulator and HTA agencies.
b. Option 14 Expanded use of registries for post-market and post-reimbursement data collection with option b) class registers recommended. Stakeholders were supportive of this option because registers are expensive to establish and maintain, requiring investment in both data systems and liaison to ensure the quality of information. A class register enables funding (if it is made available) to be targeted towards high-risk implantable devices, which have the most potential for serious consequences for health consumers *(recommendation 15)*.
c. Option 15 Enhanced data linkage to support post-market surveillance activities with option b) 'pilot' a specific data linkage project for post market surveillance purposes recommended. Stakeholders were generally doubtful of option 15 a), considering that the progress of e-health initiatives was slow and unpredictable. They saw more value in testing linkages in areas of likely high return and then applying lessons more broadly across the health system *(recommendation 14)*.

The HTA Review also made additional recommendations that were not canvassed in the options papers but were raised during focus group discussions and canvassed with peak agencies in bilateral meetings and address stakeholder concerns in relation to:

- clarifying the respective roles of the TGA, MSAC and PDC regarding the assessment of 'safety' – *recommendation 8a. and 10 b.*;

[7] The term 'public funding' means direct and indirect funding of health technologies by the Australian Government whether that funding fully or partially covers the cost of the health technology.

- strengthening the links between the market entry and HTA for reimbursement processes - *recommendation 8d.;*
- improving the rigour and efficiency of MSAC through better definition of data collection requirements for procedures recommended for interim funding and streamlining processes for accessing expert advice to inform assessments – *recommendation 9*; and
- streamlining arrangements for the Prostheses List through establishing communication channels with the TGA, restructuring the PDC and recommending changes to administration of the Prostheses List – *recommendations 10, 11 and 12*.

None of the HTA Review recommendations involves legislative change. Only the TGA and PBAC operate in accordance with specific legislation, whereas MSAC and PDC operate in accordance with administrative guidelines to implement specific legislative approaches (for example, the listing of items and benefits on the MBS and the Prostheses List respectively). The recommendations are all consistent with the current regulatory framework, but seek to achieve greater administrative efficiency.

8 Strategy to implement and review recommendations

Subject to the Government's acceptance of this Report and to its public release, DoHA intends that:

1. the HTA Review Report will be: a) published on the HTA Review website with the Review mailing list (of approximately 1500 stakeholders) advised of its release; and b) provided in hard copy to key peak agencies and members of the IDC and MTSRG, as well as other stakeholders on request;
2. a functional area within DoHA will be identified and charged with responsibility for:
    a. developing a detailed implementation plan which will include risk and stakeholder management plans and a comprehensive consultation strategy to ensure that stakeholders are consulted at all key stages during implementation;
    b. providing a coordinating and monitoring function for Review implementation activities;
    c. establishing a website to provide comprehensive information about Commonwealth HTA processes;
    d. establishing and operating the single entry point including guidelines that will assist in determining the most appropriate advisory committee(s), the most appropriate assessment pathway(s) and the likely evidentiary requirements for the different pathway(s) for the different health technologies to be assessed;
    e. coordinating the introduction of policy changes such as:
        i. independent review mechanisms and opportunities for re-submissions in a consistent manner for Commonwealth HTA processes;
        ii. updated operating procedures for administering Commonwealth HTA processes; and
        iii. the adoption and implementation of transparent and consistent policies and procedures for the management of advisory committee functions and activities.

Stakeholders will be kept apprised of implementation activities via the website proposed at 2 c. (above) and also where appropriate, the individual websites of the different Commonwealth processes for market entry and HTA for reimbursement.

Due to the comprehensive consultations during the HTA Review, it is proposed that the activities at 2 c. and 2 d. are implemented without further consultation. Items 2 a. and 2 b. are internal matters for DoHA and do not require consultation. Further stakeholder consultation around item 2 e. is anticipated and will be advertised through the proposed HTA website.

The Report also recommends that any changes to HTA regulatory processes agreed by the Government arising from the recommendations of the HTA Review should be reviewed after implementation to ensure that their operation is achieving the intended objectives, to identify any undesirable consequences of the new processes, and to recommend any further regulatory improvements that may be required. This review is proposed to commence in 2013.

Attachment 1

HTA REVIEW RECOMMENDATIONS

REC#	RECOMMENDATION
1	That the impact of the proposed changes to the Commonwealth HTA system approved by the Australian Government be evaluated within three years of the government response to this review.
2	That the rigorous consideration of evidence be consistently applied across all Commonwealth Health Technology Assessment (HTA) processes to ensure sustainability of the Australian Government's health financing arrangements.
3	That the Commonwealth HTA system be guided by the vision, goal, objectives and principles articulated in this Report.
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.
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.
6	That in order to improve the efficiency of HTA, the Department of Health and Ageing (DoHA) establish a single entry point (SEP) by July 2010 to receive applications for subsidy under the MBS, 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; g. develop and report on the achievement of performance targets for HTA for reimbursement.
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 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).

REC#	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 Australian Register of Therapeutic Goods (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 bases 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.
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, rather than conducting its own full evaluation, 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.
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. that 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.
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.
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, 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 PHI; a 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.
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.

REC#	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.
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 health technology assessments; 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.
16	That AHMC be asked to consider the need for a national approach to HTA processes, including processes required to evaluate blood and blood products.

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[iv] Productivity Commission, op cit, p. XXXVIII
[v] Medical Technology Association of Australia, 'Review of Health Technology Assessment in Australia – Submission by Medical Technology Association of Australia', Submission to the HTA Review, May 2009, p. X
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[xi] Department of Health and Ageing, 'Budget Portfolio Budget Statements 2009-10 – Budget Related Paper no. 1.10 - Health and Ageing Portfolio', Canprint Communications Pty Ltd, 2009, pp. 103, 124, 250
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[xv] Productivity Commission, 'Annual Review of Regulatory Burdens on Business: Manufacturing and Distributing Trades', Research Report, Canberra, 2008