



Australian Government
Department of Health and Ageing

REVIEW OF
Health Technology Assessment
in Australia

DECEMBER 2009



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Executive Summary and Recommendations



Executive Summary and Recommendations

New directions for HTA in Australia to support better health care and reduce regulatory costs

Key Messages

The HTA Review recommends that Commonwealth HTA processes should:

- all follow a set of shared objectives and principles;
- be part of an open, transparent, integrated system;
- make information easily available from a central website, including more information on how technologies will be assessed and how decisions are made;
- provide improved opportunities for sponsor and stakeholder input, including expanded options for seeking review of decisions;
- operate through a single entry point to assist stakeholders by receiving, guiding and monitoring all applications for reimbursement;
- be more flexible in dealing with novel and complex technologies by coordinating assessments and allowing different aspects of complex technologies to be assessed at the same time;
- speed up Medical Services Advisory Committee assessments by allowing sponsors to supply their own assessments and have these critiqued;
- simplify administration of the Prostheses List by streamlining administrative processes and removing duplication; and
- reform post-market surveillance of health technologies to strengthen patient safety and value for money for taxpayers.

Overview

The Australian Government assists Australians with the cost of their health care through a range of different funding arrangements. The cost 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. Health technology assessment (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.

This Review of Health Technology Assessment in Australia (HTA Review) has been conducted as a Better Regulation Ministerial Partnership between the Minister for Health and Ageing, the Hon Nicola Roxon MP, and the Minister for Finance and Deregulation, the Hon Lindsay Tanner MP. The HTA Review has been undertaken by the Department of Health and Ageing (DoHA) in consultation with the Department of Finance and Deregulation (DoFD).

A key objective of the HTA Review is 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 is 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.

Government cannot subsidise every new medical technology. HTA provides a means by which new technologies can be assessed and prioritised against existing health care interventions (and other government funding priorities). This is achieved by determining the best value for money for the Australian community by considering both clinical effectiveness (that is, whether they improve health outcomes and by how much), and cost-effectiveness (that is, how much they cost compared to alternatives, in terms of the health outcomes achieved), to ensure that funds are used to support the lowest cost health care interventions for achieving the maximum health improvement. Consistent application of evidence across all Commonwealth HTA processes will build a foundation on which health financing arrangements can be made more sustainable.

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.

HTA processes can occur across the life cycle of a technology, and involve:

- horizon scanning to identify new and emerging health technologies for governments and health systems for planning purposes;
- market regulation to assess the intrinsic safety and performance of therapeutic goods, as intended for use by manufacturers;
- HTA for reimbursement to assess the comparative safety, clinical and cost effectiveness of health technologies being considered for subsidy; and
- post-market surveillance to monitor the impact of technologies in routine clinical use.

The particular HTA processes that have been the focus of the HTA Review are:

- regulation of therapeutic goods for market entry, currently undertaken by the Therapeutic Goods Administration (TGA);
- approval of funding under the Medicare Benefits Schedule (MBS), currently informed by the Medical Services Advisory Committee (MSAC) and relevant implementation consultative committees;
- listing of prostheses for private health insurance coverage, as currently informed by the Prostheses and Devices Committee (PDC); and
- listing of hybrid and co-dependent technologies as currently informed by MSAC, the Pharmaceutical Benefits Advisory Committee (PBAC) and PDC.

Any changes to regulatory processes agreed by government arising from the HTA Review should be reviewed after implementation to ensure that their operation is achieving the intended objectives.

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.

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.

A Policy Framework for Commonwealth HTA

The Commonwealth HTA system is complex and has many interdependencies. Each HTA agency has discrete functions and has evolved over time to respond to different needs. Individually, most of these processes function well, and in some cases are regarded as world leaders in their field.

Nevertheless, previous reviews of HTA in Australia have identified a range of concerns such as duplication and differing approaches to methodologies, evidence requirements, transparency and communication across the HTA agencies. A common concern is that sponsors of new medical procedures or devices often must navigate two (TGA and then MSAC or PDC) and, in a small number of cases three separate HTA processes (TGA, MSAC and PDC) in order to secure market entry and reimbursement approval. If use of the diagnostic technology is intended to affect the use of a medicine, PBAC may also be involved.

During the HTA Review consultations, stakeholders repeatedly expressed concerns that there is a lack of a strategic, systematic and integrated framework for Commonwealth HTA functions. Typical of many submissions was the comment that:

Enhanced arrangements that take a holistic not silo approach are required for assessment for subsidy and listing purposes.¹

There was a general acknowledgment by stakeholders that, for example, an explicit, agreed set of principles is crucial to guide the strategic direction and operation of the system, even though there may at times be a need for "trade-offs" between them.

Accordingly, this Report proposes a policy framework for Commonwealth processes for market entry and HTA for reimbursement in Australia, consisting of a vision, goal, objectives and principles.

While not all aspects of the framework will apply to each function to the same extent, such a framework will assist with:

- ensuring the goals of HTA support broader social and economic goals of the Australian community;
- developing a shared and consistent approach across the processes;
- clearer delineation of roles and responsibilities of each component of the HTA system;
- improved transparency;
- encouraging a consumer and patient focus without increasing regulatory burden;
- more robust performance measurement and accountability;
- more efficient use of scarce clinical and HTA expertise;
- reducing unnecessary and poorly designed regulation; and
- facilitating and encouraging links between HTA and broader health system goals.

Vision for a sustainable, efficient Commonwealth HTA system

The proposed vision articulates an aspiration for Commonwealth HTA processes at the highest level:

Australians have timely, equitable and affordable access to the cost-effective health technologies needed to manage their health.

Goal of Commonwealth HTA processes

The proposed goal articulates how and on what basis these Commonwealth HTA processes will contribute to the Australian health system:

The goal of Commonwealth HTA processes is to maximise beneficial health outcomes to the Australian population within the overall funds available whilst being cognisant of the other important goals of the health system.

Objectives of Commonwealth HTA processes

The proposed objectives articulate the approach to informing robust decisions:

That Commonwealth HTA processes use the best available evidence and efficient methods to inform robust decisions about market entry and the subsidised use of health technologies. The Commonwealth HTA system should also continually improve the evidence base for assessment and operate according to agreed principles.

Principles underpinning Commonwealth HTA processes

Commonwealth HTA processes should be:

- sustainable;
- transparent, accountable and independent;
- consultative and reflective of Australian community values;
- administratively efficient;
- flexible and fit for purpose; and
- informed by robust and relevant evidence.

Recommendation 3:

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

Creating Stronger, More Efficient Health Technology Assessment Processes for Reimbursement

Implementing this framework for HTA will require concrete, practical changes across the entire system. However, the current system does have many strengths. Changes need to build on these strengths and avoid undermining current capacity.

Improved public information

A single website for Commonwealth HTA

Applicants and other interested parties rely on publicly available information such as websites and guidelines for their understanding of the Commonwealth HTA system. It is clear, however, that much information is scattered across various websites and is otherwise difficult to access.

Creating a single website that clearly describes the roles and functions of Commonwealth HTA processes would assist all stakeholders in accessing and understanding the Commonwealth HTA system.

Reporting on performance

Better and more consistent performance information would assist in demonstrating the extent to which Commonwealth HTA processes are effective and efficient. The HTA Review proposes that DoHA develop a set of key performance indicators (KPIs) and key activity data for Commonwealth HTA processes by June 2010, which would allow stakeholders to monitor the performance of individual processes over time and to compare performance between separate processes. Such measures would address:

- the effectiveness of the processes in achieving their objectives, such as to provide quality advice to the Australian Government;
- the efficiency of the way this is done, such as through tracking the timeliness of assessments; and
- the quality of the individual stages, such as particular HTA processes.

In addition, stakeholders sought clear maximum time limits on all Commonwealth HTA processes as is currently the case with PBAC. In this regard, the HTA Review suggests that a set of KPIs and key activity data address:

- time to process an application including reporting the minimum, maximum and average time over a 12 month period, taking account of the level of complexity of the assessments;
- effective operation of expert committees – for example, whether the committees operate in accordance with their terms of reference, adhere to meeting schedules and publish outcomes in accordance with targets, as appropriate;
- the level and type of expertise involved in assessing applications; and
- the proportion of applications that were supported, conditionally supported or rejected in a 12 month period.

Post-assessment measures that would be useful to stakeholders include:

- the alignment of the HTA outcome with final reimbursement decision; and
- the extent to which up-take of the technology matched the assumptions in the HTA.

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.

Greater transparency and procedural fairness

Transparency is paramount to ensuring equity, fairness and, most importantly, scientific rigour on which health care decisions are based.²

There was widespread stakeholder concern about the extent of transparency and procedural fairness in the current system. Some stakeholders felt that the currently opaque arrangements reduce confidence in what might actually be sound outcomes.

Better, more transparent conduct of HTA will reduce the impetus for aggrieved parties to seek review, but the current disparate review processes across the system should be made more consistent.

Because of factors such as the different statutory base for the various processes it is unlikely that one standard review process or mechanism is feasible. Instead, the HTA Review suggests that all processes align their review arrangements against a set of shared principles. These principles should ensure that the review processes:

- encourage resolution informally whenever possible;
- be limited to considering information provided as part of the initial application;
- not create any opportunities for sponsors or others to manipulate the system (such as to seek review where a re-submission with better information is more appropriate); and
- ensure that the advisory committee responsible for the matter under review properly takes account of the outcomes of the review in re-considering the matter.

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.

Streamlined and better coordinated processes

The degree of complexity of a process is a key driver of regulatory costs. The HTA Review identified a number of problems in current arrangements where a technology is required to be assessed through multiple processes. These include:

- the sequential nature of processes can result in delays of several years before reimbursement arrangements are finalised;
- applicants being required to supply the same information in different formats to several HTA processes, particularly in regard to the assessment of aspects of devices to determine safety and efficacy by the TGA, MSAC and PDC;
- poor understanding by stakeholders of the division of roles and responsibilities of different HTA processes, as well as unexplained variations in HTA processes, exacerbated by poor communication within and between departmental secretariats;
- applicants being expected to navigate the HTA system themselves with little support or guidance, which can create difficulties when they are unfamiliar with the different processes; and
- applicants having difficulty monitoring and tracking the progress or status of their application.

Accordingly, the HTA Review proposes two major changes to the current system in order to streamline regulatory processes, increase efficiency and reduce complexity for all stakeholders:

- the creation of a single entry point (SEP) for all applications for reimbursement; and
- allowing concurrent assessment of technologies across the relevant agencies.

Single entry point

In some cases, applicants are currently required to sequentially navigate at least two or three (and in some instances four) different public entry points within DoHA and the TGA in order to achieve their objective of market entry and public or private reimbursement. While the four entry points have different processes and approaches to the management and assessment of applications, they nevertheless contribute to increased regulatory costs through duplication, complexity and delay.

A frequent suggestion from stakeholders was that a 'single entry point' should receive, allocate and monitor progress of applications. During the consultations, two different options for the SEP were canvassed – one placed the SEP before consideration of an application by the TGA (that is, the TGA would receive all applications even if no reimbursement were sought) and the other option had the SEP only deal with applications requesting reimbursement.

Stakeholders held mixed views on which of these models had the greatest merit. Ultimately, the HTA Review considers that, in the light of the benefits of having a clear demarcation between market regulation and reimbursement processes, a SEP dealing only with applications for reimbursement is the better option.

The proposed SEP would halve the number of entry points to Commonwealth HTA processes (from four to two) and provide better coordination and integration of HTA processes by facilitating appropriate communication and collaboration between the TGA, MSAC, PBAC and PDC, as well as public and private payers and state and territory governments. It should also assist in standardising application requirements and guidelines, where appropriate.

The proposed functions of a SEP include:

- a public interface with stakeholders (through a website and guidance documents);
- a single liaison point for applicants and the HTA processes;
- the capacity to monitor and track the progress of applications;
- responsibility for organising broad-based, pre-lodgement meetings – which could provide a ‘whole-of-HTA system’ view to aid an applicant’s understanding of how the application could progress through the various advisory committees and processes, and the likely evidence requirements;
- a coordination function for those applications which would need to be assessed by multiple HTA processes and advisory committees, such as those proposing hybrid or co-dependent technologies;
- management of information sharing between the HTA processes, advisory committees and applicants; and
- responsibility for coordination of evidence requirements and assessment processes to promote greater consistency across the HTA processes and advisory committees.

Concurrent assessment and coordination across advisory committees

A number of stakeholders noted that the current sequential system of assessments by the different agencies can create extended delays in achieving return on investment for a particular technology. The HTA Review agrees that Commonwealth HTA processes should allow applicants to choose whether they prefer either to apply concurrently for market entry and HTA for reimbursement, or enter the market first to gather evidence to inform a later application for reimbursement.

In some instances (particularly for co-dependent and hybrid technologies), the SEP would coordinate the provision of consolidated, comprehensive advice to the Australian Government from a number of advisory committees on a range of aspects of a complex service involving a mix of technology types.

A more flexible, risk-based approach to assessment and evidence

A fundamental goal of the HTA Review is to make the current system more flexible, responsive and adaptable, and reduce regulatory costs. Current HTA processes, each of which generally deals with a limited variety of technologies, are already struggling to adapt to the pressure of the growing diversity and number of emerging and converging health technologies, and are unlikely to be sustainable in their current form in the longer term.

Stakeholders argued that simple technologies, such as orthopaedic screws, were subject to what was felt to be excessive scrutiny, while other technologies which may be associated with greater risks (such as new radiation oncology techniques) were subject to inadequate assessment.

Consistent with international best practice, the HTA Review proposes that the degree of rigour of HTA processes take into account the risks (including the level of uncertainty in the evidence base relating to those risks) of the technology under consideration. A risk-based approach would vary the amount and strength of evidence required for the assessment of different technologies, informed through the development and use of HTA risk classification tables and also aligned where relevant with any emerging international standards.

The factors taken into account under this approach primarily relate to the potential risks and benefits of the technology, such as:

- the unit cost of the technology;
- the severity of the disease being treated;
- the size of the population who may benefit;
- the availability of alternative technologies to manage the same clinical condition;
- the degree of certainty regarding the scale of the likely risks and benefits; and
- equity and access implications.

Once these factors have been weighed, the appropriate HTA approach can be chosen in terms of:

- the most appropriate assessment methodology (such as extent of literature analysed, economic model applied, costs and benefits considered, or comparator used);
- the amount, type or quality of evidence required to support the assessment (such as the number of years' follow-up evidence); and
- the assessment and appraisal pathway(s) followed.

The level of risk and the characteristics of the required assessment/appraisal should be applied consistently across all HTA processes. Stakeholders stressed that, even though different agencies had different roles, it was essential that they use a common language.

In summary, the HTA Review considers that a more risk-based approach to assessment should be undertaken by MSAC and PDC to ensure that the intensity of assessment matches the risk posed by use of the health technology. This approach should reflect both the risk of harm to the patient and the financial risk to the government on behalf of the taxpayer and to society more broadly.

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.

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).

Strengthening linkages between market entry and HTA for reimbursement

Medical devices used in Australia are regulated under the *Therapeutic Goods Act 1989* (the Act). Devices are classified in light of the intended use and the risk the device presents to the patient, the user and the environment. In 2007-08, over 5,600 devices were submitted for inclusion on the ARTG to enable their sale and use in the Australian market. Over 90 per cent of these devices will never be submitted for HTA for reimbursement and thus the market entry regulatory regime is crucial for ensuring the timely entry of safe technology into use by Australians.

Australia's market regulations for health technologies already incorporate the principles of the international regulatory model developed by the Global Harmonization Task Force (GHTF) which includes the United States (US), Europe, Canada, Japan and Australia. The underlying philosophy of the GHTF regulatory framework is to remove unnecessary duplication of reviews in different regulatory jurisdictions, firstly by harmonising regulatory requirements between jurisdictions where possible, and then by establishing collaborative agreements between jurisdictions to recognise outcomes of reviews already undertaken.

Australia has already put in place a Mutual Recognition Agreement with Europe in respect of conformity assessment certificates, and is in the final stages of implementing similar arrangements with Canada.

Notwithstanding these arrangements, the HTA Review identified a number of areas where the regulatory regime should be changed.

The first of these is in regard to the current prohibition on Third Party Conformity Assessment (TPCA). Overseas-made devices (except those devices which contain medicines or materials of human or animal origin or blood products) can enter the Australian market on the basis of assessments conducted by TPCA bodies and under mutual recognition agreements between Australia and the European Community. Manufacturers of Australian-made devices can only seek conformity assessment certification from the TGA. Manufacturers (both overseas and domestic) contended that enabling them to use TPCA (for all types of medical devices) would reduce regulatory timeframes and make it more likely devices would be manufactured in Australia. The TGA has commenced formal consultation on this issue, and should respond by July 2010 with a view to implementing agreed changes by 2011.

The second issue is that some stakeholders suggested that the safety and performance of some joint replacement prostheses are not adequately evaluated prior to inclusion on the ARTG (resulting in risks to consumers and cost to payers). In response to these concerns, the TGA has invited submissions on a proposal to re-classify these devices to require a higher level of regulatory oversight. If implemented, this would provide for more appropriate pre-market regulation for these implants while also enhancing the TGA's post-market controls over this important and higher risk group of medical devices. The HTA Review recommends that where the amendment of regulations is proposed, this be finalised by the end 2010.

Finally, during consultations for the HTA Review, stakeholders expressed the view that one of the most critical aspects of HTA is to protect Australian consumers from health technologies which cause harm. The TGA currently has this responsibility, which it exercises by ensuring that goods listed on the ARTG are 'free from unacceptable risk'. This is a minimum standard, which is appropriately a precondition of any government reimbursement for a new technology. Overall, the HTA Review finds that the TGA provides its assessment in an efficient, transparent and timely way. Most stakeholders were supportive of current TGA procedural arrangements. The HTA Review did, however, find that some stakeholders were concerned that MSAC and PDC also considered the safety of new technologies as part of their assessment, which was perceived as a duplication of the TGA's role as the market regulator. This was particularly the case for higher-risk devices.

The HTA Review concluded that the TGA should re-assess its current requirements for pre-market assessment of higher-risk devices for entry in to the market, with a view to addressing these perceived shortcomings, and develop the evaluation processes to ensure the safety assessments undertaken can satisfactorily inform the requirements of the 'downstream' HTA agencies, namely PDC and MSAC. More explicit and detailed information about the TGA's safety assessment of a device should be provided to PDC and MSAC in order to provide assurances about the level of intrinsic safety of the device.

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.

Improving the rigour and efficiency of MSAC

MSAC plays an important role in ensuring that medical services associated with new procedures and devices are subject to HTA before being funded through the MBS.

Although MSAC receives relatively few applications (around 14 per year), it is important that these assessments are conducted in both an appropriately rigorous and timely manner. Currently, the time taken to complete an assessment averages 18 months from acceptance to appraisal. In addition, stakeholders consider that:

- MSAC is slower, less flexible and possibly less consistent in its recommendations than other Commonwealth HTA processes.
- The current model which relies on MSAC conducting its own evaluation, rather than critiquing assessments provided by sponsors, results in inefficient use of resources.
- The establishment of expert advisory panels is considered unacceptably slow.
- There is currently no targeting of assessment effort based on an application's alignment with health priorities or potential for improved clinical outcomes.
- The link between MSAC's conclusions and the Medicare Benefits Schedule (MBS) fees and descriptors agreed by the Medicare Benefits Consultative Committee (MBCC) is less robust than for other comparable HTA processes.

MSAC has recently commenced implementation of a number of initiatives to address these concerns and reduce regulatory costs. It has established an agreed coordination point within the TGA to facilitate more timely advice on the eligibility of products for listing. In addition, two previously separate sections within the MSAC secretariat were merged to improve project management and the flow of information to the MSAC Executive.

A number of other changes are being made to the management of the assessment process. For example, one cause of delays has been the identification late in the assessment process of the need to change the clinical protocol or comparator. In some cases this has required a complete re-consideration of the approach to the assessment.

In addition, the relationship between the Economic Sub-Committee (ESC) and MSAC is being changed so that an ESC member attends initial meetings of the advisory panel to facilitate better decision-making on the economic methodology of assessments.

The HTA Review endorses MSAC's approach. An improvement in MSAC's processes will reduce regulation, increase flexibility and allow assessments to proceed more quickly (in a defined time period) and efficiently for sponsors who have the capacity to conduct a full cost-effectiveness assessment prior to submission to MSAC. It will also allow for the assessment of applications requiring a full HTA to be conducted after submission where this was necessary or where sponsors lacked the resources to do so.

In regard to the delays in MBS listing following MSAC advice in support of public funding, it is important that the Australian Government retain the responsibility for deciding whether or not to implement new MBS items based on MSAC advice, taking into account the broader fiscal and policy priorities of the government. However, greater engagement between MSAC's ESC and MBS financial modellers, and between MSAC clinical experts and areas drafting MBS item descriptors, would reduce delays between advice and listing and potentially enhance MSAC's understanding of broader policy issues affecting its appraisals.

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.

Streamlining management of the Prostheses List

The Prostheses List plays a dual role as part of Commonwealth HTA processes and as part of the regulation of private health insurance in Australia. It therefore plays an important role in ensuring the sustainability of the health system, in particular the private hospital and insurance sectors. The current Prostheses List arrangements were established to control significant increases in the benefits paid for prostheses in the earlier part of this decade.

Since its establishment the PDC arrangements have been highly successful at controlling the growth in prostheses costs. The trend that occurred between 1999 and 2002 in the growth of the cost of prostheses outstripping the growth in the number of services has now been controlled and costs are moving in line with volume. Maintaining this success in controlling the costs of prostheses is critically important to ensuring that both government and consumer contributions to private health insurance remain financially sustainable.

The PDC has been successful in meeting its objective to control private health expenditure on prostheses, and has dealt quite effectively with the large workload that this has involved (over 1,000 applications, 3,000 products, 4,000 benefit negotiations and 6,000 amendments to the list each year). However, this Review provides an opportunity to revise current arrangements which impede progress for reform of Prostheses List activities to develop a more sustainable model for the future, as recommended by the Doyle Review to reduce regulatory burden (including costs) imposed on the medical devices industry.

Currently, benefit negotiations are conducted for each new product that is listed, and for every product that is being reviewed. This can amount to thousands of benefit negotiations every cycle. This is a very resource-intensive approach.

The PDC has sought to simplify the Prostheses List and, since its establishment in 2005, has reviewed around half of the products on the list to identify consistent grouping schemes, as well as progressively reducing the differential in benefits for products within these groups.

However, progress has been slow, as the review process requires the development of grouping schemes by clinicians with limited time available to devote to this work, agreement from stakeholders with competing interests, and complex offers and negotiations for every single product affected by a review. One of the current reviews being conducted by the PDC involves around 2,500 products, and is still not complete after almost two years.

Stakeholders expressed concerns about the application process, which requires them to submit applications within a specific time window. Several sponsors sought a 'rolling' or continuously updated list to address the delay, but private hospitals and insurers considered that the impact of this change on their business processes would not be manageable. Such a change would also present significant logistical difficulties in managing an already difficult PDC workload.

A broader issue is the approach taken by the PDC in assessing the safety of devices which are being considered for listing. Medical device industry stakeholders expressed their concerns to the HTA Review that this represented an unnecessary duplication of the TGA's role, imposing additional costs and delays in the listing process. The HTA Review concluded that any evidence relating to the lack of safety of a device should be referred to the TGA. PDC may decline to recommend listing a device where there is insufficient evidence to support private health insurance funding.

Finally, a growing issue has been the growth of 'gap' items on the Prostheses List. This occurs where the sponsor wishes to list an item, but is not willing to accept the 'minimum' benefit recommended by the PDC for that item for payment by the insurer, but also negotiates a 'maximum' benefit. The difference between the minimum and maximum benefit must be met by the patient as an out of pocket or 'gap' payment.

Many of these concerns relate to the role and composition of the PDC. Accordingly the HTA Review sees merit in a major restructuring of the PDC arrangements.

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.

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.

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.

Improving post-market surveillance of health technology

Post-market surveillance has an important role to play in protecting the community and in ensuring the efficiency and sustainability of the health system.

The HTA Review recommends action in five related areas to improve the post-market surveillance of devices. These are to:

- adopt a more proactive and sustained approach to post-market surveillance for device safety;
- expand the scope of post-market surveillance beyond the current focus on safety to include the collection of cost-effectiveness data to support future reimbursement decisions;
- make selective use of registers to collect post-market surveillance data on specific, high-risk implantable devices;
- explore opportunities for better health data linkage to generate evidence on the utilisation and effectiveness of health technologies; and
- use data from post-market surveillance to evaluate technologies funded for reimbursement on an interim basis.

A more proactive approach to post-market surveillance for device safety

The current post-market surveillance system relies heavily on device manufacturer/sponsor reporting, which in turn relies on the sponsors awareness of emerging problems. If concerns are identified and validated, the TGA may cancel or suspend the ARTG entry of particular therapeutic goods, or direct other action such as a recall, safety alert or product improvement by the manufacturer.

However, reporting may be incomplete or delayed, particularly when a device is no longer regarded as 'novel', because of reliance on reporting by clinicians, consumers or health organisations.

Submissions to the HTA Review suggested that there needs to be greater public awareness of the opportunities and mechanisms whereby both health service providers and consumers can more actively participate in post-market surveillance, such as through the formal TGA processes for reporting adverse events associated with device use.

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.

Expanding the scope of post-market surveillance

Current post-market surveillance arrangements, such as those managed by the TGA, focus exclusively on ensuring regulatory compliance and safety of medical devices.

There are two reasons to consider expanding the scope of post-market surveillance to collect information useful for HTA.

The first is that often only limited real-world data are available at the time of the initial HTA. In addition, a particular device may be used in different circumstances, for different purposes, in different patients, or in combination with other procedures or technologies not considered at the time of the original approval. Therefore, the initial HTA for reimbursement and decision to subsidise a health technology could, in many cases, be considered a crucial first step in gauging the efficacy and comparative cost-effectiveness of a technology, rather than the only step.

A second reason to enhance post-market surveillance is that there is increasing pressure to accelerate entry of what may be very new technologies (including surgical procedures) to the health system which have relatively little evidence supporting their longer-term costs and benefits. Expanded post-market surveillance may provide a means by which some technologies could be subsidised on a conditional basis (based on satisfying an initial assessment), with evidence collected from actual patient utilisation. This more flexible approach is consistent with the principles of better regulation.

For Australia to follow a similar path, careful consideration of the roles and responsibilities of each stakeholder (Australian, state and territory governments, clinicians and consumers, as well as device manufacturers and sponsors) and associated infrastructure and regulatory requirements (such as to permit data linkage) would be required.

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.

Investigating the scope for better health data linkage

Medical devices are rarely used in isolation. In most cases the device is part of wider intervention such as surgery, and may also be associated with the use of medicines or other treatments or tests that may continue to be required for some time.

Underpinning any proposal to link datasets should be an ethical framework that offers sufficient assurances of privacy and confidentiality to service providers and clients and protections against the use of personal information for purposes other than those originally intended. Such protections and protocols need to inform not only the actual process of linking client records but also related processes such as obtaining client consent, data storage, transfer, encryption and release.

Stakeholders saw more value in testing linkage in areas of likely high return and then applying lessons more broadly across the health system.

Using data from post-market surveillance to guide investment in technologies

During the options development phase of the HTA Review, stakeholders generally agreed that disinvestment in relation to comparatively ineffective devices was desirable. However, a substantial number of those consulted (particular industry and clinician stakeholders) considered that the market worked effectively to discourage the use of outdated or ineffective technologies and that no government intervention was required to proactively review and identify specific technologies for disinvestment. On the other hand, others noted that a number of procedures and devices continue to be used and subsidised despite common knowledge that they are at best ineffective or at worst harmful.

A recurring theme in submissions and consultations is that the current HTA system heavily emphasises the initial assessment of technology but does not sufficiently address the ongoing relevance of a technology. The term 'disinvestment' was used to cover a range of processes that might answer questions such as:

- Should a technology be removed from the market?
- Should a technology continue to be publicly funded?
- Should the eligible population be reviewed?
- Should the price (benefit) paid for technologies increase, decrease or stay the same?

Such an approach could encourage more robust and efficient processes around all health care decision-making, including reallocation (or reinvestment) of funding to interventions, including devices, that offer overall health gains more efficiently. In the face of increasing health expenditure, it will become increasingly difficult for governments to fund new health technologies unless they have the capacity to identify and remove funding for those that are less effective.

Selective use of registers to collect post-market surveillance data

'Clinical registers are databases that systematically collect health-related information on individuals who are:

- treated with a particular surgical procedure, medicine or device (e.g. joint replacement);
- diagnosed with a particular illness (e.g. stroke); or
- managed via a specific healthcare resource (e.g. treated in an intensive care unit).¹³

In Australia, the best known register, the National Joint Replacement Registry (NJRR), was established a decade ago to define, improve and maintain the quality of care for individuals receiving joint replacement surgery. It is considered to have delivered substantial benefits and is estimated to have reduced the number of unnecessary revision operations by 1,200 procedures per year and saved the health sector and consumers around \$44.6 million since it was established in 1999.

In the light of this experience, the HTA Review supports the development of additional registers.

However, registers can be difficult to establish and expensive to run. Accordingly, the initial focus for any new register should be for high-risk implantable devices for which consumer safety risks are most critical.

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.

Longer-term directions

This Review has made a number of recommendations to strengthen the conduct of HTA by Australian Government agencies in the short- to medium-term.

The HTA landscape is, however, constantly changing, and extends beyond direct Australian Government responsibilities. In addition, the consultations conducted as part of the HTA Review identified a number of issues that will require sustained, coordinated action over the longer-term and that were not necessarily able to be addressed as part of the HTA Review's terms of reference.

Many health technologies are separately assessed by each state and territory government, or through joint arrangements between the Australian and the state and territory governments.

Similarly, the development of a skilled HTA workforce and a research capacity to develop HTA methodologies and evidence requires a national approach (such as for blood and blood products).

Accordingly, the HTA Review proposes exploration of a set of longer term strategic issues to inform possible future national activity. These are:

1. improved planning and system integration;
2. a national strategic framework for HTA involving the Australian Government, states and territories and other key stakeholders;
3. greater patient (health consumer) focus;
4. increased investment in HTA-related research; and
5. increased capacity of the HTA workforce.

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.

CHAPTER ONE

Introduction to the HTA Review



1 Introduction to the HTA Review

1.1 Background to the HTA Review

The Minister for Health and Ageing, the Hon Nicola Roxon MP, and the Minister for Finance and Deregulation, the Hon Lindsay Tanner MP, jointly announced the Review of Health Technology Assessment in Australia (HTA Review) in December 2008 as a Better Regulation Ministerial Partnership (see Appendix A).

The HTA Review is one of the first of a series of Better Regulation Ministerial Partnerships (Partnerships), which are an initiative of the Minister for Finance and Deregulation, the Hon Lindsay Tanner MP, and his ministerial colleagues. The Australian Government's Better Regulation agenda reflects a policy commitment to well-designed and targeted regulation.

In this context, the HTA Review is also a key 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.⁴ Appendix C details the findings and recommendations of these earlier reviews and the current status of activities to respond to, or how the HTA Review will address them.

In addition, the HTA Review is a part of the government's broader reform agenda for the Australian health system and complements the 2009–10 budget measure *'Medicare Benefits Schedule – Quality Framework for Reviewing Services'* (the MBS Quality Framework) which is developing a framework for reviewing Medicare Benefits Schedule (MBS) items which have not been assessed through the Medical Services Advisory Committee (MSAC). The Australian Government has provided \$9.3 million over two years to develop and implement the new evidence-based framework for managing the MBS into the future. The MBS Quality Framework involves the introduction of a new MBS listing process from 1 January 2010 for applications not assessed by MSAC. Items determined to be eligible for MBS funding will be listed on a time-limited basis (normally three years) subject to a new process for setting the MBS fee, with a formal evaluation process at the end of the time-limited period. A strong evidence base will be the pre-requisite to ongoing MBS listing. New listing, pricing and review processes will be introduced throughout 2010 following consultation with providers, consumers and other experts. The MBS Quality Framework also involves the development of processes to review existing MBS items to ensure that they are based on best clinical practice and are priced appropriately. The reviews will provide a sound evidence base for improving reimbursement arrangements, including through amendments to fees and/or descriptors, or removal of items.

Recommendations arising from the HTA Review have been developed to be consistent with the principles underpinning the MBS Quality Framework.

1.2 The Australian Government's Regulatory Reform Agenda

The Australian Government's Better Regulation agenda reflects its commitment to microeconomic reform to drive productivity growth by engendering a culture of continuous regulatory improvement – where regulation is efficient and fit for purpose. Better Regulation will reduce the regulatory costs to Australian business, and the not-for-profit sector, supporting productivity, employment and economic growth.

The benefits of greater patient safety and more sustainable health financing arrangements through the use of HTA should outweigh the costs of such regulation. However, where HTA processes cause unnecessary costs or delays, because they are inefficient, uncoordinated or poorly targeted, there may be little net public benefit. The Australian Government acknowledges that additional costs and delays in achieving return on investment may appropriately occur with the assessment of the safety and efficacy of new health technologies prior to sale in Australia, or with the evaluation of their cost effectiveness before the government subsidises their use.

The HTA Review has identified opportunities to streamline the assessment and approvals process for health technology products, therapeutic goods and medicines both for government funding and to enable them to be released into the Australian market.

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.

1.3 Previous Reviews

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

- the Regulation Taskforce report, *Rethinking Regulation – Report of the Taskforce on Reducing Regulatory Burdens on Business* (January 2006)⁵ (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),⁶ 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)⁷ (known as the 'Doyle Review'), which made a series of recommendations specific to the Prostheses List and the work of the Prostheses and Devices Committee (PDC); and
- the Productivity Commission report, *Annual Review of Regulatory Burdens on Business: Manufacturing and Distributive Trades* (September 2008)⁸, which made recommendations around the efficiency of the Therapeutic Goods Administration's (TGA) processes in regulating health technologies.

The HTA Review presents an opportunity to further consider and, where appropriate, to address findings of earlier reviews, noting that considerable work has already been undertaken by the government to address many of the issues identified in these reviews. A summary of the findings of these reviews, and progress in implementing recommendations from these reviews, is at Appendix B.

1.4 HTA Review Terms of Reference and Scope

Ministers Roxon and Tanner asked DoHA to conduct the HTA Review (in consultation with Department of Finance and Deregulation (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 HTA Review was to canvass opportunities for reform within existing funding levels and consistent with government policy objectives.

Figure 1.1: Summary Terms of Reference for the HTA Review

The HTA Review is to report against the following terms of reference (which are detailed in full in Appendix C) 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-dependentⁱ and hybridⁱⁱ technologies.

ⁱ 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.

ⁱⁱ 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)

The Commonwealth HTA processes in scope for the HTA Review are:

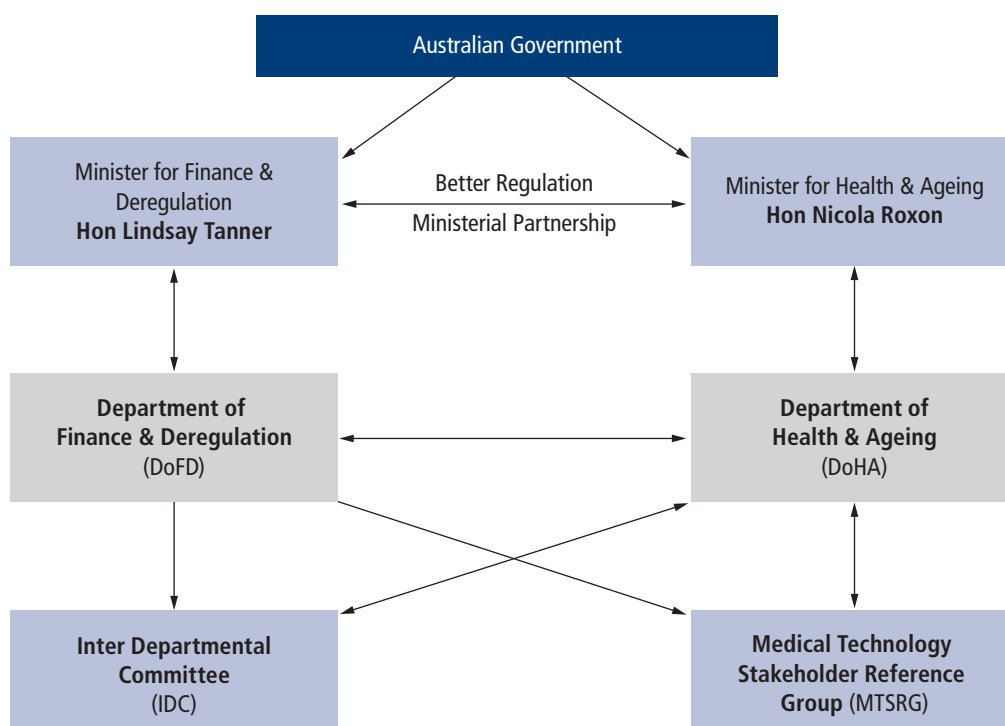
1. the regulation of therapeutic goods for market entry, currently undertaken by the TGA;
2. the approval of funding under the MBS, currently informed by the MSAC and relevant implementation consultative committees;
3. the listing of prostheses for private health insurance coverage, as currently informed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

Processes specifically out-of-scope for the HTA Review include those: performed by PBAC (except where there is an interface between 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.

1.5 Management of the HTA Review

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 Innovation, Industry, Science and Research (DIISR), Veterans' Affairs (DVA), Prime Minister and Cabinet (PM&C) and Treasury.

In addition, DoHA established the Medical Technology Stakeholder Reference Group (MTSRG) as 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.

Figure 1.2: Summary of governance arrangements for the HTA Review

An overview of the governance arrangements (including committee membership) is at Appendix D.

In managing the HTA Review, and consistent with its conduct as a Better Regulation Ministerial Partnership, DoHA has worked in close and productive collaboration with DoFD. DoFD actively participated in the Review's bilateral meetings with key peak stakeholders bodies, attended focus groups and contributed to the development of HTA Review material.

1.6 Methodology

The methodology for the HTA Review was designed with the aim of ensuring a comprehensive, publicly accessible, transparent process that took account of the views of all stakeholders.

Activities included:

- 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 HTA Review;
- preparation of a public discussion paper ('Review of Health Technology Assessment in Australia – A Discussion Paper') (see Appendix E) to inform the preparation of stakeholder submissions;
- analysis of the 86 stakeholder submissions received in response to the discussion paper (see Appendix F);
- internal consultations and analysis within DoHA, including a review of current Commonwealth HTA processes (see Appendix G), existing literature and an analysis of previous reviews;

- 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;
- 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 (see Appendix H);
- 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 (see Appendix I);
- preparation of a set of five options papers describing proposals to address the terms of reference. The options were developed taking account of stakeholder feedback on issues with Commonwealth HTA processes (see Appendix J);
- conduct of a second round of focus group consultations consisting of 11 sessions involving 113 participants to seek feedback on the proposals (see Appendix K); and
- 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 (see Appendix L).

1.7 This Report

This Report presents a feasible, staged reform agenda which addresses the strongly held views of stakeholders in relation to the Commonwealth HTA processes that are within the scope of this Review. It has been finalised in consultation with the HTA Review governance committees – the Australian Government IDC and the MTSRG.

This Report presents 16 recommendations which provide a strategic way forward for Commonwealth HTA processes in the next decade.

In making its recommendations to government, the HTA Review has been 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 publicⁱⁱⁱ 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.

ⁱⁱⁱ 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

1.8 Implementation Review

Any changes to HTA regulatory processes agreed by the government arising from 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.

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.

CHAPTER TWO

An Overview of Health Technology and Health Technology Assessment in Australia



2 An Overview of Health Technology and Health Technology Assessment in Australia

2.1 What is Health Technology?

While health technologies can be defined as including all innovations in the provision and arrangement of health care, the HTA Review has had a particular emphasis on diagnostic and therapeutic goods and services (including prostheses, devices, diagnostic tests, and medical and surgical procedures).

However, 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', 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. These are discussed in more detail in section 2.4 of this Report.

2.2 The Impact of Health Technology on the Health System

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.⁹

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.¹⁰ 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 innovations¹¹; and
- technology has contributed around one-third of the increase in real total health expenditure in the decade from 1992–93 to 2002–03.¹²

2.3 The Medical Technology Sector in Australia

In its submission to the 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.¹³

Figure 2.1 lists the key characteristics of the medical technology industry in Australia.

Figure 2.1 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: MTAA¹⁴

In its submission to the HTA Review 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.¹⁵ ... Australia exports most of the medical devices it produces and imports most of the medical devices it consumes.¹⁶

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.¹⁷

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.

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

In recent years most countries have experienced exponential growth in health technologies such as new medicines and diagnostic tools, tele-medicine, and surgical equipment. These innovations provide a major opportunity for governments, 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 cost-effective new treatments.¹⁸

Sustainability of health financing arrangements

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 this Report, are the PBS for pharmaceuticals, the MBS for medical services, and subsidised private health insurance (PHI) 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
- PHI – \$2.4 billion.¹⁹

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 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 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 focus of HTA

The key questions that HTA typically aims to answer for each new health technology, in comparison to alternative interventions, are:

- Is it safe?
- Does it improve health outcomes overall?
- Is it cost effective?

Effective assessment of health technologies includes:

- evaluating the comparative harms and benefits, using clinical evidence of patient safety, efficacy and clinical effectiveness^{iv}; and
- understanding the aetiology and prevalence of disease and knowledge of best practice treatment pathways.

A well-performing HTA system will:

- facilitate patient access to cost-effective health technologies that improve health outcomes;
- minimise the diffusion of technologies that are ineffective or harmful;
- contribute to value for money investments in health technology in the context of limited health care resources;
- keep pace with evolving technologies, clinical practices and HTA methodologies;
- provide clear information on processes, rules and outcomes to stakeholders; and
- ensure the system itself is designed to achieve these outcomes in the most timely, effective, efficient and targeted way.

Balancing competing demands

The various groups of HTA stakeholders have different sets of interests they wish to see reflected in and addressed through the design and management of the HTA system.

These include:

- 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;

^{iv} 'Efficacy' measures how well a technology works in ideal circumstances such as clinical trials or the laboratory whereas 'effectiveness' relates to how well a health technology works in regular practice.

- health technology suppliers – 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.

Inevitably, tensions arise amongst different stakeholders about the best means to achieve these objectives, some of which are reconcilable, some are not. Furthermore, differences of opinion arise about the best means to balance these competing interests within finite budgets to ensure Australians have access to safe, effective and cost-effective health technologies with minimal delay and red tape. Ensuring equitable access to health technologies on the basis of need, as well as ensuring broad community acceptance of decisions made around prioritisation of health technologies is also a challenge.

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). The publication of HTA Reports will assist clinicians and consumers to make more informed decisions.

Managing the challenges of co-dependent and hybrid technologies

As health care is evolving, there is an increasing number of co-dependent and hybrid technologies, ranging from a single product with several components to several types of services linked along a clinical pathway. The use of diagnostic testing (including genetic testing) to refine patient selection and eligibility for high cost procedures, devices and particularly medicines, and the continued development of pharmacogenomics (a trend sometimes referred to as 'personalised medicine'), will provide a whole new set of tools and approaches for tackling disease, and challenges for their assessment.

Defining the technologies

Co-dependent technologies are those technologies that are dependent on another technology either to achieve their intended effect or to enhance their intended effect.²⁰

The most common emerging group of co-dependent therapies are those targeted to distinct patient populations and requiring a specific diagnostic technology in order to be delivered to the appropriate patient population. Current examples of this are: bone densitometry testing associated with access to alendronate (Fosamax) for the treatment of osteoporosis; and in situ hybridisation (ISH) testing related to eligibility for trastuzumab (Herceptin) for the treatment of breast cancer.

Hybrid technologies combine the characteristics of different health technologies (e.g. a medicine or a medical device or a biologic) in one intervention (e.g. drug eluting stents for treating cardiovascular disease or photodynamic therapy for treating skin disease).

The HTA Review found that current Commonwealth HTA processes are challenged by co-dependent and hybrid technologies and require urgent adjustments in order to manage the complexities of assessing these technologies for market entry and reimbursement.

Assessments of co-dependent technologies conducted to date have predominantly involved co-dependent pharmaceuticals and diagnostic tests. Each component part is currently considered separately by the relevant advisory committees using different methodological approaches to assessing evidence against the HTA criteria, and with applicants required to make multiple applications, often sequentially. For example, patient eligibility for a pharmaceutical recommended by PBAC might require confirmation of a diagnosis using a particular test before the pharmaceutical can be claimed through the PBS. Difficulty has arisen when the required diagnostic test has not been listed on the MBS. In some instances, applications have been submitted independently to both MSAC and PBAC, while in others, separate applications have been submitted sequentially to the two advisory committees. However, due to their co-dependence, the benefits of their joint use (as distinct to the benefit of each technology in isolation) are critical to their appraisal.

In respectively assessing a diagnostic test and a pharmaceutical, MSAC and PBAC rely on different assessment and appraisal processes. MSAC generally has access to a more limited evidence base, often requiring a methodological linking of evidence according to specific rules (for diagnostic tests) to allow an evaluation of the broader societal impact of the service. This is methodologically more complex and time-consuming, and requires a multidisciplinary evaluation. PBAC relies on well-resourced submissions from industry, with higher levels of evidence within a more homogeneous and better resourced clinical discipline, allowing PBAC to conduct its appraisal within prescribed and relatively short time-frames.

The lack of an integrated approach to assessing co-dependent technologies results in duplication of effort and potentially significant barriers to patient access.

The definitional ambiguity around hybrid technologies presents issues for current Commonwealth HTA processes because this type of technology can incorporate a medical procedure or a device or a medicine, and each of these components is assessed by a different advisory committee – MSAC, PBAC or PDC. This presents challenges as to which reimbursement scheme is appropriate and thus which assessment process should be used.

The key tasks for enhanced arrangements for assessment of co-dependent and hybrid technologies include defining primary responsibility for the overall assessment; and improving coordination between not just the advisory committees such as PBAC and MSAC (and their respective secretariats), but also with the TGA.

The TGA's processes are probably the most advanced for handling hybrid technologies at this point, by taking into consideration:

- which element (device, medicine or biologic) provides the principal therapeutic effect (the principal mode of action of the product); and
- which element(s) provide (s) the supporting or ancillary effect, as they relate to the definition of medicine and medical device.²¹

The element considered to be delivering the principal therapeutic effect in a hybrid technology determines whether the product is considered to be a medical device or a medicine, and is usually determined by the manufacturer's intended purpose for the product.

The TGA's assessment of a co-dependent technology (such as a medicine delivered by a separate device) generally follows a similar pathway, but because the two elements are supplied separately to the market, two separate areas within the TGA will assess the application. Where the medical device elements of co-dependent technologies are utilised to 'activate' the medicinal element of the therapy, the device is assessed to ensure it complies with the essential principles and performs as intended by the manufacturer. The synergistic effect of the co-dependence is assessed clinically in the evaluation of the medicinal element of the two.

While the TGA's approach to assessing these technologies largely determines how they are handled by subsequent advisory committees, it is important that definitional issues and protocols about how these technologies should be treated are resolved at the outset of the HTA process. This will assist in ensuring that the application is assessed by the most appropriate advisory committee, and directed to the most appropriate assessment pathway. It should be noted that defining these technologies is further confounded by the fact that there is not always international consistency about how they should be treated, which in turn can be confusing for overseas manufacturers registering products in Australia.

Gaps in the evidence base for hybrid and co-dependent technologies

There can be difficulty producing the level of evidence necessary to assess hybrid technologies for reimbursement because of difficulty obtaining direct evidence of a link between the particular combination of technologies and any health gain, due to the fact that changes in health status can result from interactions between individuals and a wide range of factors in their environment, including the technology. This can make it difficult to collect the specific evidence necessary to demonstrate that the technology is the key contributing factor to the health gain.

In the case of co-dependent technologies, there can be different timeframes for the development and assessment of each technology. For example, in many instances the development of a diagnostic test and a medicine are undertaken by different companies at different times, which can have a significant impact on the quality and type of trial evidence available for the combination of both products at the time of product launch. In addition, some devices and tests have been developed by small-scale researchers without the resources to undertake suitable studies to validly estimate the long-term costs and outcomes associated with the technology.

Submissions to the HTA Review commonly identified concerns with the evidence base for co-dependent technologies where a diagnostic technology (pathology testing/diagnostic imaging) is involved.

Other evidentiary challenges in regard to hybrid and co-dependent technologies include:

- establishing an appropriate comparator;
- methodological difficulties associated with undertaking the economic evaluation of diagnostic tests:
 - Even when a diagnostic test has demonstrable clinical utility, it may be difficult to prove that the test is cost effective compared to the alternative of doing nothing, unless the broader consequences of doing nothing (in terms of overall morbidity and mortality associated with the disease in question) are taken into account;
 - This difficulty is accentuated in the context of genetic tests where it may be the asymptomatic relatives of a patient who would benefit from a test but the benefits that would accrue will not be captured in a simple comparative cost-effectiveness model focused on the patient;²² and
- the cost effectiveness of a diagnostic test is dependent on what treatments are available at the time of the analysis and may differ depending on which therapy is included in the economic modelling.

2.5 Current Commonwealth HTA Processes

In keeping with international practice, HTA in Australia has four broad elements: horizon scanning, market regulation, HTA for reimbursement, and post-implementation management. These elements are summarised in Table 2.1 and the following sections describe the current arrangements in more detail.

Table 2.1: Summary of current Commonwealth HTA functions

Function	Purpose
Horizon scanning	To identify new and emerging health technologies to inform governments and health systems for planning purposes
Market regulation	Assessment of the intrinsic safety and performance of therapeutic goods, as intended for use by manufacturers
HTA for reimbursement	Comparative assessment of safety, clinical and cost effectiveness of health technologies for consideration for subsidy
Post-market surveillance	Surveillance of health technologies in routine clinical use

Horizon scanning

The aim of horizon scanning is to identify and anticipate major new and emerging health technologies that are likely to have significant impacts or implications on health systems.²³

Horizon scanning in Australia is currently undertaken by the Health Policy Advisory Committee on Technology (HealthPACT) which reports to the Clinical, Technical and Ethical Principal Committee (CTEPC), a subcommittee of the Australian Health Ministers' Advisory Council (AHMAC). It is part of the Australian and New Zealand Horizon Scanning Network (ANZHSN). It has representation from the Australian, state and territory and New Zealand (NZ) governments and NZ health system representatives²⁴, HealthPACT offers a forum for the sharing of information obtained through HTA processes at the state/territory and local levels'.²⁵ HealthPACT's terms of reference are to 'complement, but precede health technology assessment'.²⁶

AHMAC may refer a new technology (such as may have been identified in a report from HealthPACT) to MSAC to undertake HTA. More commonly, the states and territories use the horizon scanning reports to identify and describe emerging technologies to assist in planning and further evaluation before their introduction into their respective health systems.²⁷ Current technologies considered under HealthPACT's horizon scanning activities include 'devices, diagnostic tests and procedures, and other surgical and non-surgical interventions,' but not pharmaceuticals.²⁸

Market regulation

Market regulation aims to ensure that new therapeutic goods are safe, perform as intended and are produced using appropriate quality controls before granting marketing approval in Australia. Market regulation also ensures that goods that are found to be unsafe are removed from the market (see section 5.3). This is currently the responsibility of the TGA, which is part of the Australian Government's health portfolio.

The role of the TGA

The TGA was established in 1989, with the current medical devices regulatory scheme commencing in 2002. The market entry functions, roles and responsibilities of the TGA and its advisory committees (Medical Device Evaluation Committee (MDEC) and its supporting sub-committees) are prescribed in legislation.

Medical devices used in Australia are regulated under the *Therapeutic Goods Act 1989* (the Act). Medical devices cannot be marketed in Australia unless they are approved by the TGA for inclusion on the ARTG or are specifically exempted by legislation. In making a decision to include a medical device in the ARTG, the Secretary of DoHA (or delegate) considers an assessment report and approves the medical device if quality, safety and efficacy are demonstrated. The TGA assessment of safety requires that the medical device should be 'free from unacceptable risk'.

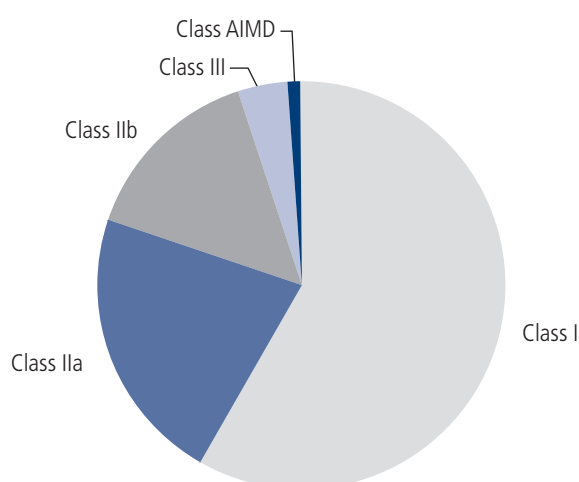
The regulatory framework uses a classification system to categorise medical devices based on the risk the device presents to the patient, the user and the environment. The classification rules are based on the manufacturer's intended use, the level of risk presented by use of the device and the degree of invasiveness in the human body.

The five classes of medical devices, starting with the lowest designated level of risk are:

- Class I (low risk)
- Class IIa (low-medium risk)
- Class IIb (medium–high risk)
- Class III (high risk)
- Active Implantable Medical Devices (AIMD)

As at December 2009 there were around 33,000 devices included on the ARTG. Figure 2.2 shows the distribution of these devices by class.

Figure 2.2: Distribution of devices on the ARTG by class as at December 2009



Source: TGA

Interestingly, although the higher-risk Class III devices account for only four per cent of all devices on the ARTG, they accounted for 13 per cent of new devices included during 2007–08. These data reflect the way in which higher risk medical devices are assessed and entered on to the ARTG.

The TGA conducts three key assessment processes for medical devices:

- conformity assessment procedures that assess requirements imposed on manufacturers;
- assessment of applications for inclusion of devices on the ARTG; and
- post-market monitoring, surveillance and review of medical devices.

The TGA uses a risk-based approach to assess the safety and performance of devices, against essential principles of safety and performance as defined in the Act. The essential principles set out the requirements relating to the safety and performance characteristics of medical devices. The principles may define results to be achieved, performance levels, hazards to be addressed or issues to be considered, but do not necessarily specify how they must be satisfied or complied with.

The Act was amended in 2002 to introduce a new system for medical device regulation incorporating the principles of the international regulatory model developed by the GHTF. The GHTF currently includes the member economies of the United States, Europe, Canada, Japan and Australia. Regulatory frameworks based on the GHTF model are also in various stages of introduction in many countries in South East Asia, Latin America, the Middle East and Africa.

The underlying philosophy of the GHTF regulatory framework is to remove unnecessary duplication of reviews in different regulatory jurisdictions, firstly by harmonising regulatory requirements between jurisdictions where possible, and then by establishing collaborative agreements between jurisdictions to recognise outcomes of reviews already undertaken. The GHTF and related international agreements seek to facilitate timely access of medical devices to the market and reduce costs to the manufacturer.

Australia has already put in place a Mutual Recognition Agreement with Europe in respect of conformity assessment certificates, and is in the final stages of implementing a Memorandum of Understanding with Canada in respect of assessment of Quality Management Systems associated with the manufacture of medical devices.

HTA to inform reimbursement decisions

Current arrangements

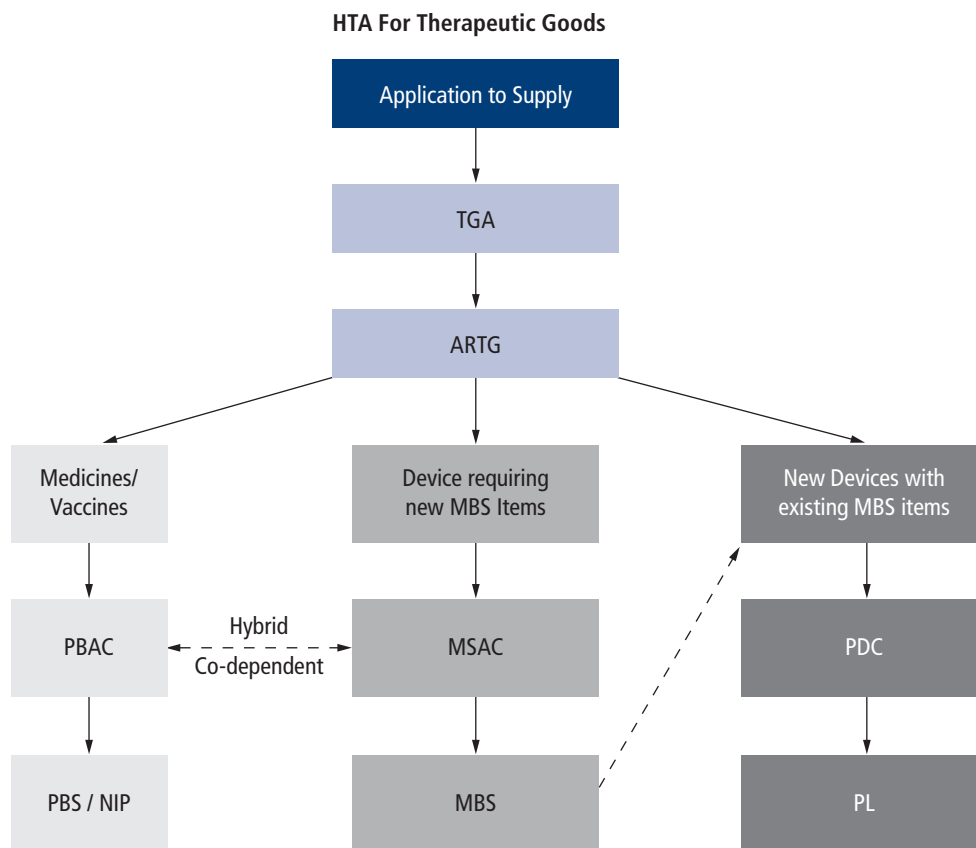
Once a technology has been approved for entry to the Australian market, a sponsor or manufacturer may seek to have it assessed by the Australian Government for public and private funding. HTA for reimbursement assesses health technologies in regard to their comparative clinical effectiveness (including comparative effectiveness) and cost effectiveness. This includes medical services, surgical interventions, medical procedures, diagnostic technologies (including pathology), devices, vaccines and pharmaceuticals (and combinations of these including hybrid and co-dependent technologies) as shown in Table 2.2.

Table 2.2 Summary of scope of current Commonwealth HTA coverage.

Type of Health Technology	Public and/or Private Funding Mechanism(s)	Committee Currently conducting HTA
Prostheses (surgically implantable medical devices)	Prostheses List	PDC
Pharmaceuticals and Vaccines	PBS/NIP	PBAC
Medical Services (associated with technologies)	MBS	MSAC
Diagnostic tests	MBS	MSAC

A diagram representing these Commonwealth HTA functions is shown in Figure 2.3 below.

Figure 2.3: Overview of Commonwealth HTA processes



Public funding through the MBS

MSAC was established in 1998 to strengthen arrangements for assessing new technologies and procedures before they are considered for reimbursement under the MBS.

Its terms of reference require it to advise the Minister on the strength of the evidence relating to safety, clinical effectiveness and cost effectiveness and also on the circumstances under which medical services involving new technologies and procedures should be eligible for public subsidy. The MSAC assessments are undertaken by external experts using a comparative approach in which the proposed service is compared with services currently receiving public reimbursement. All costs associated with supporting MSAC are met from DoHA resources.

Once the Minister notes the MSAC advice, DoHA either takes no further action (in respect of a negative appraisal), or (for a positive appraisal) negotiates with the medical profession through consultative committees to determine the proposed MBS item descriptor and fee, and undertakes costings (which must be agreed with DoFD) before providing further advice to the Minister. The Minister then makes a decision within the context of broader government priorities about whether the proposed medical service should be included in the Health Insurance Regulations (which give effect to a new MBS item).

Public funding through the PBS

PBAC was established in 1954, with its functions, roles and responsibilities prescribed in legislation. It assesses comparative clinical and cost effectiveness for the purposes of advising the Minister on the eligibility of pharmaceuticals and vaccines for public subsidy under the PBS and National Immunisation Program (NIP). The PBAC assessment of clinical effectiveness involves an assessment of the harms versus the benefits of a pharmaceutical or vaccine against suitable comparators. Assessments of applications are mainly undertaken by DoHA staff (many with pharmaceutical, scientific or clinical expertise) or evaluation groups under contract. Cost recovery for this function will be implemented from 1 January 2010.

Once PBAC has recommended a pharmaceutical for listing on the PBS, the Pharmaceutical Benefits Pricing Authority (PBPA) makes a recommendation on the proposed price for a new PBS item based on advice from PBAC, including consultation with the applicant and other sources. Where the projected net cost is less than \$10 million per annum, the Minister notes the advice, and a delegate (of the Minister) approves the inclusion of the product on the PBS. If the projected cost is greater than \$10 million per annum, then approval by the Minister and Cabinet within the context of broader government priorities is required. The Minister (or delegate) then authorises the inclusion of pharmaceuticals in legislative instruments which gives rise to the PBS.

Private health insurance reimbursement for prostheses

The Minister established the PDC in 2004 to advise on which products should be included in the Prostheses List and the appropriate benefit for private health insurance reimbursement purposes. The Minister has also approved criteria in addition to those prescribed in legislation for eligibility for listing on the Prostheses List. The PDC assesses comparative clinical effectiveness and cost relative to clinical effectiveness for the purposes of determining an appropriate benefit. The prostheses listing arrangements operate under full cost recovery. Assessment of clinical effectiveness is conducted by external experts.

The PDC makes a recommendation to the Minister (or delegate) on the appropriate benefit for a product to be included on the Prostheses List. PDC's recommendation is based on benefit negotiations conducted by the Prostheses and Devices Negotiating Group (PDNG). A delegate (of the Minister) approves the inclusion of products in the Prostheses List by signing Rules which gives rise to the List.

Post-market surveillance

The aim of post-market surveillance (PMS) is to identify whether health technologies continue to be as safe, effective or cost effective as when originally approved for market entry or reimbursement, or as compared to new health technologies under assessment. PMS also aims to report adverse events and apply vigilance to marketed technologies to ensure manufactures, sponsors, health care providers and users are aware of these events.²⁹

The TGA plays the major role in current PMS functions, focussing on the evaluation of the intrinsic safety and performance in practice of therapeutic goods (health technologies, devices and prostheses) which have been approved by the TGA for supply and use in Australia. The TGA also manages reported adverse events of these goods in practice.

2.6 The International Context

In order to fairly assess the strengths and weakness of Commonwealth HTA processes, and consider proven options for change, there is a need to consider how HTA is undertaken internationally and how Australia links into and compares against international systems. It is important to note that comparison of HTA systems is not straightforward, as other health systems differ in scope and process from the Australian health system, and approaches to HTA vary across systems.³⁰

The Australian HTA system currently successfully undertakes all of the key elements of HTA that form part of other reputable international HTA systems. These elements can be defined³¹ as:

- horizon scanning where emerging technologies with potentially significant impacts on the health system are identified;
- comparative technology assessment where new technologies are assessed with respect to safety, efficacy, effectiveness and cost effectiveness against alternative clinical strategies; and
- monitoring and review of a technology's use and impact on the health system.

DoHA (with PBAC and MSAC) is a member of the international professional HTA society, Health Technology Assessment International (HTAi), which aims to achieve continual improvement in HTA practice. In 1992, Australia was the first country to introduce as a mandatory criterion the consideration of cost effectiveness as part of formal listing of pharmaceuticals through the PBAC process. PBAC continues to be noted internationally as a robust system whilst the MSAC and PDC processes have not yet achieved the same reputation. The reasons for this are explored in more detail in the coming chapters.

Overview and comparison of the Australian, United Kingdom, Canadian and United States HTA systems

This section provides an overview and comparison of the Australian, United Kingdom (UK)/European Union (EU), Canadian and United States (US) HTA systems. These systems provide varying levels of similarity to the structure of the Australian HTA system in countries of a similar financial standing.

In particular the UK system and the Canadian system are commonly praised, and stakeholders have frequently compared them favourably against Australia's system during consultation for the HTA Review. Due to the frequency of comparisons against these systems, their status as good HTA systems and their similarities with Australia, a broad overview of the UK, and Canadian systems, and comparison with the Australian system, follows.^v

^v This table was sourced and adapted from an academic source. Given the limited knowledge of the decision making behind the development of the table, as well as inherent differences in other systems such as the United States, other systems have not been inserted for comparison.

Table 2.3: Overview of HTA systems

	Australia	United Kingdom	Canada
Polymaking	Centralised – health care financed by public and private sources	Centralised – health care financed and provided by the central government	De-centralised – provincial government finance health care
Influence of HTA recommendations on government	Non-binding (exception – PBAC decisions not to recommend listing are binding)	Binding	Non-binding
Accessibility of decisions	Open	Open	Open
Level of activity and resources	Medium funding, high output	High funding, medium output	Medium funding, high output
Public perception	Low	High	Low

Source: Adapted from P Healy & Dr M Pugatch, 'Theory versus Practice -Discussing the Governance of Health Technology Assessment Systems', Stockholm Network, 2009

Market entry

There are strong similarities in market entry across Australia and other countries which are reinforced by mutual recognition agreements for market entry of medical devices, such as the Mutual Recognition Agreement between Australia and the European Community on medical devices conformity assessment.

For a medical device, market entry in the member states of the EU requires confirmation that it is safe and performs to its manufacturer's specifications. This is achieved by requiring a manufacturer to demonstrate compliance with the relevant EU Medical Devices Directive which has, in turn, been replicated in legislation in each of the member states. Compliance with these requirements is assessed by a third party known as a Notified Body, which has been assessed and notified by a regulatory authority (Competent Authority) of a member state. After successful assessment in one member state, the manufacturer affixes the CE Mark, and the product can be freely supplied in all other member states without further assessment. In Australia, the TGA undertakes these assessments. The role of post-market surveillance is undertaken by the Competent Authority with the Notified Body reviewing a manufacturer's reporting compliance during regular audits of the manufacturers operations.

In Canada, market entry assessment is undertaken federally by Health Canada. The threshold for market authorisation is seen as more stringent than that applied in Australia because Canada requires evidence of efficacy of products to be supplied and reviews the data generated by trials to rate device efficacy. The TGA requires information indicating that a device is efficacious and performs as intended, determined by reviewing the manufacturer's summary of the trial data in conjunction with the findings of the expert report.

In the US, market entry is undertaken by the centralised Food and Drug Administration (FDA) which assesses quality, safety and efficacy. Evidence requirements often require full clinical trial data, similar to market entry in Canada. Data are reviewed by FDA reviewers or by third-party assessors for certain low-risk devices.

Health technology assessment

In the UK, HTA is undertaken for England and Wales by the National Institute for Health and Clinical Excellence (NICE), which produces guidance on prioritised or “needs-led” topics under the banners of public health, clinical practice, and the assessment of effectiveness and reimbursement of health technologies within the UK National Health System (NHS). NHS organisations in England and Wales are required to provide funding for technologies recommended by NICE in its guidance.

In Canada, comparative effectiveness is assessed by the provinces in conjunction with national coordination by the Canadian Agency for Drugs and Technologies in Health (CADTH). CADTH is an independent agency funded by the jurisdictions (federal, provincial and territories). Funding decisions are made on an individual basis by the jurisdictions.

In the US, HTA is undertaken to a lesser or greater degree and by a wide range of publicly and privately funded organisations, consistent with its fragmented health care system. The Agency for Healthcare Research and Quality (AHRQ), a federal government agency, focuses more on comparative effectiveness and less on cost-effectiveness. HTA assessments are used by the Centres for Medicare and Medicaid Services to inform national coverage decisions for Medicare and Medicaid. The AHRQ undertakes the HTA, or commissions it to one of its Evidence-Based Practice Centers. State-funded health care arrangements, academic organisations and large managed care organisations, such as Blue Cross and Blue Shield and Kaiser Permanente, also perform their own HTA. Some of these are funded by AHRQ as Evidence-Based Practice Centers.

In Australia, Commonwealth HTA is managed within DoHA and provides HTA advice directly to Australian Government decision-makers.

In the UK and Canada, the same HTA agencies assess all types of health technology in order to ensure consistent methods and approaches, however there are different streams within the agencies that generally assess pharmaceuticals separately to other health technologies. CADTH manages the Common Drug Review as a process distinct to the assessment of other health technologies; most pharmaceuticals assessed by NICE are now the result of Single Technology Assessments, whereas most other technologies assessed by NICE remain the result of Multiple Technology Assessments, the original process for HTA introduced by NICE. In Australia, pharmaceuticals are assessed separately to medical devices, procedures and diagnostic tests. In the UK, clinical guidance decisions from assessment are binding on health services, unlike the generally non-binding advice from Commonwealth HTA advisory committees in Australia and the non-binding advice from CADTH in Canada.

Broad comparison of Australia and international systems

The comparison of the TGA, MSAC and PDC processes against eight international HTA systems and the EU in the Allen Report ^{32 vi} has been summarised below, divided into five criteria for assessing HTA processes. This summary identifies Australia’s broad strengths and weaknesses against numerous international systems.

vi The Allen Report was commissioned by DoHA in 2008 to undertake research and analysis, including the development of baseline data on other HTA systems. It compiled the available information from individual international HTA process sources.

Assessment timeframes

The TGA and PDC assessment timeframes are in the middle internationally. MSAC's timeframes are longer than other processes, which is noted to be due in part to the burden of proof for evidence resting with MSAC's evaluators rather than with the applicant.

System integration

At the market entry level Australia, like all countries, relies on a single body. Australia has separate bodies for assessment of clinical and cost-effectiveness for pharmaceuticals, medical procedures and devices, unlike most comparable countries which have a single body. In the Canadian system, HTA is conducted both federally and provincially, and in the US, private insurers also conduct independent HTA. Market entry and HTA are separate in Australia and the US, and Australian HTA only informs publicly funded reimbursement and price setting (except for PDC, which relates to private insurance).

Regulatory burden

For market entry, the TGA seeks full recovery for the cost of operating the medical devices program whereas Canada and the US seek partial cost recovery. The burden of evidence lies with applicants for the TGA, and this is consistent internationally. For HTA, MSAC carries the burden of evidence collection and assessment, and does not cost recover, consistent with other HTA processes overseas where this could be determined. The burden of evidence rests with applicants to PDC, which operates under full cost recovery.

Communication and appeals

Processes for the TGA appear to be broadly in line with other countries: the TGA provides formal opportunities for manufacturer input. MSAC provides opportunities for comment and disseminates outcomes, like other processes internationally, but does not have internal or independent review processes, unlike some comparable international processes. PDC provides opportunities to comment and is subject to internal review.

Procedural transparency

In Australia, there is more procedural transparency than in many other countries. The TGA has a consumer issues expert on MDEC, which assesses very few medical device applications proportional to the number received by the TGA. MDEC does not make its unfavourable decisions publicly available. MSAC has consumer representatives (including on its advisory panels) like PBAC, has a large range of material publicly available, but does not provide for public input or stakeholder submissions like PBAC and the UK NICE system. PDC's role and composition, which includes consumer representation, is unique compared to any system, and is difficult to compare broadly. It does advise of reasons for rejections, but does not make all its decisions publicly available.

Discussion

These comparisons show that Australia's HTA system is generally functioning well and comparative to other international systems in most areas. There are, however, specific areas in which Commonwealth HTA processes could be improved, such as the timeliness of MSAC assessments, and stronger linkages between the processes for undertaking HTA for different types of technologies.

It is also evident that the Australian system is more similar to its international counterparts than commonly thought. The size of single HTA agencies like NICE and CADTH leads to similar issues around fragmentation and the development of 'silos' as seen in Australia. International bodies have historically struggled to find the desired balance around the optimal structure for HTA, with many that have moved towards single agencies in the past now diversifying into different assessment streams, which risks losing the benefits associated with a single agency. To address this risk, CADTH established the Common Drug Review (CDR) stream to ensure consistency of decision-making across the provinces in Canada.³³

In addition, NICE is considered as a notable system by stakeholders, but issues around access to health technologies outside of England and Wales in the UK are often not discussed. Similarly, in the US, Medicare and Medicaid only reimburse approved health technologies for limited population groups. The Australian funding system in comparison provides national access to MBS, PBS and Prostheses List reimbursement, though some equity issues remain around the varied purchasing strategies between different states and territories for technologies used in public hospitals.

As well as at the structural level, international systems are attempting to balance a number of other important considerations in recent years. These considerations include the sustainability of HTA systems and reimbursement structures, methods for disinvestment and smarter investment decisions, post-market surveillance of technologies, HTA workforce capacity and uncertainty in the evidence base for technologies. These topics are similarly concerns within Australia and are addressed in later chapters of the HTA Review.

In recognition of the numerous challenges posed by HTA in many countries, several international collaborations have been established to improve information exchange and reduce duplication, improve and standardise best practice and increase harmonisation of practice internationally. These collaborations include the European Network for HTA (EUnetHTA), the International Network of Agencies for HTA (INAHTA), HTAi and the Global Harmonisation Task Force (GHTF). Commonwealth HTA advisory committees and their secretariats cooperate closely with these international bodies in the development of HTA methodologies and approaches.

Recommendation 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.

CHAPTER THREE

A Policy Framework for Commonwealth HTA



3 A Policy Framework for Commonwealth HTA

3.1 Introduction

The individual processes and interactions between current Commonwealth HTA agencies and committees are complex. Each HTA agency has discrete functions and has evolved over time to respond to different needs. Individually, most of these processes function well, and in some cases are regarded as world leaders in their field.

Nevertheless, previous reviews of HTA in Australia have identified a range of issues and challenges arising from current arrangements. These problems include perceived duplication and differing approaches to methodologies, evidence requirements, transparency and communication. A common concern is that sponsors of new medical procedures or devices must navigate two (TGA and then MSAC or PDC) and, in a small number of cases, three separate HTA processes (TGA, MSAC and PDC). If use of a diagnostic technology is intended to affect the use of a medicine, PBAC may also be involved.

Internationally, some countries have begun developing and implementing frameworks to guide their HTA functions. In 2004, for example, Canada developed a *Health Technology Strategy 1.0* to provide:

...a comprehensive strategy for technology assessment which assesses the impact of new technology and provides advice on how to maximize its effective utilization in the future.³⁴

During the HTA Review consultations, stakeholders expressed concerns about the lack of a strategic, systematic and integrated framework for Commonwealth HTA processes.

The submission from the National Coalition of Public Pathology commented that:

Enhanced arrangements that take a holistic not silo approach are required for assessment for subsidy and listing purposes.³⁵

This was a recurring theme in the consultations conducted as part of this Review. For example, there was a general acknowledgment that an explicit, agreed set of principles is crucial to guide the strategic direction and operation of the system, even though there may at times be a need for 'trade-offs' between them.

Accordingly, this chapter proposes a policy framework for Commonwealth processes for market entry and HTA for reimbursement in Australia, consisting of a vision, goal, objectives and principles.

While not all aspects of the framework will apply to each function, the framework provides the means for guiding a systematic and consistent approach to implementation and integration of the different functions to form a unified Commonwealth HTA system.

It is proposed that a framework will assist with:

- developing a shared and consistent approach across the processes, such as in the use of methodologies;
- clearer delineation of roles and responsibilities;
- improved transparency and independence of processes;
- encouraging and fostering a consumer and patient focus without increasing regulatory burden;
- more robust performance measurement and accountability;
- more efficient use of scarce clinical and HTA expertise;
- reducing unnecessary and poorly designed regulation of HTA; and
- facilitating and encouraging links between HTA and broader health system goals.

During the HTA Review, stakeholders were closely consulted about both the value of establishing a framework for Commonwealth HTA processes and the key components of such a framework. There was widespread support for a more systematic approach and explicit, guiding, high-level statement of direction for the system.

3.2 Vision for a Sustainable, Efficient Commonwealth HTA System

The proposed vision articulates an aspiration for Commonwealth HTA processes at the highest level:

Australians have timely, equitable and affordable access to the cost-effective health technologies needed to manage their health.

3.3 Goal of Commonwealth HTA Processes

The proposed goal articulates how and on what basis these Commonwealth HTA processes will contribute to the Australian health system:

The goal of Commonwealth HTA processes is to maximise beneficial health outcomes to the Australian population within the overall funds available whilst being cognisant of the other important goals of the health system.

3.4 Objective of Commonwealth HTA Processes

The proposed objective articulates the approach to informing robust decisions:

That Commonwealth HTA processes use the best available evidence and efficient methods to inform robust decisions about market entry and the subsidised use of health technologies. The Commonwealth HTA system should also continually improve the evidence base for assessment and operate according to agreed principles.

3.5 Principles Underpinning Commonwealth HTA Processes

Commonwealth HTA processes will reflect the following principles:

Principle	Description
Sustainable	<ul style="list-style-type: none"> Assessments and appraisals^{vii} contribute to a sustainable Australian health system through informing evidence-based decisions about the subsidised use of health technologies Appraisals inform, and are informed by, evidence from post-market monitoring of subsidised health technologies to guide the continued investment or disinvestment in these technologies An HTA workforce with up-to-date skills and expertise is built and maintained
Transparent, accountable and independent	<ul style="list-style-type: none"> Assessments and appraisals are undertaken objectively and impartially Functions, roles and responsibilities are clearly defined and evident to all interested parties Processes and information requirements are publicly communicated and clearly explained Involved parties are kept informed of the progress of applications throughout the assessment and appraisal processes Processes are fairly and consistently applied, and provide all interested parties with an opportunity to contribute Applicants and other parties are able to seek access to an independent review mechanism of Commonwealth HTA assessment and appraisal processes The outcomes of appraisals meet the information needs of Australian Government decision-makers Advice and recommendations arising from appraisals (with supporting facts and reasons) are publicly disclosed Key activity and performance data are reported
Consultative and reflective of Australian community values	<ul style="list-style-type: none"> Takes into account broader societal perspectives on health technology, including access, equity and the financial impacts on consumers Structured consultation occurs with interested parties, including consumers Appraisals consider the impact of health technologies on the other relevant aspects of the health system as reflected in government policy and in Australian community values
Administratively efficient	<ul style="list-style-type: none"> Process duplication is minimised by coordination to share relevant information and expertise Regulatory burden and costs are minimised (without diminution of scientific rigour and health system sustainability) Assessment and appraisal processes are streamlined to provide a timely outcome The HTA workforce is expert, experienced and equipped to process the full range of applications received

vii For the purpose of these principles, the term:

- ‘assessment’ means ‘evaluation of the evidence base for the health technology by an HTA evaluator’;
- ‘appraisal’ means ‘the consideration of the evidence and other relevant factors by the advisory committee’; and
- ‘decision-making’ means ‘the final funding decision.’

Principle	Description
Flexible and fit for purpose	<ul style="list-style-type: none"> Processes and methodologies should be adaptable to technological change The full range of current and emerging types of health technologies can be appropriately assessed Applications are efficiently directed, assessed and managed through the relevant process(es) The assessment of a health technology is commensurate with the risk of harm to the patient and cost to the Australian Government and community Appraisals inform any risk sharing arrangements considered between the Australian Government and applicants
Informed by robust and relevant evidence	<ul style="list-style-type: none"> Assessments are based on a systematic review of the best available evidence and aligned with contemporary clinical practice Assessments utilise internationally generated evidence where relevant to the Australian context Assessments consider appropriate comparators within the relevant Australian clinical context Assessments and appraisals are informed by multi-disciplinary expertise to ensure their overall credibility Methodologies for assessing health technologies are continually reviewed and updated in the light of validated Australian and international developments

Recommendation 3:

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

CHAPTER FOUR

Stronger, More Efficient Market Regulation and Health Technology Assessment for Reimbursement



4 Stronger, More Efficient Market Regulation and Health Technology Assessment for Reimbursement

4.1 Introduction

This chapter addresses HTA Review Terms of Reference 1, 2, 4 and 5 by recommending short- and medium-term changes to improve the clarity and consistency of HTA processes. These represent the practical administrative steps that can be taken to ensure that regulatory settings are set at correct thresholds so that Commonwealth HTA processes are not weighed down with unnecessary or inefficient processes.

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. It is important to build on these strengths and in developing recommendations for responding to the current inefficiencies, the HTA Review was conscious of the need to preserve the recognised benefits of current arrangements and avoid undermining current capacity.

The processes used by the TGA (and PBAC) are widely regarded by most stakeholders and applicants as clear, consistent and appropriate. The TGA's processes are well understood and predictable, with clearly articulated requirements, costs and timeframes, and performance objectives and reporting that have been agreed with industry. The TGA is generally considered to provide clear guidelines which underpin and support transparent processes and decision-making. Overall it is viewed by stakeholders as having a strong, consultative relationship with industry. In addition, the TGA is generally perceived to be fair and consistent in its assessment processes and decision-making.

However, it is important to note at this point that, in submissions to the HTA Review, some consumer representatives and the PDC expressed a countervailing view about some aspects of TGA performance. The CHF³⁶ highlighted concerns held by some consumers regarding perceived flaws in the TGA pre-market assessment processes which have led to unsafe products being allowed entry to the Australian market. The PDC submission³⁷ to the HTA Review noted that some members of PDC (including clinicians, insurers and consumers) considered that the TGA's safety assessment procedures for medical devices are inadequate and that PDC clinicians exercise a more thorough and appropriate assessment of the clinical safety and efficacy of devices. This criticism is addressed in more detail later in this chapter.

In regard to MSAC's processes, the HTA Review found an increasing level of transparency, with the underlying processes and evaluations well documented. Recent steps to improve transparency include the publishing of the MSAC Public Summary Document describing the rationale for MSAC's advice to the Minister. Interactions with applicants through pre-lodgement and debriefing meetings and the invitation of applicants to nominate relevant clinical experts to assist in undertaking the evaluations were appreciated by stakeholders. The committee's level of clinical input and expertise and its flexibility in being able to make decisions in the face of uncertain evidence and adapt assessments as required were also regarded as strengths.

PDC's strength lies in the important contribution it has made to controlling previously rapid and unsustainable increases in costs for prostheses funded through private health insurance. Some stakeholders praised PDC's broadly-based stakeholder representation. In regard to its processes, PDC's publication of explicit dates for lodgement of applications and release of each Prostheses List assists both the devices industry and the private hospital and private health insurance industries with business planning.

However, 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. These are:

- 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;
- clarifying the respective roles of the TGA, MSAC and PDC regarding the assessment of 'safety';
- 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;
- strengthening the links between the market entry and HTA for reimbursement processes;
- improving the rigour and efficiency of MSAC by allowing submission based evaluation, better definition of data collection requirements for procedures recommended for interim funding, and streamlining processes for accessing expert advice to inform assessments; and
- streamlining arrangements for the Prostheses List through establishing communication channels with the TGA, restructuring the PDC and recommending changes to administration of the List.

4.2 More Transparency and Procedural Fairness

Transparency is paramount to ensuring equity, fairness, and most importantly, scientific rigor on which health care decisions are based.³⁸

There was widespread stakeholder concern about the lack of visibility and transparency and apparent lack of some aspects of procedural fairness in the current Commonwealth HTA processes. While often supportive of many of the HTA outcomes, some stakeholders felt that the currently opaque arrangements in MSAC and PDC reduce confidence in what might actually be sound arrangements. Improvements are required to engender confidence in processes and make it easier to assess ongoing performance of the HTA system.

These stakeholder concerns include a desire for:

- an easy-to-access overview, or map, of the whole Commonwealth HTA system;
- more extensive and clearer guidance on HTA processes with greater consistency in approach and presentation across all parts of the Commonwealth HTA system;
- clearly defined roles and responsibilities for the advisory committees, expert advisers and evaluators;
- delineation of the exact sequence, requirements, coordination processes and likely timing of each step of the various processes;
- how to find out further information about the processes;
- more open, timely and mandated communication between the various advisory committees;
- clearer explanation of the rationale(s) for advisory committee decisions;
- better handling of conflicts of interest especially for members of HTA advisory committees and supporting committees and panels;
- an independent review mechanism for advisory committee advice;
- better performance information, reporting and evaluation; and
- standardised timelines for HTA processes and for each key step within each process.

The HTA Review proposes a substantial overhaul of the communication and management of processes to improve administrative efficiency and engender greater stakeholder confidence.

Improved public information

A single website for Commonwealth HTA

Applicants and other interested parties rely on publicly available information such as websites and guidelines for their understanding of the Commonwealth HTA system. As the Report on the second set of consultations noted:

A repeated response was about broadening access to information about the HTA system for the general public. A number of participants considered that unlike the FDA in the USA, HTA for market regulation and reimbursement had minimal profile with the Australian general public and health consumers.³⁹

The HTA Review found that information about Commonwealth HTA processes is neither presented in a systematic manner nor in a single location. For example:

- DoHA currently does not have an overall 'HTA' website. Instead, information on each of the HTA processes and advisory committees is contained on separate sites with different style, functionality and poor linkages; and
- individual advisory committee guidelines have limited or no information about other related Commonwealth HTA processes. For example, an application form may require an ARTG number or an MBS item number, but not describe why this is required, how the requirement might be met or which area of DoHA an applicant will need to deal with.

Better access to guidance

A key element of transparency and fairness is stakeholder understanding of how their application will be assessed. The consultations identified that DoHA could provide greater clarity and predictability about current HTA arrangements including through the development of:

- a guide to all Commonwealth HTA processes as a whole, as well as the purpose of each individual process and the interactions between the different TGA and DoHA HTA processes and advisory committees; and
- a standard approach to the structure and content (to the extent possible) for all HTA process guidelines, using consistent definitions and language and including descriptions of:
 - the appointment, roles and responsibilities of the advisory committees;
 - processes for handling conflict of interest;
 - decision-making processes and criteria;
 - review mechanisms;
 - processes subsequent to HTA, but prior to a decision to provide reimbursement;
 - estimated timelines for HTA processes; and
 - the roles of particular stakeholders.

Reporting on performance

Stakeholders stressed that better, more accessible performance information is crucial to enhancing accountability and confidence in the system.

The HTA Review considers that better performance information and greater consistency of information across the HTA processes would assist in demonstrating the extent to which Commonwealth HTA processes are effective and efficient. The HTA Review proposes that a set of KPIs for each of the Commonwealth HTA processes be developed – these should include measures where DoHA and/or the relevant advisory committee have control over the outcomes. Eventually these measures would be aligned so that stakeholders can compare performance between HTA processes and over time. In addition, key activity data (e.g. numbers of applications assessed) is of interest to stakeholders and should also be made publicly available.

Reporting of results against KPIs should be made publicly available on HTA websites.

Effective performance information for the HTA system is required to monitor and communicate performance in three dimensions:

- the effectiveness of the processes to achieve their objective, such as to provide quality advice to the Australian Government;
- the efficiency of the way this is done, such as through tracking the timeliness of assessments; and
- the quality of the individual stages, such as of particular HTA assessment reports.

Currently, each HTA agency collects, analyses, and reports on a variety of information, as summarised in Table 4.1.

Table 4.1: Current HTA performance data

HTA Process	Performance Measures	Current Indicators
TGA (MDEC) advice for inclusion on the ARTG	Yes. Performance measures are in the Business Plan published on the website	<p>Application process activities – numbers of applications:</p> <ul style="list-style-type: none"> • received • approved/rejected/terminated • in process • processed within target times <p>Effective operation of expert committees:</p> <ul style="list-style-type: none"> • committees operate in accordance with terms of reference, meeting schedules met, minutes and resolutions published in accordance with target as appropriate.
MSAC advice for listing on the MBS	No	<p>MSAC publishes an annual performance report which contains some activity data.</p> <p>Developing performance measures as part of current reform activity in line with HTA Review findings.</p>
PDC advice for listing on the Prostheses List	No	PDC publishes the PDC Bulletin after each cycle which contains some activity data.
PBAC advice for listing on the PBS	Yes. Published and reported against on the PBAC website	<p>Core Indicator 1 – PBAC submissions by number</p> <p>Core Indicator 2 – PBAC submissions by outcome</p> <p>Core Indicator 3 – Initial major submissions by outcome</p>

In regard to the important indicator of timeliness, the TGA has target timeframes for each assessment pathway and legislatively imposed penalties if it does not meet timeframes. Both PBAC and PDC have defined cycles whereas MSAC has no set timeline for completion of assessments.

Most stakeholders are interested in having clear maximum time limits on all Commonwealth HTA processes as is currently the case with PBAC. The HTA Review suggests that a set of KPIs and key activity data address:

- time to process an application including reporting the minimum time, maximum time, and average times over a 12 month period, taking account of the level of complexity of the assessments;
- effective operation of expert committees – for example, whether the committees operate in accordance with their terms of reference adhere to meeting schedules and publish outcomes in accordance with target as appropriate;
- the level and type of expertise involved in assessing applications; and
- the proportion of applications that were supported, conditionally supported or rejected in a 12 month period.

In relation to this last indicator, it is important to note that there is no correct level of supporting or rejecting applications that should be targeted. An important determinant of how many applications are supported or rejected will be the quality and evidence-base of new technologies that are assessed. However, this is nevertheless a useful indicator to consider, as a very high level of supported applications may suggest that assessments lack rigour, while a very high level of rejected applications may suggest a lack of clarity around evidence requirements, making it difficult for sponsors to assess the likelihood of success.

Post-assessment measures that would be useful to stakeholders include:

- the alignment of HTA outcome with final reimbursement decision; and
- the extent to which up-take of the technology matched the assumptions in the HTA.

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.

Improved review mechanisms

Providing opportunities for review is an important part of public administration. During the consultations stakeholders regularly expressed concern at the limited and varying scope to seek explanation of decisions or the ability to seek a review. Stakeholders acknowledged that better communication of the conduct of HTA and the basis for decisions could go some way to minimising the use of review mechanisms.

Currently, the extent and type of review mechanism vary across the various HTA processes.

The TGA has a legislated internal review process whereby an independent TGA officer delegated by the Minister reviews the initial decision regarding listing on the ARTG. In the case of an adverse outcome for the applicant in the final decision there is an opportunity for an external merits review through the Administrative Appeals Tribunal (AAT).

Following PDC recommendations, sponsors can request an internal review on procedural grounds only. The internal review process is conducted by the Secretary of DoHA or their nominee. The reviewer may consult the sponsor and PDC as part of the process. On completion of the internal review, the reviewer makes recommendation(s) to the PDC. In addition the Minister's decision to grant or not grant an application to list a prosthesis on the Prostheses List is judicially reviewable under the *Administrative Decisions (Judicial Review) Act 1977* (ADJR Act) and may also be judicially reviewable under the *Judiciary Act 1903* (Judiciary Act).

There is no internal review mechanism for MSAC recommendations to the Minister for the funding of new medical services through the MBS. The following may be judicially reviewable under section 39B of the Judiciary Act depending on the facts of each case:

- MSAC's appraisal and advice to the Minister;
- DoHA's submission to the Minister (which combines MSAC's appraisal with policy advice from the department); and
- the Minister's decision to note advice from MSAC.
- Applicants are able to reapply to MSAC should new evidence regarding their technology become available.

PBAC allows applicants to apply for an Independent Review coordinated by a convenor and conducted by an independent reviewer, in the case of a disputed negative decision. Alternatively sponsors may apply to the Federal Court for a review of a PBAC process and the decision may be judicially reviewable under the Judiciary Act.

There are a number of issues to be considered in developing any new review mechanisms, including the type of review, who conducts the review, and the particular matters to be reviewed. Because of factors such as the different statutory base for the various processes it is unlikely that one standard review process or mechanism is feasible.

The current independent review arrangements in PBAC relating to advice to not recommend PBS listing, is a model that could translate to both MSAC and PDC. The PBAC review is based on information which has already been presented to the committee. No new information or evidence beyond that considered by the committee may be considered in a review.

In circumstances in which new information or evidence is likely to be relevant to the committee reconsideration, the option of re-submission should be pursued rather than review. It is important to note that there is no time incentive or disincentive for a sponsor to seek a review in preference to making a re-submission to the committee.

The HTA Review suggests that all processes align their review processes with a set of shared principles. These principles could include:

- Whenever possible, encourage resolution informally. The review should be limited to considering information provided as part of the initial application.
- The review process should not create any opportunities for sponsors or others to manipulate the system. It would be better to encourage a re-submission with a more favourable case for listing than to stagnate in a review process over a less favourable case.
- The results of independent reviews should be provided back to the primary committee responsible for providing advice to the Minister, to enable re-consideration of the original matter.

As review mechanisms can be resource intensive, reducing resources available for HTA of other new technologies, it may be reasonable for an appropriate fee to be charged where a sponsor seeks a review.

Table 4.2: Overview of current opportunities for applicants to provide comment and/or seek review

HTA Agency	Application (Point at which a review may be sought)	Assessment Report/Conclusions (Point at which a review may be sought)	Appraisal and Recommendation/Advice (Point at which a review may be sought)	Listing and Pricing Decision (Point at which a review may be sought)
TGA	Rejection of application \ classification of device Sponsor has opportunity to correct application errors	Clarification of application information Sponsor has opportunity to clarify application (and comment on delegate's report)	TGA recommendation advice Internal review AAT ADJR	N/A
MSAC	Rejection of application based on eligibility Eligibility criteria are available to the applicant in the MSAC Guidelines, and all applicants are offered a pre-lodgement meeting at which eligibility criteria are explained	Findings of assessment report Applicant has opportunity to comment on draft evaluation protocol for assessment and on the draft assessment report	MSAC advice No opportunity for internal review but applicant may submit a new application MSAC's assessment advice to the Minister may be judicially reviewable under s 39B of the Judiciary Act depending on the circumstances	Final descriptor and fee of MBS item No opportunity for review Any decision by the Minister in relation to MSAC's advice may be judicially reviewable under s 39B of the Judiciary Act depending on the circumstances
PDC	Rejection of application based on incomplete information and lack of correct application fees Sponsor has opportunity to correct application errors	Benefit negotiation Sponsors are able to negotiate a minimum benefit and a maximum benefit with the Prostheses Devices Negotiating Group ('PDNG') for their prostheses, prior to the negotiated minimum benefit and the maximum benefit being provided to the PDC Clinical Advice to PDC No opportunity for review	PDC proposed recommendation to Minister Sponsor has opportunity to comment PDC final recommendation to Minister The PDC's recommendation to the Minister is subject to internal review and also may be judicially reviewable under s 39B of the Judiciary Act depending on the circumstance	Decision by Minister's Delegate Internal review of process may be sought at this stage Publishing of the Prostheses List Internal review of process may be sought at this stage The Minister's decision to list is subject to judicial review under the ADJR Act and, depending on the circumstances, under s 39B of the Judiciary Act

HTA Agency	Application (Point at which a review may be sought)	Assessment Report/Conclusions (Point at which a review may be sought)	Appraisal and Recommendation/ Advice (Point at which a review may be sought)	Listing and Pricing Decision (Point at which a review may be sought)
PBAC	All are accepted by DoHA in PBAC consideration No opportunity for review/comment	Finalised critique of submission – comment sought Sponsor comment sought	Finalised Economic Sub-Committee Advice Sponsor comment sought PBAC appraisal and recommendation if negative Independent Review ADJR and also may be judicially reviewable under s 39B of the Judiciary Act depending on the circumstance or the sponsor may resubmit with new information	Outcome of pricing negotiation by Minister's delegate and sponsor If no agreement, resubmission possible

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.

4.3 Streamlined and Better Coordinated Processes

The HTA Review found that the lack of clarity, consistency and coordination of existing Commonwealth HTA processes results in duplication of some activities. Areas of duplication include: the requirement to submit multiple applications containing similar information when more than one committee, or agency, is involved in assessing a device; repeated, full re-assessment of the same basic technology if a small aspect of its composition changes (e.g. the type of glue or screws); and the way in which 'safety' is assessed by the TGA, MSAC and PDC. This increases the cost of complying with HTA for applicants, but does not generate any compensatory benefits for the rigour of HTA decisions. This is most significant for those with hybrid or co-dependent technologies who need to apply to several advisory committees.

During the HTA Review, there was extensive canvassing of the option for Commonwealth HTA processes to be undertaken by a single entity that could consider comparative effectiveness of all health interventions, taking a whole-of-health-system and technology-neutral perspective. However, there was general agreement among stakeholders and within Australian Government agencies that attempting to impose this vision on current arrangements would be likely to result in a system that is insufficiently sensitive to the particular risks and evidence that must be considered for different kinds of health technologies, and which might therefore produce unreliable recommendations.

Stakeholders were also concerned that combining the functions of assessment for market entry and HTA for reimbursement might lead to fiscal considerations influencing decisions about which technologies would be allowed into the market, even if they were safe and applicants were not seeking reimbursement. The HTA Review

agreed that the roles of deciding market entry and HTA for reimbursement should continue to be kept separate.

In addition, amalgamating HTA processes and committees that are at different stages of development would create a substantial risk of reducing the capacity and quality of the higher performing processes and committees. In the shorter term, it is more important to improve the performance, transparency and consistency of the existing HTA processes through the progressive implementation of common approaches. This will also avoid disruption to HTA processes that are currently working well.

While there is a need for separate HTA processes to continue in respect of each set of funding arrangements, there is considerable scope for them to become more aligned, more streamlined, easier to navigate and less costly for applicants.

The HTA Review considers that an essential, streamlining step to make HTA processes simpler for applicants is the creation of a single entry point (SEP) for all Commonwealth HTA processes considering reimbursement (that is, for PBAC, MSAC and PDC). As the sponsors of many therapeutic goods included on the ARTG do not go on to seek appraisal for reimbursement, the HTA Review considers that the TGA should continue to operate its application process separately. However, information about HTA processes for reimbursement and the SEP should be made available to all applicants seeking inclusion on the ARTG.

Single entry point

Applicants seeking listing on the PBS and Prostheses List require their product to be included on the ARTG before it can be formally considered by PBAC and PDC. Applications for MBS listing are generally for medical procedures that use devices which must all be registered on the ARTG before being considered by MSAC. Therefore, applicants are currently required to sequentially navigate at least two or three (and in some instances four) different public entry points within DoHA and the TGA in order to achieve their objective of market entry and public or private reimbursement. The four entry points have different processes and approaches to the management and assessment of applications.

The HTA Review identified a number of opportunities to improve the management of HTA applications, particularly for those involving several HTA committees:

- The sequential nature of these processes can result in delays of several years before reimbursement arrangements are finalised.
- Applicants report supplying the same information in different formats to several HTA processes, particularly in regard to the assessment of aspects of devices to determine safety and efficacy by the TGA, MSAC and PDC.
- Roles, responsibilities and application criteria for different HTA processes are poorly understood, and communication within and across departmental secretariats could be improved.
- HTA processes need to evolve to effectively deal with novel, particularly co-dependent and hybrid, technologies.
- Applicants are expected to navigate the HTA system themselves, which can create difficulties for applicants unfamiliar with the different processes.
- Applicants report difficulty monitoring and tracking the progress or status of their application (particularly where one HTA process is a prerequisite for a subsequent process, such as listing on the MBS being required before PDC can consider an application for the Prostheses List).

The HTA Review found overwhelming support for the proposal to streamline applications through a SEP, especially when accompanied by other proposals to improve HTA processes including a risk-based approach to assessment, and better consultation and communication. The SEP was considered to offer the greatest benefit for applications for hybrid or co-dependent technologies, which are served poorly under current arrangements.

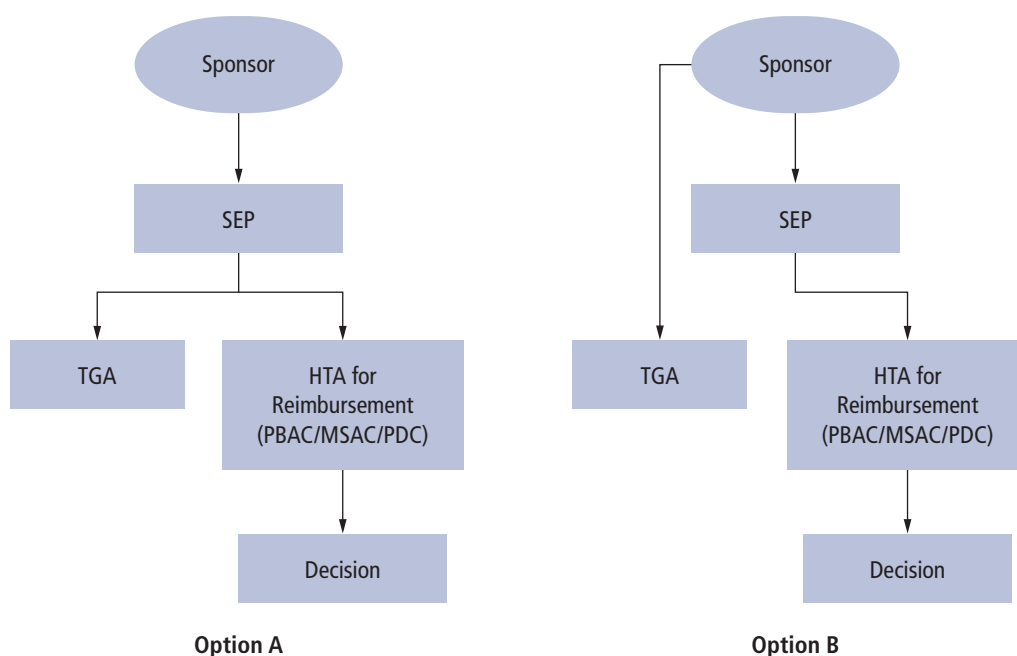
Some stakeholders were concerned that the SEP may become simply another layer of administration further delaying consideration of applications, and were keen that it should not slow down existing processes that work well, or remove flexibility in assessment processes. Others noted that the SEP would add no benefit unless the subsequent HTA processes also improved. One focus group participant said the worst outcome would be that 'the single door turned into the black hole'.⁴⁰

Some stakeholders envisaged the SEP as a specific entity actively managing the process, rather than just an entry point such as a web portal. A common view expressed by stakeholders was that, irrespective of the nature of the entry point, a reformed system ought to allow for the assessment of a technology for both market entry and reimbursement concurrently. In other words, the assessment for reimbursement could begin before final regulatory approval was given, with the understanding that, should regulatory approval be refused, all further processes would cease.

However, applicants (particularly from smaller companies) wanted the flexibility to be able to choose to submit the regulatory component of the application (for market entry) ahead of the reimbursement component, in order to manage the workload of gathering and presenting evidence for the reimbursement phase.

During the options development phase of the HTA Review, two different options for the SEP were canvassed. These are represented below in Figure 4.1. Under Option A, all applications would go to the SEP for allocation between the TGA and any relevant HTA reimbursement agency. Under Option B, sponsors would continue to submit their initial application to the TGA for market entry, but all applications for reimbursement would be made through the SEP.

Figure 4.1: Options for a single entry point



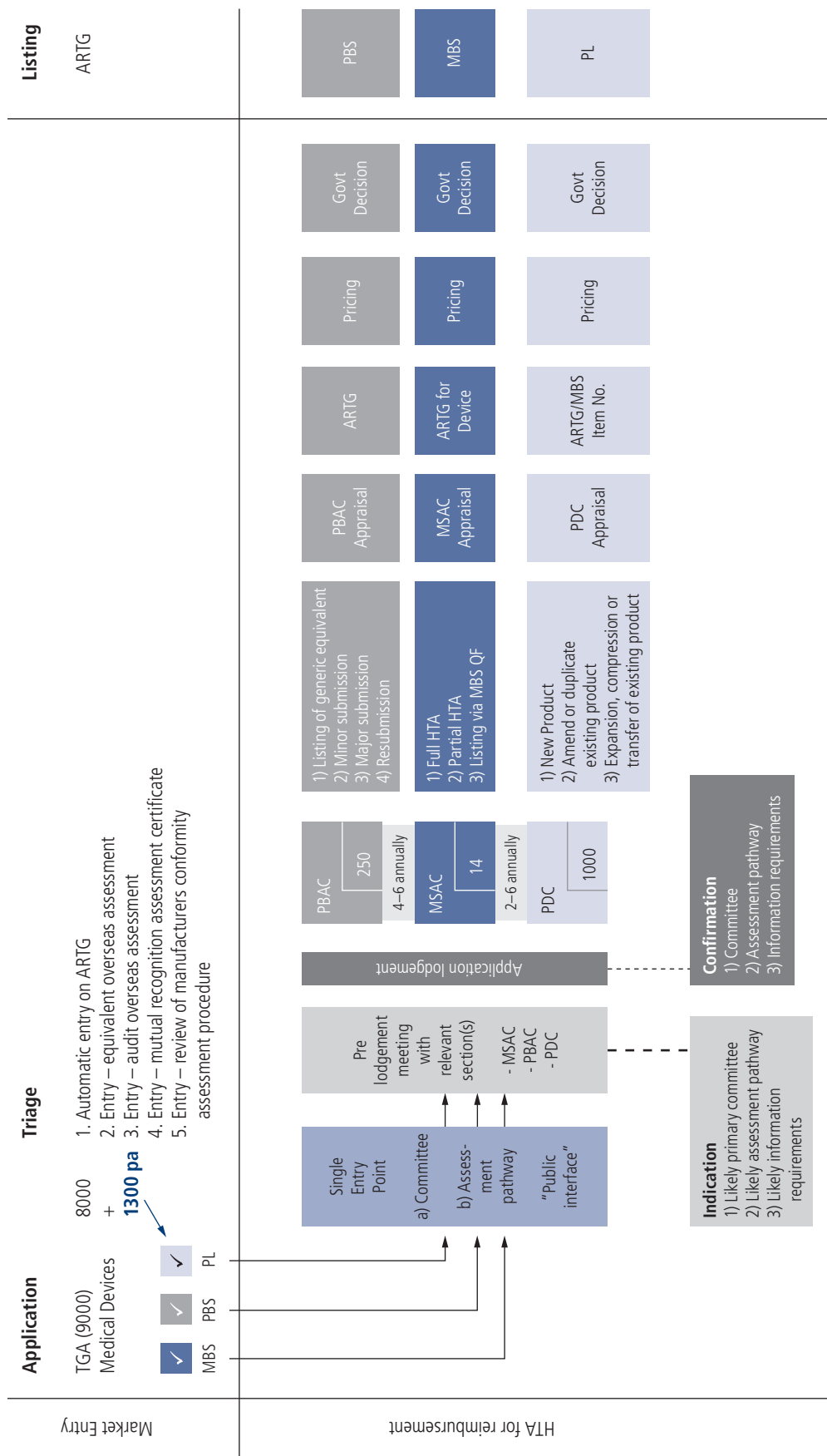
Single entry point for Commonwealth HTA processes

Taking account of a broad range of stakeholder views on this matter, the HTA Review supports the introduction of a SEP after TGA market entry (Option B) because:

- The vast majority of devices will go only to the TGA for assessment and interposing an additional step between the TGA and the sponsor 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 SEP 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.

Figure 4.2 shows how the SEP might operate in more detail.

Figure 4.2: Future pathways through the HTA system



Proposed functions of a single entry point

The proposed SEP would reduce the number of entry points to Commonwealth HTA processes from four to two. It could provide for better co-ordination and integration of Commonwealth HTA processes by facilitating appropriate communication and collaboration between the TGA and MSAC, PBAC and PDC, as well as public and private payers and state and territory governments. It could also standardise application requirements and guidelines, where appropriate, including the management of pre-requisites (ARTG number, MBS item).

The proposed functions of an SEP could include:

- a public interface with stakeholders (through a website and guidance documents);
- a single liaison point for applicants and the HTA processes;
- the capacity to monitor and track the progress of applications;
- responsibility for organising broad based pre-lodgement meetings – which could provide a “whole-of-HTA system” view to aid an applicant’s understanding of how its application could progress through the various Commonwealth HTA processes and advisory committees, and the likely evidence requirements;
- a coordination function for those applications which would need to be assessed by multiple HTA processes and advisory committees such as hybrid or co-dependent technologies;
- management of information sharing between the HTA processes and advisory committees and applicants; and
- responsibility for coordination of evidence requirements and assessment processes to promote greater consistency across the HTA processes and advisory committees.

These functions will greatly assist stakeholders in making submissions to, monitoring the progress of, and understanding outcomes of the Commonwealth regulatory processes for HTA.

A more flexible, risk-based approach to assessment and evidence

A fundamental goal of the HTA Review is to make the current system more flexible, responsive and adaptable. The current system is already under pressure to respond to the growing diversity of health technologies and it is clear that current processes, based on an historical view of a limited variety of technologies, is not sustainable in the longer term.

Stakeholders repeatedly referred to examples of technologies, such as orthopaedic screws, that were subject to what was considered excessive scrutiny, while other technologies which may be associated with greater risks (such as new technologies for radiation oncology) were subject to inadequate assessment. Put simply, stakeholders are concerned that current Commonwealth HTA processes are not sufficiently tailored to the risk of the technology, whether that risk is expressed in terms of financial or health outcomes or the degree of novelty of the technology.

Both the TGA and PBAC already have a risk-based approach to assessing applications, whereas MSAC and PDC have a 'one size fits all' approach. While this approach may be less challenging to administer, it can be administratively and resource inefficient as each application is subject to the same level of assessment regardless of the complexity or the risks of the procedure or device. Adopting a 'fit-for-purpose' approach to applications should enable more efficient processing of applications, but may also require secretariats to have appropriate technical expertise and tools required to 'stream' applications according to an agreed risk based classification approach. Similarly, applicants will need to have a clear understanding of the evidentiary requirements associated with each classification of risk.

In conjunction with the proposed SEP, the HTA Review proposes that a new approach be adopted to the conduct of assessments that recognises this diversity. Such an approach is known as 'risk-based assessment' but encompasses a number of factors which should be considered according to the technology and its context. These primarily relate to the potential risks and benefits of the technology, which can be expressed in terms of:

- the unit cost of the technology;
- the severity of the disease being treated;
- the size of the population who may benefit;
- the novelty of the technology and the availability of alternatives;
- the degree of certainty regarding the scale of the likely risks and benefits; and
- equity and access implications.

Once these factors have been weighed, the appropriate HTA approach can be chosen in terms of:

- the most appropriate assessment methodology (such as extent of literature analysed, economic model applied, costs and benefits considered, or comparator used);
- the amount, type or quality of evidence required to support the assessment (including the number of years' follow-up evidence required); and
- the appraisal and decision-making pathway.

The level of risk and the characteristics of the required assessment/appraisal should be applied consistently across all HTA processes. Stakeholders stressed that even though different bodies had different roles, it was essential that they use a common language.

The consequences of the current lack of consistency and transparency were considered to be:

- inconsistent or unpredictable application requirements, assessments and decisions;
- duplication of work by applicants and HTA committees;
- inefficiencies due to insufficiently substantiated applications; and
- concerns about the fairness of Commonwealth HTA processes.

A risk-based approach would vary the amount and strength of evidence required for the assessment of different technologies, informed through the development and use of HTA risk classification tables.

These would be tools that, based on an initial assessment of the characteristics and clinical performance of the health technology, could assign an individualised risk rating (e.g. rating the net financial risks to government and/or risks to the patient compared to the risks of harm from alternative clinical management options which would otherwise be available to the patient). This could consist of a table or a series of tables comparing relevant factors to derive an individualised risk rating, akin to the TGA's risk classification system and the work of the Global Harmonisation Task Force (GHTF) on risk management principles.

These tables could enable applicants to identify the likely evidentiary requirements for an application and the likely level of assessment (e.g. full or streamlined). However, in order to ensure that a 'fit for purpose' approach is appropriately implemented, this tool could only provide an indication of the assessment approach, but could not predict the likely outcomes of the subsequent appraisal or funding decision.

In addition, it would be desirable to achieve international harmonisation of HTA risk assessment methods and evidentiary requirements. It would therefore be prudent to implement an Australian approach gradually, limiting the assignment of a low level of risk only to those circumstances where this is clearly without controversy.

A particular circumstance that is worth examining as an initial priority would be co-dependent technologies, where the overall management of a patient relies on more than one funding mechanism to deliver the overall health care intervention (e.g. the MBS-funded procedure to insert the device funded by private health insurance or the MBS-funded pathology test to determine the eligibility of a patient for a PBS-funded medicine). In these situations, a comprehensive HTA assessment may be more efficient and informative than separate HTA assessments of each component. Coordinated consideration of applications in these circumstances will affect the evidentiary requirements of the separate HTA pathways.

Stakeholder concern regarding risk assessment of health technologies and consequential evidentiary requirements should be mitigated by a gradual introduction and a clearer articulation of the reasoning behind these evidentiary requirements (e.g. comparative safety and financial implications for government). It is also possible that a more transparent approach to risk classification and evidentiary requirements will further reduce the perceived inflexibility of the system to accommodate other relevant factors.

In summary, the HTA Review considers that a more risk-based approach to assessment should be undertaken by MSAC and PDC to ensure that the intensity of assessment matches the risk of the health technology. This approach should reflect both the risk of harm to the patient and the financial risk to the government on behalf of the taxpayer. Appropriate levels of evidence will be required to inform the assessment of health technologies classified as being high risk.

Recommendation 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; and
- g. develop and report on the achievement of performance targets for HTA for reimbursement.

Concurrent assessment and coordination across advisory committees

A number of stakeholders noted that the current sequential system of assessments by the different agencies can create extended delays in achieving funding for a particular technology.

Where appropriate and to the extent possible, Commonwealth HTA processes need to allow flexibility for those applicants who prefer either to apply concurrently for market entry and HTA for reimbursement or enter the market first to gather evidence to inform an application.

As the MTAA noted in its submission:

The period between the lodgement of an application to MSAC and the listing of the procedure on the MBS averages around 24 months. The sequential processing of medical technology approvals creates an unreasonable barrier to market entry, particularly when coupled with additional delays from TGA registration and the minimum of six months to list on the Prostheses List. The sequential periods mean that several years' delay can be imposed on patient access to new technology. Given the short life cycles of many medical technologies, beneficial products may not get to market.⁴¹

The assessment process can be even more protracted if the device is a more complex one that either relies on other technologies (such as a diagnostic test) to be effective, or consists of several elements, each of which needs to be assessed. In either case, the technology will not be able to be fully utilised or subsidised until all elements are assessed.

The suggested response to this difficulty is to allow concurrent assessments. That is, instead of requiring each assessment to be finished before proceeding to the next assessment or step, appropriate parts of other relevant assessments could be conducted at the same time.

The HTA Review considers that capacity for concurrent assessment should be introduced. However, concurrent assessment should not reduce evidentiary requirements, and significant investment of public funds in assessing new technologies may be postponed until critical antecedent processes have been finalised.

The SEP, discussed above, could facilitate communication between the TGA and other Commonwealth HTA processes on the progress of a technology towards inclusion on the ARTG to enable appropriate processes of HTA for reimbursement to commence while the TGA assessment is under way.

In some instances, consolidated advice to the Australian Government on a range of aspects of a complex service involving a range of technology types may need to be managed, through the SEP, bringing to bear advice from a number of advisory committees. If a product is being assessed for both public and private reimbursement concurrently, there would need to be close coordination to reduce the scope for conflicting assessments and ensure that consistent advice is provided to the government.

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 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).

4.4 Strengthening Linkages between Market Entry and HTA for Reimbursement

Responsibility for assessing safety of medical devices

During consultations for the HTA Review, stakeholders expressed the view that one of the most critical aspects of HTA is to protect Australian consumers from health technologies which cause harm. The TGA currently has this responsibility, which it exercises by ensuring that goods included on the ARTG are 'free from unacceptable risk'. This is a minimum standard, which is appropriately a precondition of any government funding or reimbursement for a new technology.

Overall, the HTA Review finds that the TGA provides its assessment in an efficient, transparent and timely way. Most stakeholders were supportive of current TGA procedural arrangements. The HTA Review did, however, find that some stakeholders were concerned that MSAC and PDC also considered the safety of new technologies as part of their assessment, which was perceived as a duplication of TGA's role as the market regulator. For example, stakeholder focus groups revealed that:

...participants considered safety assessment to be TGA's role and there was limited understanding about the nature of MSAC's cost effectiveness methodologies and the role of safety assessment in evaluation of clinical effectiveness and how this might differ from the market entry safety assessment undertaken by TGA.⁴²

There was widespread frustration expressed by participants – particularly industry sponsors – that PDC was also assessing the safety of medical technologies. Stakeholder uncertainty about the role of PDC was exacerbated by a perceived lack of transparency in the Committee's processes and decision-making.⁴³

Where such activities duplicate work already undertaken by the TGA, this imposes additional regulatory burden, delays and costs imposed on applicants. However, not all such assessments create duplication. For example, MSAC assesses the safety of the medical or surgical service that may use a technology (rather than assessing the inherent safety of the technology itself), and does so by comparing the safety of the proposed new service to the safety of an alternative medical service. Furthermore, MSAC assesses the comparative safety of new surgical techniques (that may use existing technologies), which are not subject to assessment by the TGA. These roles of MSAC in considering comparative safety of medical services are appropriate and should continue.

As well, criticisms have been raised during consultations for the HTA Review of PDC's consideration of safety of devices in its processes. The HTA Review found that PDC is directly duplicating TGA activities in safety assessment (or at least making its own judgements regarding the safety of certain devices). This is discussed further in section 4.6 of this chapter. PDC may decline to recommend listing of a product where it considers that there is insufficient evidence of clinical effectiveness to support listing, but should refer any evidence of lack of safety of a product to the TGA for further action.

The HTA Review considers that ensuring minimum safety standards are met in relation to particular technologies should be a responsibility clearly and solely of the TGA. However, concern was raised by some stakeholders, particularly those currently involved in PDC and MSAC processes, who consider that the TGA in some areas is failing to require applicants to meet a sufficiently high standard of safety.

The HTA Review considers it appropriate for the TGA to re-assess its current requirements for pre-market assessment of higher-risk devices for entry into the market, with a view to addressing these perceived shortcomings. The TGA should also develop its evaluation processes to ensure the safety assessments undertaken can inform the requirements of the 'downstream' HTA agencies, namely PDC and MSAC. More explicit and detailed information about the TGA's safety assessment of a device should be provided to PDC and MSAC in order to provide assurances about the level of intrinsic safety of the device. This may avoid the perception that PDC and MSAC reassess the intrinsic safety of a device, duplicating the role of the TGA.

While inclusion on the ARTG should be a precondition of any decision by another HTA agency to recommend a technology for reimbursement, this does not necessarily mean that inclusion on the ARTG must be achieved before an application for reimbursement may be made. However, HTA agencies may reasonably postpone significant investment of public funds in assessing new technologies until after the TGA has included the

technology on the ARTG (see discussion of concurrent processes in Section 4.3 of this chapter). The SEP, discussed above, could facilitate communication between the TGA and other HTA agencies on the progress of a technology towards inclusion on the ARTG to enable appropriate processes of HTA for reimbursement to commence while TGA assessment is under way.

Where HTA processes (or other stakeholders) identify concerns about the intrinsic safety of a particular technology, clear mechanisms should be available for drawing these concerns to the immediate attention of the TGA. Further discussion of this issue, and other aspects of post-market surveillance, is in Chapter 5.

Reform of TGA processes

The TGA is currently undertaking formal consultation on reforms in a number of areas that have been raised prior to the conduct of the HTA Review. These consultations will conclude after the HTA Review has reported. Any reforms proposed from these consultations are likely to necessitate changes to the regulations under the *Therapeutic Goods Act 1989*. The TGA is required to comply with government rules established through the Office of Best Practice Regulation (OBPR) and DoFD including the preparation of a Regulation Impact Statement and the seeking of OBPR and DoFD agreement to proceed where there are any significant regulatory impacts (including impacts on costs or competition). The proposed regulatory changes will be subject to Parliamentary approval. It is anticipated that any agreed regulatory changes would not be implemented until 2011. Any changes to the Regulations generally involves a two-year transition (phase in/phase out) period from when the regulation is introduced.

The areas on which consultation is underway are:

Third party conformity assessment

Manufacturers do not have a choice of certification body for the purposes of conformity assessment where the product is made in Australia or contains a medicine or material of human or animal origin or blood products. In these instances, only the TGA is permitted to conduct conformity assessment. Overseas manufacturers can enter the Australian market on the basis of assessments conducted by overseas regulatory agencies (mainly those in the European Union). Australian manufacturers contend that a choice of a TPCA body would reduce regulation timeframes and costs and create a level playing field with overseas manufacturers.

In response to these concerns the TGA has invited submissions:

- on the use of third-party organisations for conformity assessment of medical devices or of manufacturers; and
- to determine an appropriate balance of regulatory involvement in the process.

Specifically, the TGA has identified three broad issues for consideration:

- What role should the TGA have in issuing conformity assessment certificates?
- What requirements, if any, should apply if third party assessment was available for Australian device manufacturers intending to supply in Australia and/or for ones containing designated materials?
- If external bodies are allowed to undertake assessments of Australian made devices and/or ones with a designated material, should they be permitted to issue certificates or should they provide reports for review and acceptance by the TGA?

Reclassification of joint replacement implants

In response to evidence to suggest that the performance of some medical devices is not adequately demonstrated prior to supply (resulting in premature revision and subsequent risk to the patient), the TGA has invited submissions on a proposal to re-classify joint replacement implants (including total and partial hip, knee and shoulder implants) to require a higher level of regulatory oversight (by increasing the classification of these devices from Class IIb to Class III). This proposal would provide for an increased level of pre-market regulation for these implants while also enhancing the TGA's post-market controls over this important group of medical devices. Specific issues associated with the current level of regulation of orthopaedic implants that require consideration are:

- the long-term performance reports, which suggest the need for increased pre-market review;
- the need for an enhanced capacity to monitor post-market performance of these devices;
- the benefits in aligning Australian requirements with international standards, especially as approximately 90 per cent of devices used in Australia are imported;
- the importance of balancing timely access to innovative therapies with appropriate regulatory oversight;
- the costs of regulation and the potential for this to result in a reduction in the numbers of joint implants available on the market; and
- potential risks associated with joint implants that are unacceptable in Europe being supplied in Australia as a result of the classification change in Europe from Class IIb to Class III.

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 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.

4.5 Improving the Rigour and Efficiency of MSAC

MSAC was established in 1998 to strengthen the sustainability of the health system by ensuring that new health technologies are properly assessed in regard to their safety, effectiveness and cost-effectiveness before being subsidised via the MBS. MSAC's comparative approach to the assessment of new and emerging technologies and procedures is an important component in ensuring that Australians have timely and affordable access to appropriate health services, and that resources are invested in the most cost-effective services.

Role of MSAC

In providing advice to the Minister on the strength of available evidence relating to the use of new technologies, and on the circumstances under which public funding should be supported, MSAC plays an important role in ensuring that medical services associated with new procedures and devices are appropriately assessed before being funded through the MBS. On average, MSAC receives around 14 applications a year.

The establishment of MSAC has significantly increased the rigour of the assessment of potential new MBS items in its areas of responsibility, improving the financial sustainability of the MBS and its ability to support improved health outcomes for Australians.

The National Health and Hospital Reform Commission (NHHRC) has recognised the importance of these processes, stating in its report:

We have recommended that the Australian Government should continue to apply existing processes to ensure that the inclusion of services on the MBS is driven by a robust evidence base. This means that all 'new' services (whether provided by medical practitioners or other health practitioners) should be subject to the same rigorous approval processes to ensure that there is clear evidence about their safety, effectiveness and cost-effectiveness. We believe that this is vital to ensuring the financial sustainability of the MBS. A forward-looking approach would also build in regular review and evaluation of new services (say, after three years) under the MBS to ensure that they were meeting policy objectives.⁴⁴

Current issues with the operation of MSAC

Consultations during the HTA Review revealed stakeholder concerns that:

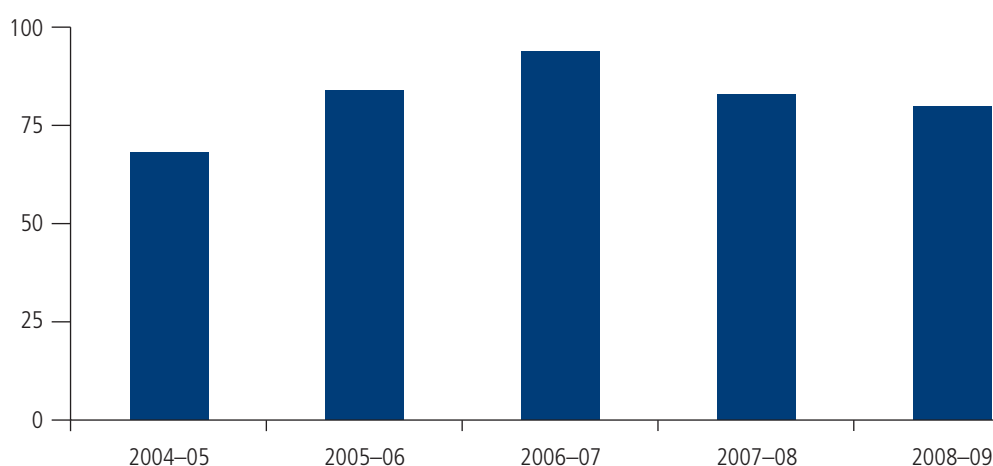
- MSAC has been slower, less flexible and possibly less consistent in its recommendations than other Commonwealth HTA processes.
- The current model which relies exclusively on MSAC conducting its own evaluations, rather than critiquing assessments provided by sponsors, results in long timelines and inefficient use of scarce HTA resources.
- The establishment of expert advisory panels is considered unacceptably slow. These panels are an essential part of the current MSAC process and develop the evaluation protocol (essentially the clinical parameters for the review) but can take up to six months to be formed and to meet for the first time.
- The quality of evidence available to MSAC to review a service that has received interim public funding is often inadequate to address the issues of uncertainty that prevented a recommendation for full public funding on an earlier application.

- There is currently no targeting of assessment effort based on an application's alignment with health priorities and/or potential for improved clinical outcomes.
- The link between the MSAC's advice and the ensuing MBS fees and descriptors agreed by the Medicare Benefits Consultative Committee (MBCC) appears less robust than for other HTA processes.

The most significant stakeholder criticisms specific to MSAC are the concern that its processes are too slow, and that there is considerable uncertainty about whether or when MSAC advice will be reflected in the MBS.

As shown in Figure 4.3, MSAC takes around 75 weeks to complete an assessment. However, much of this time is taken by the initial consideration of the application's eligibility and the establishment of an advisory panel. The actual conduct of the assessment by the evaluators only accounts for around half the time taken. This indicates that there are likely substantial efficiencies to be gained in streamlining the set-up of arrangements for an assessment.

Figure 4.3: Weeks taken to complete an MSAC assessment



Source: DoHA

Note: Period is calculated from initial receipt to MSAC recommendation.

MSAC reforms in progress

The timeliness of MSAC assessments should be enhanced by some of the broader recommendations of this Review (such as promoting the consistent use of evidence across all HTA processes, facilitating better communication between the TGA and other HTA agencies, the allowing of concurrent assessments by HTA processes established for different purposes, and coordination through the SEP of co-dependent and hybrid technology assessments).

A significant cause of delay in undertaking assessments following an application is the time taken to establish and convene the first meeting of an advisory panel of relevant experts. MSAC has held discussions with a number of peak clinical and consumer bodies with a view to expediting this process, for example by nominating standing panels of experts who have indicated a willingness to assist in MSAC assessments, and by reviewing the role of experts in providing advice outside the formal advisory panel process. These initiatives are intended to shorten the time taken to complete an assessment, by forming advisory panels within six weeks of acceptance of an application.

Further improvements in timeliness could also be achieved by the acceptance by MSAC of an applicant's clinical and economic evaluation as an alternative to the current process in which an application is assessed on the basis of a commissioned evaluation. Under this arrangement (which is analogous to the process used by PBAC), the application's submission would be subject to a quality assurance critique before appraisal by the Committee. This approach would allow MSAC to agree specific assessment and appraisal timeframes with applicants, unlike the current process in which the time taken to collect and evaluate the evidence (including obtaining access to expert advice) can be subject to considerable uncertainty.

MSAC is actively considering many of these issues and has already implemented a number of initiatives. It has established an agreed coordination point within the TGA to facilitate more timely advice on the inclusion of relevant products on the ARTG. In addition, two previously separate sections within the MSAC secretariat were merged to improve project management and the flow of information to the Committee Executive.

A number of other changes are being made to the management of the assessment process. For example, one cause of delays has been the identification late in the assessment process of changes to the clinical pathway or comparator. In some cases this requires the re-consideration of the approach to the assessment. The role of MSAC's Economics Sub-committee (ESC) is being changed so that an ESC member attends the initial meeting of each advisory panel to facilitate better decision-making on the economic methodology of assessments.

MSAC is currently focusing on initiatives to improve:

- process efficiency and the timeliness of MSAC advice;
- flexibility; and
- accountability and transparency.

Five working groups have been established to develop new approaches in the following areas:

- triage processes – for determining the application pathway for complex technologies and ensuring that the rigour of the assessment is appropriate to the risk of the technology under review;
- economic modelling – to strengthen and streamline modelling of MBS impacts;
- submission-based evaluations – streamlined assessment processes where the applicant has already conducted a technical and cost-effectiveness study;
- restructuring templates – to streamline the collection and dissemination of information; and
- access to expert advice – to improve consultation with stakeholders and ensure the integrity of the assessments.

A continuing challenge for managing MSAC assessments has been the variability in the volume of applications, and the resulting difficulty in managing the workflow to a limited pool of external HTA evaluators without paying excessive costs in order to maintain a standing capacity that may not be used. One expected benefit of the greater use of applicant-generated submissions will be to allow more flexibility in the use of external HTA evaluators.

Future changes

The HTA Review endorses MSAC's recent initiatives, which should allow the committee to operate more quickly and efficiently for applicants who have the capacity to conduct a full cost-effectiveness assessment prior to submission to MSAC, and for the assessment of applications requiring a full HTA to be conducted after submission where this was necessary or where applicants lacked the resources to do so.

These changes will streamline MSAC's processes to create faster and more efficient consideration of applications, while also enhancing their rigour, particularly in considering financial costs. This will help MSAC to promote and maintain the sustainability of funding for the MBS. Proposed activities under the MBS Quality Framework should complement MSAC's work, providing a greater level of rigour and analysis across areas of MBS funding that have not yet benefited from assessment by MSAC.

In regard to the delays in MBS listing following a positive recommendation from MSAC, it is important that the Australian Government retain the responsibility for deciding whether or not to implement new MBS items based on MSAC advice, taking into account the broader fiscal and policy priorities of the government. However, there are opportunities in which the process leading to the decision by government to list a new service on the MBS following a positive appraisal by MSAC could be shortened. These include having MSAC provide more detailed implementation advice to government, including proposing a specific MBS item descriptor and fee (based on MSAC's clinical and economic evaluation) for the new service.

This would involve improved communication and consultation between MBS policy areas in DoHA and the MSAC HTA evaluators. In particular, greater engagement between MSAC's ESC and DoHA's MBS financial modellers, and between MSAC clinical experts and areas drafting MBS item descriptors (to ensure proposer consideration of issues such as the implications for safety net entitlements, who will provide services and what other MBS rules might apply), would reduce departmental delays between advice and listing and potentially enhance MSAC's understanding of broader policy issues affecting its appraisals.

Government decision-making might also be assisted by advisory committees such as MSAC providing an indication of the relative priority of the various technologies that are recommended for funding, so that government and other funders can obtain additional expert advice to assist in prioritising the introduction of new services where this is necessary due to financial constraints.

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.

4.6 Streamlined Arrangements for the Prostheses List

The Prostheses List is a legislated list of the benefits that private health insurers must pay for prostheses that are provided to a privately insured person as part of an episode of hospital treatment. The Prostheses List therefore plays a dual role as part of Commonwealth HTA processes and as part of the regulation of private health insurance in Australia. As is discussed below, it plays an important role in ensuring the sustainability of the health system, in particular the private hospital and insurance sectors.

Accordingly, it is important to consider the regulatory impact of any changes to the current arrangements on both the medical devices industry and the private health insurance industry. Any changes to existing arrangements also need to be consistent with the government's policy objective that private health insurance remains affordable and accessible for the Australian population.

The current Prostheses List arrangements were established to control significant increases in the benefits paid for prostheses in the earlier part of this decade. In 2001-02, the Private Health Insurance Administration Council (PHIAC) reported that while the *number* of services (as shown in Figure 4.4) involving prostheses had slightly decreased in that year, there had been a 41 per cent *increase* in underlying prostheses costs.^{viii}

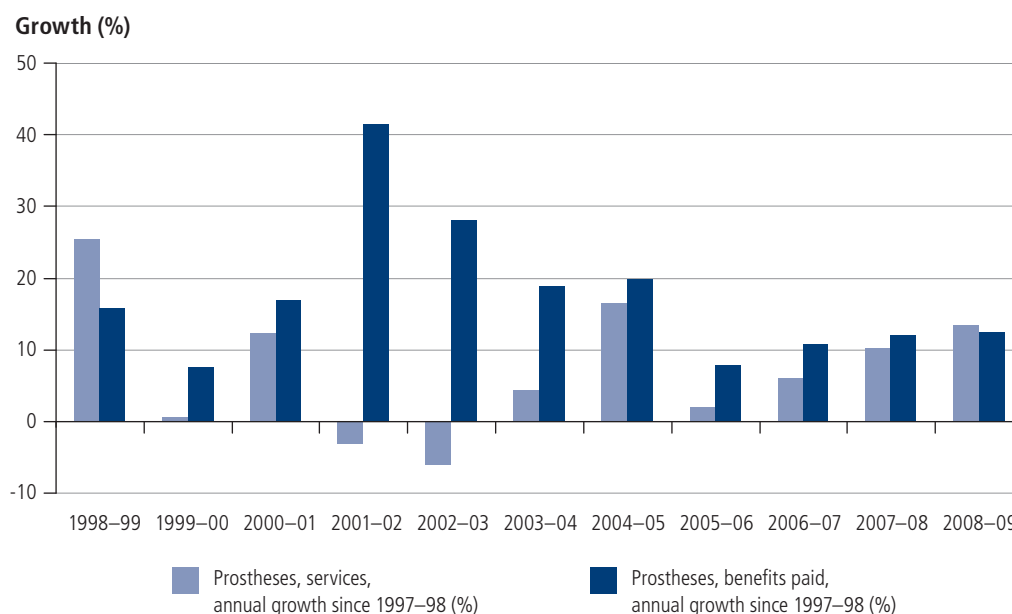
Prostheses claims increased by a further 28 per cent in 2002-03, 19 per cent in 2003-04 and 20 per cent in 2004-05. This inflation in prostheses expenditure contributed to increases in premium costs and made private health insurance less affordable for consumers.

In response, the government introduced reforms aimed at moderating the rate of increase, through the current legislative arrangements which are administratively supported by the PDC and its subcommittees. The legislation took effect on 31 October 2005.

^{viii} PHIAC noted that coding changes to prostheses had artificially decreased the number of items recorded resulting in a 46% increase in the average price of prostheses. Adjusting for the coding changes appeared to result in an estimated increase in the number of prosthetic items of 11% over the year, with the increase in the average benefit paid for prostheses being closer to 28%.

Since its establishment the PDC arrangements have been highly successful at controlling the growth in prostheses costs. As Figure 4.4 shows, the pattern of the growth in the cost of prostheses outstripping the growth in the number of services that occurred between 1999 and 2002 is now being controlled and costs are moving in line with volume. Maintaining this success in controlling the costs of prostheses is critically important to ensuring that both government and consumer contributions to private health insurance remain financially sustainable.

Figure 4.4 Benefits paid and services growth (%), 1998–99 to 2008–09



Source: Private Health Insurance Administration Council, 'PHIAC A Report, various quarters', <<http://www.phiac.gov.au/for-industry/industry-statistics/datatablesphiaca/>>, accessed 27 November 2009

Achieving this degree of control over the cost of prostheses is a substantial achievement but requires a heavy workload. As shown in Figure 4.5, the PDC has a substantial workload of new assessments, review of existing groupings and amendments to current listings.

Figure 4.5: Workload indicators for PDC

Task	Average number each year (two cycles)
Clinical assessment of new applications and negotiation of benefits	1000 products
Review of existing groupings and benefits for appropriateness	3000 products (note this is inflated at the moment due to the continuation of the non-CAG orthopaedic product review over several cycles)
Amendments to listings (e.g. sponsor transfers, name change, suffix, grouping)	6000 amendments

The efforts of the PDC to systematically review all benefits on the Prostheses List are behind schedule due to a heavy workload assessing new items, and an unwieldy review process. Consistent with the Doyle Review recommendations, this needs to be addressed as a matter of urgency.

Background to the current prostheses listing arrangements

The Prostheses List stipulates benefits that must be paid by private funders for medical devices and human tissue products. In order to reduce the regulatory burden associated with HTA, it would be possible to abolish the Prostheses List and allow health insurers to negotiate benefits for prostheses under contractual arrangements with hospitals or medical device sponsors, in much the same way as health insurers negotiate contractual benefits that they will pay for hospital accommodation and theatre banding, or professional fees for medical and allied health service providers.

Although one insurer submitted that:

*Once there is appropriate information provided about clinical best practice and information on price, there would be no need for prosthesis price regulation as all the relevant information would be available for commercial arrangements to be made between private health insurers, private hospitals and device manufacturers. Private health insurers would make payments on a casemix basis, where the benefit paid for a private hospital visit would be inclusive of hospital and prosthesis costs. Similar price signals have been effective in reducing pressure on prosthesis costs in the public sector*⁴⁵

there would appear to be consensus that regulation of private health insurance benefits for prostheses costs should continue, at least until there is better information available about clinical best practice (there are recommendations to the government in the NHHRC report about the development of clinical guidelines).

Also, with the exception of hospital 'theatre band' costs, there are default or minimum benefits prescribed under Australian Government legislation for insured hospital treatment. These operate in the absence of a contract between the insurer and the service provider, and protect privately insured people by ensuring that they will receive minimum benefits for treatment under their hospital insurance policies. The HTA Review also notes that this regulation assists in protecting consumers and the government's significant financial investment in private health insurance.

Workload

One result of the pressure of the backlog and new applications is that the PDC departs from established processes in order to meet its mandated timeframes. These departures from established process are usually aimed at ensuring that a sponsor's product can be listed at the next available opportunity (rather than the sponsor having to wait another six months until the next list is made). Some examples of departure from established guidelines include:

- offering 'truncated benefits' where there is not enough time remaining in a cycle for a full benefit negotiation (which requires at least 15 days for a sponsor to consider two benefit offers, as well as time for the development of those benefit offers, and PDC consideration and endorsement of the agreed benefits). This has become a regular feature of Prostheses Lists and occurs where clinicians do not finish clinical assessments of new listing applications within the allotted time; and

- PDC making recommendations based on advice from individual clinicians – many products are considered by Clinical Advisory Groups (CAGs). However, many other products are referred to two members of the Panel of Clinical Experts (PoCE). In some specialty areas there are insufficient clinicians to assess all new applications due to clinician workload or conflicts of interest. During some cycles particular products have not been able to be assessed at all as there were no clinicians available to conduct the clinical assessment component of the Prostheses List application process. For particular products, such as orthopaedic screws, the PDC has instigated the concept of substantial clinical equivalence which may reduce the evidence requirements and level of assessment conducted on the product.

These issues indicate that the current Prostheses List arrangements are not sustainable and need to be changed.

During the HTA Review a number of concerns emerged in regard to the PDC's functioning. Some of these are similar to concerns raised more broadly about Commonwealth HTA processes and relate to the general transparency of its operations. The HTA Review identified a number of specific issues, which relate to:

- the role of the PDC in relation to safety assessment;
- the composition of the PDC and its various supporting committees;
- administration of the Prostheses List; and
- the setting of benefits.

Assessment of safety

The TGA has the statutory responsibility for assessing the quality, safety and efficacy of medical devices entering the Australian market.

The perception has emerged among stakeholders that the PDC and its CAGs and PoCE also see their role as assessing the safety of devices. Medical device industry stakeholders expressed their concerns to the HTA Review that this represented an unnecessary duplication of the TGA's role, imposing additional costs and delays in the listing process. Other concerns by medical device industry stakeholders are that the PDC's approach to assessment:

- reflects a lack of understanding on the part of the PDC (and CAGs and PoCE) of the assessment activities of the TGA, in particular that the TGA does not undertake comparative assessment but instead focuses on the intrinsic risks of the device;⁴⁶ and
- is not transparent, with applications rejected due to 'insufficient clinical evidence' without any detail being provided on the nature of the evidence gap.

The Focus Group Report on the first round of consultations for the HTA Review found:

There was widespread frustration expressed by participants – particularly industry sponsors – that PDC was also assessing the safety of medical technologies. Stakeholder uncertainty about the role of PDC was exacerbated by a perceived lack of transparency in the Committee's processes and decision-making.⁴⁷

Consistent with this perception the PDC has currently defined its role as to consider the safety, clinical effectiveness and the cost relative to the clinical effectiveness of other products, which is outside of the scope approved by the Minister. In its submission to the HTA Review, the PDC stated that some of its members considered the TGA assessment procedures were inadequate and that PDC's clinicians conduct a more thorough and appropriate assessment.⁴⁸ However, the PDC did not provide any evidence to support this contention.

The drift in the focus of the PDC towards comment on device safety appears to have occurred for a number of reasons:

- insufficient understanding of the current processes of the TGA, possibly reflecting poor communication between the TGA and PDC; and
- a confusion on the part of PDC members on the meaning of its current approach to assess comparative effectiveness (including comparative safety) and cost relative to clinical effectiveness.

CAGs and the PoCE were established to advise the PDC on the relative clinical effectiveness of each product proposed for listing compared with:

- products used for the same or similar purposes that are listed as a prosthesis on the Prostheses List; or
- current treatment for the indications the products are designed to treat.

The HTA Review found that there are a number of reasons to constrain the PDC from making recommendations on the basis of concerns with the intrinsic safety of products:

- the TGA has already conducted its assessment of the safety of the device consistent with Australia's international obligations and current harmonised practice;
- its CAGs and PoCE only have a short time to assess a large number of applications, do not have access to HTA expertise, and are therefore unable to conduct a thorough safety review;
- if any safety concerns are identified, they should be referred to the TGA in its role as regulator for consideration; and
- the blurring or overlap for assessing safety dilutes accountability for what is a fundamental aspect of regulation.

Committee structure, roles and membership

The PDC membership consists of:

- four clinicians, one of whom is the Chair, as nominated by the Australian Medical Association (AMA);
- four insurer nominees, nominated by the Australian Health Insurance Association (AHIA);
- two private hospital nominees, one nominated by the Australian Private Hospitals Association (APHA), and one by Catholic Health Australia (CHA);
- one consumer, nominated by the CHF;
- one nominee of the MTAA; and
- an ex officio member from DVA.

Medical device industry stakeholders have expressed concerns that a single industry member on the PDC (versus four insurer members) is not sufficient to present their views effectively given that a decision-making quorum^{ix} can exist without any medical device industry representation.

In addition, stakeholders have questioned the quality of PDC's assessment of cost relative to effectiveness as there is no requirement for members to have expertise in health economics.

As a result of PDC's current membership structure, formulation of advice has tended to be made on the basis of the background of the members. As a result, the PDC is perceived by some as being more 'representative than expert'. Notwithstanding this perception, the PDC seeks to work by consensus whenever possible.

The Policy Advisory Group (PAG) was established to provide advice to the Minister on prostheses policy and created the current prostheses listing arrangements. As with the PDC, the PAG has members from each of the major private health industry stakeholders with competing views on the appropriate level of reimbursement of prostheses by private health insurers. Therefore the PAG found it difficult to reach agreement on any issue. The PAG has not met for some time.

The Prostheses and Devices Negotiating Group (PDNG) negotiates benefits with sponsors of products recommended by the PDC for listing on the Prostheses List. Members of the PDNG are nominated by the AHIA and appointed by the PDC. The PDC may also appoint nominees of the APHA and CHA as members.

Stakeholders have been critical of the benefit setting process that is a feature of the current prostheses listing arrangements. In particular, the lack of transparency around the process for determining benefits, the perceived bias of the PDNG and the administrative workload associated with setting a benefit for every product on the Prostheses List.

The Doyle Review recommended that the PDC, PAG and PDNG be abolished and replaced by a new Prostheses Committee, with an independent chair, clinicians nominated by relevant professional colleges or associations, other members with health economics and health industry knowledge and representation from DoHA.⁴⁹

However, the HTA Review found that it would also be desirable to include a nominee of private health insurers on the new committee (as they are the funders of prostheses benefits, and should be directly represented in the process which establishes requirements for this funding), a nominee of the medical devices industry and a nominee with consumer expertise.

This would improve transparency and consistency in decision-making, and reduce perceptions of bias due to the structure of the current committee and its sub-committees.

Better administration of the Prostheses List

The current listing arrangements have been operating for just over four years and are still evolving. Currently, applications for the Prostheses List can only be made twice a year, with a new list being made 25 weeks after the close date for applications.

When it was established, the PDC was expected to review the large number of listings and benefits that were 'grand-parented' from earlier agreements between various health insurers and device sponsors. Many of these agreements are not necessarily consistent or equitable and there are many products remaining on the Prostheses List that have not been reviewed, many of which have different benefits from other listed products with similar clinical effectiveness.

^{ix} A quorum is three clinician members and three health insurer members.

Simplification

The PDC has reviewed around half of the products on the list since 2005 to establish consistent grouping schemes for products with similar clinical effectiveness, and over time has been reducing the differential in benefits for products within these groups.

However, progress has been slow, as the review process requires the development of grouping schemes by clinicians with limited time available to devote to this work (usually followed by months of debate between sponsors, insurers and clinicians about the appropriateness of those grouping schemes), then benefit offers and negotiations for every single product affected by a review. One of the current reviews being conducted by the PDC involves around 2500 products, and is still not complete after almost two years.

It is essential to the proper functioning of the Prostheses List that it is reviewed to ensure that anomalies in benefits are removed. Given the experience to date, it is recommended that this work be completed by dedicated resources within DoHA, rather than the PDC and its sub-committees, as a matter of urgency. DoHA will need to source the necessary expertise to develop functional grouping schemes for those areas of the Prostheses List where these do not exist, and recommend the inclusion of particular listed products with overall similar clinical effectiveness into each group.

The outcome of this work should be to establish a single benefit paid by insurers for substantially equivalent products within a single group. In setting these benefits, it will be important to ensure that expenditure on prostheses by private health insurers continues to be restrained, although this will be balanced by the need to ensure that insured patients continue to benefit from affordable access to an appropriate range of prostheses.

To achieve this, stakeholders, including the PDC and its subcommittees, should be given the opportunity to comment on proposed changes to the Prostheses List arrangements including the proposed grouping schemes, the inclusion of products within these groups, and the recommended benefit, before these are enacted by the Minister.

Application management

Currently sponsors must submit applications within a specific time window. During the HTA Review, sponsors expressed concern that if they miss this window their application must wait until the next cycle, leading to a gap of up to 11 months between when an application is made and it is placed on the list. Several sponsors sought a 'rolling' or continuously updated list to address the delay, but private hospitals and insurers considered this would not be manageable. Such a change would also present significant logistical difficulties in managing an already difficult PDC workload.

One possible improvement would be to allow applications to be submitted at any time (allowing assessments to be managed progressively), but retain the bi-yearly listing cycle (to efficiently manage the regulatory processes and health industry impacts involved in updating the list). Where the assessment of an application is not finalised before the cut-off date for making a Prostheses List, the application would be held over until the next list was made.

Setting benefits

Product level benefit negotiations

The current processes require individual benefit negotiations to be conducted for each new product that is listed, and for every product that is being reviewed. This can amount to thousands of benefit negotiations every cycle. This is a very resource-intensive approach, and the benefit setting part of the process is also the area where most sponsors believe that transparency and fairness needs to be improved.

Negotiation of an individual benefit for every listed product can help with controlling costs (some sponsors may be willing to take a reduced benefit over competitors to increase market share). However, this does not occur with sufficient frequency to outweigh the administrative costs and perceptions of lack of transparency that arise from individually negotiated benefits.

The establishment of a single benefit for groups of products with similar clinical effectiveness would improve transparency and significantly reduce the workload for the PDC. Similar to the arrangements that apply for the review of group benefits for the PBS, if a sponsor of a listed product or a new product requested a lower benefit than currently applied for the relevant group of products, this would trigger a review of the group benefit by the PDC, with a lower benefit potentially being set for all products included in that group.

Establishing a single benefit for like products will ensure that the same price is paid for prostheses that deliver similar health outcomes, making the Prostheses List both simpler and fairer. Consistent with current policy to control costs, generally the single benefit will reflect the lowest benefit accepted for a product in a group.

Maximum benefits

The Prostheses List currently includes both a 'minimum' and 'maximum' benefit for some listed items. This occurs where the sponsor wishes to list an item, but is not willing to accept the 'minimum' benefit recommended by the PDC that the insurer must (under legislation) pay for that item. The difference between the minimum and maximum benefit must be met by the patient as an out of pocket or 'gap' payment. In effect, the maximum benefit is setting the maximum price that a sponsor can charge a privately insured patient for a prosthesis.

This feature of the list was designed to promote informed financial consent, so that patients are aware of the gap that they will have to pay for a prosthesis. However, the overwhelming majority of patients still rely on their doctor to provide this information to them before they receive the prosthesis, and the inclusion of a maximum amount on the Prostheses List does not guarantee that the doctor or hospital will provide this information to the patient.

The Doyle Review also found that, in many cases, the listed gaps were not charged by sponsors (which was not surprising in an environment where some sponsors were willing to provide prostheses to public hospitals at 30 to 40% less than the Prostheses List minimum benefit), or were absorbed by hospitals (in particular where gap amounts were small). In the absence of consistent and informed financial consent, it is unlikely that these gaps are providing any effective incentives to either patients or doctors that would affect their choice of prosthesis. It would appear that this arrangement is therefore offering minimal benefits to sponsors and no benefits to patients, but is increasing the administrative complexity of the Prostheses List and reducing certainty for patients.

As discussed above, it is recommended that there be a review of existing listings to group products which have similar clinical effectiveness for a given clinical indication. A single benefit should be determined by PDC to apply to each group of like products. This also creates the opportunity to eliminate gaps for patients, by removing the capacity of sponsors to set a higher benefit for their prosthesis than recommended by the PDC.

This single benefit should be the default price that insurers are required to pay and the capacity of sponsors to set a higher 'maximum benefit' through legislation should be removed. That is, the price that sponsors are allowed to charge for a product should be equal to the benefit that insurers are legally obliged to reimburse. This would result in no out-of-pocket costs for the patient. The Prostheses List would operate as a default benefit schedule, so that insurers, providers and suppliers could negotiate lower prices for the supply of devices.

If PDC considers that a product demonstrates significantly superior comparative clinical effectiveness at a cost proportional to that comparative superiority, PDC may decide to list that product in a new group (or sub-group) with a higher standard benefit.

Group benefits would be set (and maintained by the PDC) having regard to the need to ensure that privately insured patients have access to a reasonable range of devices in each group of products for procedures currently included in the MBS.

If sponsors are not willing to accept the standard benefit that applies to the relevant group, then the product would not be included in the Prostheses List, and sponsors would have the option of negotiating a higher price directly with hospitals and insurers (Doyle Review – Recommendation 13).⁵⁰ However, as these arrangements fall outside the regulatory arrangements for the Prostheses List, there would be no obligation on any party to participate in such negotiations.

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.

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.

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 PHI;
- 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.

CHAPTER FIVE

Improving Post-market Surveillance of Health Technology



5 Improving Post-market Surveillance of Health Technology

5.1 Introduction

Post-market surveillance has an important role to play in protecting the community and in ensuring the sustainability of the health system. Post-market surveillance aims to improve the eventual overall efficiency of HTA processes.

This chapter discusses the issues that were identified as being important in improving post-market surveillance arrangements for medical devices and addresses term of reference 3 for the HTA Review. The HTA Review found that the safety of medical devices was of paramount concern to stakeholders and that there was room for further improvement in the assessment of devices, use of devices and ongoing monitoring. The aim of these improvements is to ensure that there is an ongoing process of performance assessment over the 'life cycle' of a device, both during the period of its active clinical use and while the device is still implanted in consumers' bodies.

The HTA Review found that Australia's post-market surveillance system is viewed as functioning reasonably well for market regulation purposes, but has some weaknesses, in that it is seen as:

- too passive;
- too heavily weighted in favour of short-term safety concerns, with insufficient focus on effectiveness (especially comparative effectiveness);
- over-reliant on notification of events from suppliers and manufacturers which gives rise to a perception of possible conflict of interest;
- lacking a nationally consistent process for alerting different stakeholders in the event of a serious fault in a health technology;
- needing to move beyond a system that simply points to a possible safety concern and into the realm of quantifying risks and benefits; and
- under-utilising clinical registers to generate data that are more representative of health technology performance in the 'real world' than controlled clinical trials.

This chapter recommends action in five related areas to improve the post-market surveillance of devices. These are to:

- adopt a more proactive and sustained approach to post-market surveillance for device safety;
- expand the scope of post-market surveillance beyond the current focus on safety to include the collection of cost-effectiveness data to support future reimbursement decisions;
- make selective use of registers to collect post-market surveillance data on specific, high-risk implantable devices;
- explore opportunities for better health data linkage to generate evidence on the utilisation and effectiveness of health technologies; and

- use data from post-market surveillance to evaluate technologies funded on an interim basis.

These actions will contribute to a more sustainable health system by supporting decisions on whether:

- a device should be removed from the market because it is unsafe or superseded by other, better technology;
- funding for a device should be varied or discontinued based on its comparative performance; or
- changes should be made to who is eligible to provide or receive the device.

5.2 A More Proactive Approach to Post-market Surveillance for Device Safety

The current system relies heavily on the device manufacturer/sponsor reporting, which in turn relies on the sponsor's awareness of emerging problems. If concerns are identified and validated, the TGA may cancel or suspend the ARTG entry of particular products, or direct other action such as a recall, safety alert or product improvement by the manufacturer.

However, reporting may be incomplete or delayed because of inadequate or incomplete reporting by clinicians, consumers or health organisations, particularly when a device is no longer regarded as 'novel'.

Submissions to the HTA Review suggested that there be greater public awareness of the opportunities and mechanisms whereby both health service providers and consumers can more actively participate in post-market surveillance, such as through the reporting of adverse events associated with device use.

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.

5.3 Expanding the Scope of Post-market Surveillance

Current post-market surveillance arrangements, such as those managed by the TGA, focus exclusively on ensuring safety of medical devices and regulatory compliance.

There are two reasons to consider expanding the scope of post-market surveillance to collect information useful for HTA.

The first is that often only limited real-world data is available at the time of the initial HTA. In addition, a particular device may be used in different circumstances, for different purposes, in different patients, or in combination with other procedures or technologies not considered at the time of the original approval. Therefore, the initial HTA for reimbursement and decision to subsidise a health technology could, in many cases, be considered a crucial first step in gauging the efficacy and comparative cost-effectiveness of a technology, rather than the only step. However, at the current time few data are collected that would support ongoing assessment of comparative safety, clinical effectiveness and cost effectiveness.

A second reason to enhance post-market surveillance is that there is increasing pressure to accelerate entry of what may be very new technologies into the health system which have relatively little evidence supporting their longer-term costs and benefits. Expanded post-market surveillance may provide a means by which some technologies could be subsidised on a conditional basis (subject to satisfying an initial assessment), with evidence collected from actual patient utilisation.

Internationally, various health systems have begun to strategically position their post-market surveillance systems to encompass a more comparative effectiveness focus in addition to a vigilance focus.

For example, in 2007, the Canadian Government released its *Federal Post-market Surveillance Strategy, 2007–2012* which describes a vision for its post-market surveillance program so it is 'at the forefront of regulatory science, promotes the safety and effectiveness of health products, and is recognized for its contributions to the health and safety of Canadians'.⁵¹ In the Canadian strategy, a key success factor for improved surveillance and more effective risk management is a stronger scientific capacity based on collaboration and information sharing.

For Australia to follow a similar path, careful consideration of the roles and responsibilities of each stakeholder (Australian, state and territory governments, clinicians and consumers, as well as device manufacturers and sponsors) and associated infrastructure and regulatory requirements (such as to permit data linkage) would be required. Unplanned expansion of post-market surveillance might introduce new inefficiencies and duplication with little benefit.

Accordingly, the focus of an expanded post-market surveillance system would be to collect reliable data on whether:

- the product is being used for the intended clinical purpose (that is whether there is 'leakage' to purposes for which its clinical and/or cost-effectiveness has not been demonstrated);
- the product is being used in populations for which it has not been evaluated (such as to treat different diseases, or age groups);
- the volume of (appropriate) use is higher than forecast, implying a price reduction should be negotiated; and
- the forecast outcomes are being achieved. If it had been assumed that the technology's use would result in the avoidance of another service (such as another test or procedure), or prolong life, data could be collected to evaluate whether this actually eventuated.

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.

5.4 Selective Use of Registers to Collect Post-market Surveillance Data

Clinical registers are databases that systematically collect health-related information on individuals who are:

- treated with a particular surgical procedure, medicine or device (e.g. joint replacement);
- diagnosed with a particular illness (e.g. stroke); or
- managed via a specific healthcare resource (e.g. treated in an intensive care unit).⁵²

Data from registers and other non-interventional studies are often referred to as 'real-world data' to distinguish them from clinical trials.⁵³ In Australia, the best known register, the National Joint Replacement Registry (NJRR), was established a decade ago to define, improve and maintain the quality of care for individuals receiving joint replacement surgery. It is considered to have delivered substantial benefits and is estimated to have reduced the number of unnecessary revision operations by 1,200 procedures per year and saved the health sector and consumers around \$44.6 million since it was established.⁵⁴

Support from a range of stakeholders is critical to a register's success. Cooperation from clinicians is required in order to obtain the data necessary for the register to be effective. Registers are also expensive to establish and maintain, requiring investment in both data systems and liaison to ensure the quality of information. Although the NJRR was initially funded by the Australian Government, it is now moving to cost recovery from the device manufacturing sector. Given the sensitivity of the data collected, registers need robust governance arrangements to both protect the confidentiality, validity and reliability of data and to ensure relevant data are available to all those with an interest.

In the light of the costs and difficulty in establishing an effective register, it is recommended that the initial focus for any new register should be for high-risk implantable devices.

Establishment of such a register should be undertaken in accordance with the draft operating principles and technical standards for registers which have been developed by the Australian Commission for Safety and Quality in Health Care (ACSQHC) in conjunction with the National E-Health Transition Authority (NeHTA) and the Centre for Research Excellence in Patient Safety (CRE-PS).

5.5 Investigating the Scope for Better Health Data Linkage

Medical devices are rarely used in isolation. In most cases the device is part of wider intervention such as surgery, and may also be associated with the use of medicines or other treatments or tests that may continue to be required for some time.

Similarly, the impact of the device on the patient (whether positive or negative) will often show up in the patient's use of other medical services (such as visits to a general practitioner), use of prescription medicines or tests, or admissions to hospitals and visits to emergency departments.

A reliable assessment of the safety and efficacy of technologies requires data from a range of different systems. The multiplication of data sources within heterogeneous health systems results in both redundant and inaccessible information. The currently fragmented data systems make it difficult, if not impossible, to systematically capture these impacts. Funders, clinicians, consumers and industry may therefore lack crucial information on the effectiveness and risks of technologies.

The existence of these multiple, 'siloed' data sources reinforces the need for better data linkage. Moves towards a consistent national approach to the establishment of electronic health records, led by NeHTA (which was established by the Australian and state and territory governments to develop better ways of electronically collecting and securely exchanging health information) will over time enable better data linkage to take place.

There may also be opportunities to connect datasets that will enable significant improvements in the capacity of post-market surveillance processes to contribute to the sustainability of the health system. An example raised in consultation for the HTA Review was a proposal to formally link billing codes and catalogue numbers within the Prostheses List database. Hospitals and post-market surveillance systems such as the NJRR identify prostheses by catalogue number. Linkage of billing code and catalogue number will not only enhance capacity for evidence development, analysis and reporting but will have the added benefit of improving transparency and accountability with respect to appropriate prostheses benefit payments.

Underpinning any proposal to link datasets should be an ethical framework that offers sufficient assurances of privacy and confidentiality to service providers and clients and protection against the misuse of personal information for purposes other than those originally intended. Such safeguards need to inform not only the actual process of linking client records but also related processes such as obtaining client consent, data storage, transfer, encryption and release.

With these safeguards in place, the potential benefits of data linkage include:

- more cost-efficient research methodologies compared with traditional approaches to epidemiologic and health services research;
- adding value to existing information assets by generating a greater return on the substantial existing investment in routine administrative and clinical data sets;
- fostering collaborative research involving population health researchers, clinical researchers and biomedical scientists, with direct benefits for health outcomes; and
- better health literacy through enhancing interactions between researchers, clinicians, policy-makers, consumer groups and the mass media.

Some jurisdictions have already developed protocols, such as the Western Australian Department of Health *Practice Code for the Use of Personal Health Information* which contains the guidelines that must be followed in the design and conduct of all projects using personal health information provided by the WA Department of Health.⁵⁵

During the HTA Review, stakeholders were consulted on two options to progress data linkage. These were to:

- 'piggy back' on existing national data linkage and e-health initiatives that would then feed information into a post-market surveillance system; and
- 'pilot' a specific data linkage project for post-market surveillance purposes.

Stakeholders were generally doubtful of the first approach, considering that the progress of e-health initiatives was slow and unpredictable. They saw more value in testing linkage in areas of likely high return and then applying lessons more broadly across the health system.

5.6 Using Data from Post-market Surveillance to Guide Investment in Technologies

During the options development phase of the HTA Review, stakeholders generally agreed that disinvestment in relation to comparatively ineffective devices was desirable. However, a substantial number of those consulted (particular industry and clinician stakeholders) considered that the market worked effectively to discourage the use of outdated or ineffective technologies and that no government intervention was required to proactively review and identify specific technologies for disinvestment. On the other hand, others noted that a number of procedures and devices continue to be used and subsidised despite common knowledge that they are at best ineffective or at worst harmful.

Furthermore, some stakeholders argued that if disinvestment processes were to be adopted, reimbursement levels should be able to be *increased* ('reinvestment') in the event that post-market data proved that a technology was more cost-effective than the pre-market evidence suggested.

In the 2009–10 Budget, the government provided \$9.3 million over two years to implement the MBS Quality Framework to put in place a new evidence-based framework for reviewing services listed on the MBS, which will begin to take effect from 1 January 2010. Under the new arrangements, services will be evaluated and aligned with contemporary evidence to ensure clinical relevance and appropriate pricing. New services will be evaluated three years after being listed. The aim of this initiative is to improve health outcomes for patients and help maintain the financial sustainability of the MBS. The DoHA has commenced work on implementing this initiative and it is important that post-market surveillance of devices complements this effort.

Notwithstanding the caution expressed by some stakeholders, opportunities to improve the overall health impact of current expenditure by encouraging the use of the most appropriate technologies were identified. Such efforts should be coordinated with other related initiatives such as the development of clinical guidelines and the implementation of the MBS Quality Framework discussed above.

A recurring theme in submissions and consultations is that the current HTA system heavily emphasises the initial assessment of technology but does not sufficiently address the ongoing relevance of a technology. The term 'disinvestment' was used to cover a range of processes that might answer questions such as:

- Should a technology be removed from the market?
- Should a technology continue to be publicly funded?
- Should the eligible population be reviewed?
- Should the price (benefit) paid for technologies increase, decrease or stay the same?

Such an approach could encourage more robust and efficient processes around all health care decision-making, including reallocation (or reinvestment) of funding to interventions, including devices, that offer overall health gains more efficiently. In the face of increasing health expenditure, it will become increasingly difficult for governments to fund new health technologies unless they have the capacity to identify and remove funding for those that are less effective.

Possible criteria for selecting devices for review could include⁵⁶:

- high risk or high cost;
- the potential health, cost and equity impacts of the use of the device compared to a cost-effective alternative;
- expiry of a pre-designated time or nomination by expert clinical groups for review;
- emergence of new evidence on safety, clinical effectiveness and/or cost effectiveness that challenges previously formed conclusions;
- evidence of significant provider, geographical or temporal variations in device use for a particular condition;
- substantial change in a device to the point that it differs markedly from the initial or prototype intervention that was originally assessed or funded; and
- public interest or controversy relating to the use of a device.

The MBS Quality Framework will be seeking to develop a comprehensive framework to review existing MBS items to ensure that they are based on best clinical practice and are priced appropriately. If successful, there may be scope to adapt this approach to other areas of health funding.

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 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.

CHAPTER SIX

Longer-term Directions



6 Longer-term Directions

6.1 Introduction

This Review has made a number of recommendations to strengthen the conduct of HTA by Australian Government agencies in the short- to medium-term.

The HTA landscape is, however, constantly changing, and is a national landscape (extending beyond direct Australian Government responsibilities). In addition, the consultations conducted as part of the HTA Review identified a number of issues that will require sustained, coordinated action over the longer-term and that were not necessarily able to be addressed as part of the HTA Review's terms of reference. Accordingly, this chapter outlines a set of longer-term strategic issues to inform possible future national activity for HTA reform.

Some possible initiatives that might be undertaken to address each strategic issue are presented to stimulate further discussion. The list of initiatives is not definitive but was suggested during consultation for the HTA Review as possible ways to continue to develop a strategic approach to HTA in Australia. They may need to be revisited in the light of responses to the outcomes of the HTA Review.

The key longer-term strategic issues are:

1. improved planning and system integration;
2. the need for a national approach to HTA involving the Australian Government, states and territories and other key stakeholders;
3. greater patient (health consumer) focus;
4. increased investment in HTA-related research; and
5. increased capacity of the HTA workforce.

6.2 Key Strategic Issues

Improved planning and system integration

The HTA Review has not specifically sought to address substantive improvements to national coordination and integration (beyond Commonwealth HTA), nor has it examined health technologies which are outside of the scope of the HTA Review. Consultation during the HTA Review highlighted several classes of technology which are currently not subject to formal HTA processes (e.g. blood and blood products), or for which only some aspects are assessed as health technologies (e.g. human tissues or genetic testing).

Assessment of these technologies could be assisted by utilising HTA methodologies, enabling improved comparison of therapeutic options.

Blood and blood products

There are some similarities between blood and blood products and other products considered in the course of this Review. The 2003 National Blood Agreement (the Agreement)⁵⁷ provides for the Australian Government and states and territories to fund blood products and services on a shared basis. Products which are first evaluated by the TGA and then agreed by all governments are included on a national listing and made available to clinicians free of charge. The Agreement also outlines a process for an appropriate evidence-based evaluation and advice to governments to support decisions concerning any changes to these products and services. All proposals must be for products which are included on the ARTG and are considered initially by the Jurisdictional Blood Committee (JBC). JBC can then decide whether further information or advice is required before either making a funding decision or referring the proposal and relevant advice to the Australian Health Ministers' Conference (AHMC) for a decision.

Due to the small number of change proposals received to date for blood and blood products and the unpredictable timing of these proposals, it has been difficult for JBC to conduct a HTA process for individual products or to readily access HTA evaluators (including those with experience in health economics) who would either assess the data included in the proposal or, if necessary, collect the evidence base and submit their findings to JBC. Further, the current arrangements do not provide for an appropriately constituted group of experts (including clinical, health economist and consumer members) to advise JBC on funding proposals.

There are some parallels between the processes outlined in this Report for other therapeutic goods and those for blood and blood products, including the iterative processes to achieve inclusion on the ARTG and consideration for government funding as a result of a HTA process. Given the need to ensure that there is a rigorous and consistent process in place to assess blood products and services for funding, there may therefore be some benefit in reviewing how HTA processes may also inform the future application of best practice assessment of blood and blood products.

Genomics

Genomics is a rapidly advancing scientific field with significant potential impact on individuals and the health system. The rate of discovery and the potential applications of new knowledge call for rigorous assessment of the costs and benefits of these technologies. Many of these emerging issues are not directly within the scope of the HTA Review, such as workforce development and the regulation of direct-to-consumer test kits. The HTA Review has considered the assessment of pharmacogenomics, where a genetic test can usefully inform decisions about pharmaceutical treatments.

Preliminary policy work has been done so that, when necessary, systems for the assessment of genomics and pharmacogenomics can be implemented in a manner consistent with the broader conceptual framework for HTA processes and with other health care objectives. The National Health and Medical Research Council's (NHMRC) Human Genetics Advisory Committee was established to provide advice on these issues. The 2004 Australian Law Reform Commission Report, *Genes and Ingenuity: Gene Patenting and Human Health*, the 2005 Productivity Commission Research Report *Impacts of Advances in Medical Technology in Australia* and the 2009 Senate Inquiry into Gene Patents have all considered these issues.⁵⁸

To enable these technologies to be assessed consistent with other health technologies, the HTA system needs an improved capacity for planning and systematic integration including the capacity to review and expand the scope of technologies it assesses.

In addition to the recommendations made earlier in the HTA Review, initiatives that might be undertaken to address this issue include the establishment of:

- a national approach to HTA (discussed in more detail below), that includes a process to systematically undertake reviews of policies and methodologies affecting the scope of HTA processes to incorporate any emerging technologies (such as biologics and genomics), and defining where technologies fit within HTA processes; and
- a formalised mechanism to alert the appropriate policy areas of health technologies or related issues which may need consideration and policy review for example, those identified via horizon scanning and market entry processes such as issues around the assessment of human tissues, blood and blood products, or alternative models of care.

Consider the need for a national approach to HTA involving the Australian Government, states and territories and other key stakeholders

When implemented, the recommendations of the HTA Review will substantially improve the operation of Commonwealth HTA processes. However, HTA Review consultations indicated several areas that may benefit from further analysis.

The first is to ensure that HTA works with and complements government initiatives in regard to the sustainable funding of broader health programs, including those with a focus on preventive health and those exploring role substitution and task delegation.

The second is the need for a national approach to HTA, rather than a set of more-or-less coordinated activities. All governments face resource constraints and obligations to maximise the health benefits from their investments. States and territories must also make decisions about the clinical and cost effectiveness of new health technologies that they might fund, particularly for their public hospitals. They therefore have a similar need to ensure the sustainability of their health funding using a range of techniques, including HTA. A truly national approach requires the creation of a strategic planning and management capacity so that the system as a whole is able to respond to changes in technology, funding or health policy.

States and territories are increasingly conducting their own HTA processes with no formal links to Australian Government policies or HTA outcomes. In most cases this relates to the use of diagnostic tests, medicines, medical devices and procedures in public hospitals. There are already a number of ways the various jurisdictions can coordinate their activities, such as via AHMAC, its principal committee – CTEPC, and HealthPACT, which reports to CTEPC.

In addition, much of the information needed for improving HTA processes lies with the product sponsor, private hospitals and private health insurers. Despite this, communication between these sectors and the Australian Government is largely informal and ad-hoc.

There are a number of risks in the current situation. These include duplication and wasted effort if multiple jurisdictions conduct HTA or appraisals that may not be fully informed of current practices across the various systems, or that different conclusions may be reached by jurisdictions adopting different methodologies, leading to a technology being available in one state but not in another. While this may be appropriate where it reflects different health needs or priorities, it is not appropriate where it reflects a failure to share information to support rigorous HTA processes.

To address these areas, there is an opportunity and a capacity for enhanced cooperation between the Australian Government and states and territories, as well as other stakeholders. Consideration could be given to the need for a national approach to HTA that goes beyond government HTA processes and encompasses industry, clinicians, patients and funders.

Better linkages would enable:

- more comprehensive horizon scanning processes by including industry views and insights;
- better assessment and appraisal by ensuring real-life practices in hospitals and community settings were considered; and
- better post-implementation monitoring through a richer information base.

Initiatives that might be undertaken to implement this strategic issue include:

- development of processes through which to coordinate and guide the development of a consistent national approach to HTA, such as by expanding the role of CTEPC to oversee this development;
- further enhancements to the TGA application system to automate information transfer between the market entry and other national HTA processes;
- regular forums to exchange information between stakeholders, including governments, consumers, clinicians and industry that might lead to a national devices policy; and
- supporting the development of common methodologies and reporting to promote transferability of assessments.

Stronger patient (health consumer) focus

Consumers have multiple interests in an effective, efficient HTA system. As patients, they want timely access to safe, affordable appropriate treatments for their condition. Many consumer groups have been said to feel that 'alongside scientists, physicians and pharmaco-economists, patients have the most intimate knowledge of the disease and its effects and have valuable expertise to contribute to assessments'.⁵⁹ As carers, family members and friends, they are affected by the impact of technologies on the patient's ability to participate in family and community life. As members of the community and tax payers, more broadly, they want to be confident that funds are spent appropriately and that technologies do not pose other environmental or health risks. The WHO states that '... patients/consumers have both a moral and ethical right to participate in health care decisions, particularly within the context of a publicly funded health system.'⁶⁰

Minister Roxon has recently identified a commitment to 'build a health system with the patient at the centre, where patients benefit from seamless care tailored to their needs'.⁶¹ The Minister hosted a consumer-specific consultation in partnership with the CHF on 23 October 2009 to road test the proposed reforms of the NHHRC and highlight the central role of consumers in Australia's health care system and in the government's health reform agenda.

A major mechanism for consumer input into Commonwealth HTA processes is via the CHF. There are CHF representatives on the MSAC, PBAC, PDC and MDEC. However, there is minimal consumer input into other aspects of HTA such as reimbursement setting, review mechanisms or priority setting; or in the horizon scanning, market entry, post-implementation management or system performance and accountability phases.

The recent report by the NHHRC noted the importance of consumer input, including the need to strengthen consumer engagement and voice.⁶²

In order to achieve effective consumer input, it will be necessary to improve health literacy and put mechanisms in place to support consumers to provide informed input. The resources required to improve health literacy and enable consumer representatives to participate appropriately in HTA are likely to be high.⁶³

Initiatives that might be undertaken to implement this strategic issue include:

- development of a consumer engagement policy for HTA to provide a consistent framework for when and how consumers will participate in the various HTA processes. This might include a commitment to establish a specific mechanism for consumer input to HTA, similar to that used by the NICE in the UK;
- investigating the use of social value judgement principles⁶⁴ similar to those used in the UK system. These are the principles that NICE and its advisory bodies should follow when making decisions about the effectiveness and cost effectiveness of interventions, especially where such decisions affect the allocation of National Health Service (NHS) resources. Such principles could provide clear guidance around societal values, such as consumer choice, to be applied in HTA in Australia;
- better communication of HTA and appraisals to consumers to support more informed decision-making. One way to do this would be through the use of specific 'consumer friendly' summaries of assessment or appraisal reports;
- consumer education and health literacy programs on how to assess and understand the risks and benefits of particular technologies or procedures; and
- seeking out and publicly reporting on consumer experiences with health technologies through the use of case studies, bulletins and similar to improve consumer and provider understanding of the full impacts of technologies.

Increased investment in HTA-related research

Australia is a relatively small consumer and an even smaller producer of health technology, accounting for two per cent of the global market.⁶⁵

Nevertheless, Australia does have a highly skilled and well-regarded medical and health services research capacity. In an increasingly globalised industry, Australian health research can help ensure that medical technologies are appropriately applied in the local context. Exclusive reliance on overseas studies creates risks around the transferability of studies to, or consideration of, Australian factors such as geographic spread and health system structure. Participating in such research can also facilitate the early identification and response to changes in the evidence base for a particular technology.

During the consultations for the HTA Review it emerged that many stakeholders considered that Australia had missed a number of opportunities to engage with and influence research relevant to major technologies currently in use, but possibly being used sub-optimally. A number of barriers to participation were suggested with the most frequently mentioned being the difficulty in accessing funding from the NHMRC, and the prohibition on using MBS or PBS funding for research-related services. In addition some examples were also given where HTA decisions conflicted with, and in some cases severely disrupted established clinical trials where a decision was made by the Australian Government to make a treatment widely available that had previously only be accessible via a clinical trial.

The recent announcement to boost Australia's profile as a preferred destination for clinical trials, by the Minister for Innovation, Senator Kim Carr, and Minister Roxon, will have a significant impact on Australia's research and development effort through flow-on investment from clinical trials, and will lead to health benefits for patients receiving early access to new technologies.⁶⁶ This work recognises the importance of clinical trials being conducted in Australia, and the ability to provide patients early access to health technologies.

Initiatives that might be undertaken to implement this strategic issue include:

- the TGA to provide MDEC minutes to HealthPACT;
- explore options to enable the devices industry to formally contribute to horizon scanning through reporting of upcoming clinical trials, similar to the reporting which is currently undertaken by the medicines industry;
- the NHMRC be engaged further in pursuing collaborative arrangements in identifying research funding opportunities in relation to post-market and comparative effectiveness studies and in identifying opportunities for better implementation of agreed evidence in clinical practice; and
- investigating the possibility of changes to the MBS to facilitate clinician and patient involvement in the conduct of post-implementation studies.

Increased capacity of the HTA workforce

The HTA workforce is made up of various occupations and roles across private and public sectors such as data collection, HTA assessors, economic evaluators and health economists. In Australia this workforce is scattered across a number of sectors and jurisdictions such as Australian and state and territory government agencies,

consultants, private health insurers, industry and the public hospital system. There is a general stakeholder view that the existing workforce is not sufficient to comfortably meet the current workload of HTA and is not growing sufficiently to manage the likely, continuing increase in the use of HTA. However, there is little reliable information on current capacity. Given the increasing demand for skills in health economics and health policy research flowing from the increased sophistication and volume of HTA, workforce capacity could be a major constraint on improving the HTA system into the future.

Initiatives that might be undertaken to address this strategic issue include:

- conducting a workforce planning study for HTA practitioners. Such a plan might cover issues such as the current sufficiency of the workforce, how to better utilise current expertise, improved academic recognition and formal training options for evaluators as well as measures to increase workforce numbers; and
- fostering links with international universities and HTA processes to promote information sharing and planning.

Recommendation 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.

Table 6.1: Longer-term national approaches for enhancing HTA in Australia

Strategic Issues	Horizon Scanning	Market Entry Regulation	Health Technology Assessment	Post-implementation Management	System Performance and Accountability
Improved planning and system integration		Systematic review of policies and methodologies Mechanism to alert policy area of review needs			
National strategic framework for HTA involving states and territories and other key stakeholders	Regular forums to exchange information between stakeholders, including governments, consumers, clinicians and industry that might lead to a national devices policy Map existing activities and develop a longer-term strategy including opportunities for coordination	Improve accessibility of TGA data and assessments	Consider the need for processes to coordinate and guide a national system Regular stakeholder forums Development of common methodologies and reporting	Establish data linkages for post-implementation management	

Strategic Issues	Horizon Scanning	Market Entry Regulation	Health Technology Assessment	Post-implementation Management	System Performance and Accountability
Stronger patient (health consumer) focus			Develop a consumer engagement policy Investigate social value judgement principles Better communication of HTA outcomes to consumers Consumer education and health literacy programs	Public reporting of consumer experiences	
Increased investment in HTA-related research	Increased provision of TGA information and publications to HealthPACT Device industry contribution via reporting on trials			Collaboration with the NHMRC on comparative effectiveness research Involvement of clinicians and patients in post-implementation studies	
Increased capacity of the HTA workforce			Conduct a workforce planning study for HTA practitioners Foster international educational links		



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APPENDICES

- A Media Release Announcing the Review of Health Technology Assessment in Australia
- B Key Findings and Recommendations of Recent Reviews into Health Technology Assessment
- C Terms of Reference and Scope of the HTA Review
- D HTA Review Governance
- E Review of Health Technology Assessment in Australia – Discussion Paper
- F Submissions to the HTA Review
- G Analysis of Current Commonwealth HTA Processes
- H Report of Stakeholder Focus Groups – Issues Identification Phase
- I Stakeholder Consultations – Focus Groups and Bilaterals
- J Discussion Papers Presented to ‘Options’ Focus Groups 14–28 October 2009
- K Report of Stakeholder Focus Groups – Options Development Phase
- L Consumer Participation in the Review of Health Technology Assessment – Progress Report No. 2
- M Acronyms
- N Glossary of Terms

Appendix A: Media release announcing the Review of Health Technology Assessment in Australia



THE HON NICOLA ROXON MP
Minister for Health and Ageing

THE HON LINDSAY TANNER MP
Minister for Finance and Deregulation

MEDIA RELEASE

18 December 2008

Health technology assessment processes

Procedures for approving the use of new health technology in Australia will be examined to make it easier for new devices and services to be adopted, while maintaining patient safety.

The Minister for Health and Ageing, Nicola Roxon, and the Minister for Finance and Deregulation, Lindsay Tanner, announced today that a Health Technology Assessment (HTA) Review would be undertaken as a joint exercise between their portfolios.

Minister Tanner and Minister Roxon announced that "The HTA Review will be one of the first Better Regulation Ministerial Partnerships to be undertaken by the Australian Government, as part of its commitment to deregulation, to reduce costs to business and consumers, and contributes to the Government's productivity agenda."

The HTA Review will consider ways of streamlining, increasing timeliness and better co-ordinating arrangements for approving new health technology, to support innovation without compromising consumer safety. It will also assess ways to ensure that only medical services and devices which are clinically proven and provide value for money attract government funding.

It will also incorporate the Government's response to the 2006 Banks Review "Rethinking Regulation" and to recent Productivity Commission Regulatory Burden reports which recommended action to reduce fragmentation, duplication and unnecessary complexity in the regulation of medical devices and technologies.

The Department of Health and Ageing will conduct the review, in close consultation with the Department of Finance and Deregulation. The review will consider processes for:

1. regulation of therapeutic goods before they are released for sale, currently undertaken by the Therapeutic Goods Administration (TGA);

2. approval of Medical Benefits Schedule funding, currently advised by the Medical Services Advisory Committee (MSAC); and
3. listing of prostheses and devices for private health insurance coverage, currently advised by the Prostheses and Devices Committee (PDC).

The HTA Review will take public submissions and will also consult stakeholders through an independent Stakeholder Reference Group.

"The HTA Review is an important step towards an integrated model for evidence based assessment of health interventions. It will identify both short term improvements in assessment processes and possible longer term options for strategic reform," Ms Roxon said.

The HTA Review is expected to report in late 2009. Further information about the HTA Review and the public submissions process will be available in mid January 2009.

For media enquiries to Ms Roxon please contact the Minister's Office on 02 6277 7220

For media enquiries to Mr Tanner please contact the Minister's Office on 02 6277 7400

Appendix B: Key Findings and Recommendations of Recent Reviews into Health Technology Assessment

Recommendations	Current Status	Links to HTA Review Recommendations
1. Productivity Commission Draft Research Report on the Annual Review of Regulatory Burdens on Business – Manufacturing and Distributive Trades, September 2008		
<p>PC Response 4.5</p> <p>DoHA should introduce amendments to the Therapeutic Goods Act 1989, and regulations as necessary, to allow Australian manufacturers to choose a certification body (acceptable to the TGA), based in Australia or overseas, to verify and certify their conformity assessment procedures.</p>	<p>This issue was canvassed in the postponed negotiations to create the Australia New Zealand Therapeutic Products Authority.</p> <p>Subsequently, the government has agreed that the TGA consult with stakeholders in order to progress Australian reforms in the absence of participation by New Zealand. The TGA has conducted initial consultations with stakeholders on a possible model to enable the use of external assessment bodies in conformity assessment. The TGA released a consultation paper regarding third party conformity assessment in late December 2008 and engaged in further direct consultation with stakeholders in February 2009, with a view to releasing a response to the consultation in quarter 1, 2010. Implementation of the preferred option by the end of 2010. Any agreed resulting changes would not be implemented until 2011.</p>	<p>Recommendation 8b</p> <p>The HTA Review has recommended that this work continue.</p>
<p>PC Response 4.6</p> <p>The TGA should ensure that the outcomes of its current Medical Devices Business Improvement Program include the implementation of measures to ensure improved transparency, consistency and timeliness in decision making, including provision of clear advice regarding the reasons for all decisions. The TGA should publish specific commitments and timelines for the Improvement Program.</p>	<p>The TGA is working closely with the medical devices industry on the development and implementation of measures under the Medical Devices Business Improvement Program, which is delivering consistent, timely and transparent decision-making processes. In line with the current collaborative approach, the TGA continues to provide industry with detailed information relating to measures and timelines contained in the Business Improvement Program. The TGA is working to introduce measures that will improve transparency of decision making across all TGA programs.</p>	<p>Out of scope for the HTA Review</p>

Recommendations	Current Status	Links to HTA Review Recommendations
<p>PC Response 4.7</p> <p>The TGA should examine the scope to make greater use of acceptable prior overseas assessments. This should include identifying competent inspection bodies overseas. In general, where a device has been approved by such bodies, there should be no requirement for a further assessment by the TGA.</p>	<p>The TGA currently provides considerable scope for the consideration of prior overseas assessments. For instance, the TGA currently accepts evidence of prior overseas assessments as part of its decision-making processes, supplemented by a Declaration of Conformity to Australian Regulations for lower-risk devices.</p> <p>Further, a Mutual Recognition Agreement (MRA) has been in place with Europe since 1998 on conformity assessment and the TGA is in the final stages of establishing a Memorandum of Understanding (MOU) with Canada in relation to assessment of manufacturing Quality Management Systems (QMS) for medical devices. Manufacturers availing themselves of these agreements are able to introduce their product into the Australian market either without any further assessment in the case of the European MRA, or with assessment of only the technical file, and not the QMS, in the case of the Canadian MOU.</p> <p>Additionally, for manufacturers of high risk devices who do not utilise the provisions of either of these agreements, an abridged assessment by the TGA is conducted of the assessment undertaken by a recognised overseas assessment body rather than of the manufacturer and their product(s). This is supplemented by a Declaration of Conformity from the manufacturer that the product has undergone an appropriate conformity assessment process, and is in compliance with the requirements of the regulations. There are only four categories of the highest risk devices where the TGA is required to undertake a full conformity assessment, and even within these categories the process is often abridged in part, by taking into account assessments of some of the regulatory requirements by a recognised overseas assessment body</p>	<p>Out of scope for the HTA Review</p>
<p>PC Response 4.8</p> <p>The Australian Government should commission a comprehensive and independent public review of the overall HTA System for medical devices/technologies as soon as possible. The review should examine regulatory and policy frameworks and processes impacting on access to, and use of, devices and technologies.</p> <p>Outcomes should include options to improve the efficiency, transparency and timeliness of processes for assessing safety and performance, and suitability for public funding and reimbursement by private health funds, including:</p> <ul style="list-style-type: none"> streamlining the overall HTA framework to remove duplication and overlap; addressing inconsistencies in prostheses listing arrangements, which can impede the introduction of new technologies and distort treatment decisions; and improving the operations of the Medical Services Advisory Committee. 	<p>On 18 December 2008, the Minister for Health and Ageing and the Minister for Finance and Deregulation jointly announced the HTA Review, to be conducted as a Better Regulation Ministerial Partnership. The HTA Review will report in late 2009 and will recommend ways to improve the timeliness of patient access to beneficial technologies without compromising patient safety or value for money.</p>	<p>The HTA Review has made recommendations in relation to all these issues.</p>

Recommendations	Current Status	Links to HTA Review Recommendations
2. Report of the Review of the Prostheses Listing Arrangements (the Doyle Review) – October 2007		
1. The Prostheses List be issued three times a year in April, August and December, including all items that have completed the application or review process at least four weeks before the date of effect of the list.	Awaiting outcome of the HTA Review.	Recommendation 12
2. The requirement for an ARTG number prior to applying for listing be removed, and sponsors allowed to apply concurrently for an ARTG number and inclusion on the Prostheses List.	Awaiting outcome of the HTA Review.	Recommendation 7
3. Any safety concerns identified during the listing process should be directed to the TGA as this is its responsibility, as distinct to clinical comparability and relative effectiveness which are relevant to the listing process.	Awaiting outcome of the HTA Review.	Recommendation 10
4. The review of comparator groups should be finalised by 30 June 2008, and consistent benefits should be set for all items within groups.	Work to implement this recommendation is ongoing and will continue in the August 2010 Prostheses List cycle.	Recommendation 12
5. As the review in recommendation 4 is completed for each group, the current practice of annual review of all items be replaced by a process of review by exception initiated by a sponsor, insurer, or the Prostheses Committee. A review cannot be instigated less than twelve months after initial listing, or 24 months after the last review, and any request for review must be supported by appropriate evidence.	Work to implement this recommendation is ongoing and will continue in the August 2010 Prostheses List cycle.	Recommendation 12
6. Items that have not been used for two years and will not be used in revision surgery should be removed from the list.	This recommendation was not accepted by government.	n/a
7. Items currently listed for amounts below \$100 (with the amount reviewed from time to time) should be removed from the list by December 2008, and the costs of these items included in reimbursement arrangements negotiated between hospitals and insurers. The new Prostheses Committee should monitor this process and report to the Minister, and may recommend reinstating these items if negotiations have not been successful in maintaining the present funding balance.	This recommendation was not accepted by government.	n/a
8. Items currently included on the list that do not meet the criteria for listing as a prosthesis and autologous tissue products should be removed by no later than December 2008.	Work is ongoing to implement this recommendation and will continue in the August 2010 cycle.	Out of scope for the HTA Review

Recommendations	Current Status	Links to HTA Review Recommendations
<p>9. The following structural arrangements be adopted:</p> <ul style="list-style-type: none"> • The PDC, PDNG and the PAG be abolished. • A Prostheses Committee be formed consisting of an independent chair, clinicians nominated by relevant professional colleges or associations, other members with health economics and health industry knowledge, and representation from the Department of Health and Ageing. • The Prostheses Committee will form relevant Clinical Committees along the lines of the current CAGs augmented with health economics expertise to consider prostheses relevant to particular specialties. • The Minister will establish a panel of independent arbiters to resolve disputes between Clinical Committees and sponsors over prostheses classification and benefit levels. 	<p>Awaiting outcome of the HTA Review.</p>	<p>Recommendation 11</p>
<p>10. The following process for considering applications be adopted:</p> <ul style="list-style-type: none"> • Sponsors applying for a new listing must nominate a comparator item and an associated MBS item. • If the Prostheses Committee accepts that the comparator and the MBS item is appropriate, and the sponsor wishes to accept the same benefit level as the comparator, the committee will recommend to the Minister listing at that benefit level. (If the committee does not accept the comparator, it must suggest another.) • If the sponsor wishes to apply for an increased benefit relative to the comparator, it must provide clinical evidence of improved effectiveness and of cost effectiveness at the proposed benefit. Evidence of effectiveness should be at a minimum case series data. • If evidence of improved effectiveness is not available, the item will be recommended to the Minister for listing at the comparator benefit for 12 months to allow data to be collected, and may then be submitted for review. • Applications for increased benefits for a new item or a review of existing benefits will be considered by a relevant Clinical Committee of the Prostheses Committee, which will make a report to the sponsor including the recommended benefit level, the comparator used, and other relevant information. • If the sponsor does not accept the recommendation, the matter will be considered by a member of the panel of arbiters who will hold a discussion with the sponsor and a designated representative of the Prostheses Committee. The arbiter's finding on the benefit level will be recommended by the Prostheses Committee to the Minister. 	<p>Awaiting outcome of the HTA Review.</p>	<p>Recommendation 12</p>

Recommendations	Current Status	Links to HTA Review Recommendations
11. The government should consider establishing new registries for groups of prostheses, beginning in the cardiac specialty. As these are principally a form of post-market surveillance the cost of establishing and maintaining these registries and the existing NJRR should be recovered from relevant groups of sponsors through the TGA cost recovery arrangements.	Awaiting outcome of the HTA Review.	Recommendation 15
12. The Department of Health and Ageing work with insurers to improve data quality under the Hospital Casemix Protocol, and consider imposing sanctions on insurers under the Private Health Insurance Act 2007 if data quality does not improve significantly by June 2009.	Work is ongoing to implement this recommendation and is expected to be fully implemented by 30 June 2011.	Out of scope for the HTA Review.
13. In future, the Minister should not set maximum benefits for new items. This would have the effect of eliminating gaps.	Awaiting outcome of the HTA Review.	Recommendation 12
14. The Department of Health and Ageing should better promote access and use of the electronic versions of the list.	Work is ongoing to implement this recommendation and will continue in the August 2010 cycle.	Currently being implemented.
15. In relation to human tissue: <ul style="list-style-type: none"> The Department of Health and Ageing should carry out a comprehensive review of existing benefit levels for human tissue items, informed by cost accounting data provided by tissue banks, by June 2010. The Department should ensure it has appropriate clinical expertise available to provide advice to the Minister on the listing of human tissue items. In providing advice on items for inclusion on the list and benefit levels, the Department should have regard to the principles that no profit should be derived from trade in human tissue and items involving autologous tissue should not be listed. 	The Human Tissue Review commenced in early 2009 with submissions closing in June 2009. A report of the review is pending.	Out of scope for the HTA Review
3. Rethinking Regulation: Report of the Taskforce on Reducing Regulatory Burdens on Business (the Banks Review) – January 2006		
'The Australian Government should undertake a system-wide, independent and public review of health technology assessment, with the objective of reducing fragmentation, duplication and unnecessary complexity, which can delay the introduction of beneficial new medical technologies. Health technology assessment processes and decisions should also be made more transparent, in line with good regulatory practice.' (Recommendation 4.22)	This recommendation is addressed by the HTA Review conducted by the Department of Health and Ageing in 2009	

Recommendations	Current Status	Links to HTA Review Recommendations
4. Impacts of Advances into Medical Technology in Australia – Productivity Commission 2005		
The report did not make any recommendations; rather, it made findings about Commonwealth HTA processes and concluded that advances in medical technology has been a major factor in rising health care system costs and that health technology assessment has a key role in promoting cost effective use of new medical technologies. It also identified policy challenges for the health care system as a result of advances in medical technology.	n/a	n/a
Finding 8.2 Australia's health technology assessment (HTA) effort is fragmented along jurisdictional (national and state/territory) and sectoral (public and private) lines.	n/a	Recommendation 16
Finding 8.7 As different HTA agencies and committees examine particular types of medical technology, conducting effective HTA of combined technologies (such as new drug/device combinations and targeted therapies combining diagnosis and treatment) can pose challenges and lead to delays. With greater technology convergence expected in future, coordination difficulties and delays are likely to be magnified.	n/a	Recommendation 6e
Finding 10.3 The MSAC assessment process appears lengthy, taking 13–15 months on average to complete evaluations. This may reflect the fact that MSAC assesses the safety as well as cost effectiveness of new medical procedures and some devices, and that it may need to commission further analysis if applications do not provide sufficient information.	n/a	Recommendation 9
5. Review of the Medical Services Advisory Committee – May 2005		
Advisory Panels		
1. Include an MSAC member with relevant clinical expertise in the preliminary teleconference stage of assessments.	Implemented November 2004. Continuing without issue.	n/a
2. Develop a presentation and associated material that will provide clear, consistent direction to Advisory Panels about the roles and responsibilities of panel members, as well as the contracted evaluators and the department.	Since October 2007, Advisory Panel Guidelines are routinely updated and are provided to each Advisory Panel (AP) member at the commencement of each MSAC project.	Recommendation 9
3. Enhance and better publicise the role of Advisory Panels as follows: a. Clarify and publicise that Advisory Panel members are able to seek advice beyond the panel, provided they do not divulge the panel's discussions or conclusions; b. Investigate ways to speed up the appointment of consumer representatives to Advisory Panels; c. Chair to brief the consumer representative before the first Advisory Panel meeting; d. Revise and disseminate Advisory Panel guidelines to reflect these changes.	a) Implemented November 2005 and included in updated guidelines. Roles and responsibilities of panel members for AP were updated and placed on the MSAC internet site in April 2007. An information kit is given to all new AP members. b) Discussions have occurred with CHF with some improvement in timeliness. Other options including consumer representation from related consumer groups to the assessment (i.e. Cancer Australia, Diabetics Australia) are being considered. c) Being undertaken. d) AP Guidelines are routinely updated as required.	Recommendation 9

Recommendations	Current Status	Links to HTA Review Recommendations
MSAC Meetings		
4. Publish minutes of MSAC meetings on the committee's web site.	Public summary document published on MSAC website following each meeting. Introduced 2009.	Recommendation 5c
5. Develop an MSAC meeting cycle timetable, with earlier cut-offs for completion of review processes.	MSAC meeting cycle timetable is on the MSAC website.	n/a
6. Develop orientation package for new MSAC members.	New members routinely receive information packs on appointment, including relevant guidelines, conflict of interest declarations, and practical information about allowances. Inductions for new members are also conducted.	n/a
7. Brief members annually on committee roles and responsibilities.	Induction for new members continues without issue, and now includes sessions for existing members on contemporary issues.	n/a
8. Introduce a wider range of standard recommendations that cater particularly to decisions based on different levels of evidence, that articulate more clearly the basis on which decisions are reached.	Guidance document for the formulation of recommendations has been endorsed by MSAC.	Recommendation 2
MSAC Reports		
9. Produce a more standard template for MSAC reports, including sections that summarise expert opinion and a consumer perspective, to the extent that they might diverge from the published evidence.	Standard template being used and updated as necessary. MSAC has established a working group to review templates.	Recommendation 2
10. Record any conflicts of interest relating to Advisory Panel members and MSAC members in assessment reports.	AP's conflicts of interest routinely reported at MSAC meetings. Comprehensive conflict of interest guidelines have been developed. AP presents print-ready report to MSAC for comment and all conflicts of interest are documented through MSAC meeting minutes.	Recommendation 5e
11. Indicate in reports that an applicant has disputed elements of the report.	Applicants are provided with the draft report to comment on prior to it being signed off by the AP and referred to MSAC. Applicants' comments are noted in the referral to MSAC.	n/a
12. Publish with each assessment report a concise, 'plain English' summary of the basis for the recommendation, and distribute to interested organisations.	A one page summary (simplified and condensed version of information) is available on the website. Given the technical nature of the subject matter, DoHA believes it is not possible to further simplify the information without corrupting its usefulness and accuracy.	Recommendation 5c

Recommendations	Current Status	Links to HTA Review Recommendations
13. Include in the 'executive summary', and as a preamble to recommendations, a description of the factors that led the committee to make a particular recommendation, including its assessment of the weight of evidence and opinions underlying its decision, and any relevant contextual issues.	A template has been produced and is being used and updated as necessary for MSAC reports. This includes sections that summarise expert opinion and a consumer perspective, to the extent that they might diverge from the published evidence. Since 2009, MSAC's advice and rationale is provided in a separate Public Summary Document. This approach reinforces the separation of the report as a technical report from MSAC's role as an expert advisory committee to government.	Recommendation 9
14. Include strong qualitative elements that make clear patient and community benefits, in addition to any patient benefit measures used to estimate cost effectiveness.	New economic guidelines were endorsed at the 7 March 2008 MSAC meeting. The current guidelines will be reviewed in 2010.	Recommendation 2
15. Provide consumer-focused, 'plain English' summaries of all reports in a succinct format to all relevant colleges and consumer organisations in a format easily reproducible for their member publications.	A one page summary is published online to accompany each MSAC report. This one page summary is a simplified and condensed version of information in the report.	Recommendation 9
16. Investigate a process for monitoring the consistency of the content of reports.	Standard report and report recommendation templates have been implemented. A working group to review in 2010.	Recommendation 2
17. Where commercial-in-confidence data are involved, state clearly in the MSAC report that the assessment is based in part on the analysis of data that the applicant has asked not to be published.	This is a rare occurrence and is negotiated with the applicant on a case by case basis, where applicable.	Recommendation 2
18. Require evaluators to publish report findings in academic journals.	Although this is not a requirement of the contracts (as publication in peer-reviewed journals cannot be guaranteed), this is strongly encouraged. The evaluators are then able to report findings in academic journals after the report is placed on the MSAC website.	n/a
Communication with and Involvement of Applicants and Relevant Stakeholders		
19. Hold regular workshops for potential applicants.	The secretariat offers pre-lodgement meetings, tailored specifically to each applicant.	Recommendation 5d
20. Invite applicants to recommend which types of clinicians should be represented on the Advisory Panel considering their application.	MSAC application form has always allowed for applicants to nominate individuals to be included on Advisory Panels. Application template is being modified to make it more explicit.	n/a
21. Provide to applicants a copy of the assessment protocol for comment. Applicants' comments are considered by the Advisory Panel.	Implemented January 2005.	Recommendation 3
22. Provide to applicants a copy of the evaluators' rejoinder to the applicant's comments on draft assessment reports.	MSAC does not change the assessment report, after presentation by the AP. The applicant's comments are tabled at MSAC meetings	Recommendation 3
23. Provide to applicants a further copy of a draft assessment report if, following MSAC's consideration, the report changes significantly.	Clear parameters for any further dialogue have been developed to avoid delays.	Recommendation 3

Recommendations	Current Status	Links to HTA Review Recommendations
24. Routinely invite unsuccessful applicants to attend a 'debriefing' meeting when the Minister's decision is conveyed.	All notification letters include the offer of a debrief meeting. In the past 12 months, two applicants have taken up this offer following a negative assessment.	Recommendation 5
25. Invite stakeholders to make submissions and comment on final draft reports in respect of assessments arising from referrals from DoHA and, in respect of applications if the applicant clearly indicates that they wish it to occur.	MSAC usually adopts a 'generic' (non-proprietary) approach to assessments. Key stakeholders are advised of relevant applications, and all current assessments are placed on the MSAC website. The draft report is sent for comment to the applicant and other relevant parties where appropriate.	Recommendation 3
26. Invite peak bodies MIAA/AMA to inform organisations of referrals underway.	Implemented in 2005. The MSAC website is routinely updated with information about new applications and referrals by the use of targeted web alerts.	n/a
Communication with Stakeholders in General		
27. Hold meetings with stakeholders (e.g. AMA, MIAA) each triennium to explain the process and to receive feedback.	Stakeholders are routinely invited to meetings with MSAC.	n/a
28. Update the MSAC website more frequently and also include the following additional information: <ul style="list-style-type: none"> a. criteria outlining what constitutes acceptable levels of evidence; b. regular reports of the status of applications and review timelines and revision of timelines as necessary (include applications awaiting assessment); c. roles and responsibilities of MSAC, HealthPACT, Horizon Scanning Unit, Advisory Panels, evaluators, applicants and other groups (e.g. ASERNIPS, the NHMRC); d. an on-line newsletter; and e. links to related sites. 	<p>a) Levels of evidence used by MSAC are published on its website. MSAC's advice to the Minister on the strength of the evidence for each application is also published on the website.</p> <p>b) The MSAC website is routinely updated with information about new applications and referrals and the status of current assessments.</p> <p>c) The MSAC website provides information and links to relevant information. A separate Horizon Scanning Website is maintained for HealthPACT activity which is linked to the MSAC website.</p> <p>d) Ad hoc email bulletin notifying subscribers of published reports rather than a newsletter has been implemented.</p> <p>e) Implemented August 2006.</p>	Recommendations 1, 4, 5 and 9.
29. Provide succinct and timely information regarding MSAC, its work and the process for applications to the medical colleges in a format easily reproducible for their member publications.	Information is readily available and updated regularly on the MSAC website. Alerts about changes are emailed to subscribers.	Recommendation 4
Assessment Guidelines/Procedures		
30. Develop a standard format for assessment protocols.	A standard template for MSAC assessment protocols has been developed and is updated as necessary.	Recommendation 5
31. Develop and publicise guidelines and criteria for referring to MSAC technologies already in use.	This information is available on the MSAC website.	Recommendation 5

Recommendations	Current Status	Links to HTA Review Recommendations
<p>32. Develop guidelines to allow for rigorous but abbreviated assessments where either:</p> <ul style="list-style-type: none"> • technologies are low cost and low risk; • there is insufficient evidence on which to base an assessment; • substantial, conclusive Level 1 evidence exists; or • the committee is assessing a technology for a second time to incorporate a small body of new evidence, and the parameters of the review (comparators, indications, patient group etc.) have not changed. 	Guidelines have been developed and approved. Several applications have been assessed using an abbreviated assessment process.	Recommendations 6 and 9
33. Develop guidelines on the relationship of evidence requirements to other factors such as the nature of the procedure or technology, the size of the target group, and access to alternative treatments.	Guidelines have been developed.	Recommendation 6
34. Investigate a process of peer review for assessments.	MSAC assessment reports are made available internationally through the MSAC website, and advice about completed assessments is routinely provided to international HTA bodies.	Recommendation 2
35. Investigate how the UK National Institute of Clinical Excellence ensures that outcomes considered are relevant to patients and how it incorporates broader consumer issues into its assessments (in consultation with the Consumers Health Forum of Australia).	Research related to international practice, and the UK particularly, highlighted not only the benefits but the high demand for commitment and funding that is required. CHF has had 30 representatives on MSAC AP as well as a number of other panels within DoHA. Meetings and discussions have been held with the CHF to improve consumer participation in the MSAC process and to incorporate broader consumer issues.	Recommendation 2
Performance Measurement		
36. MSAC Executive to formally monitor the progress of each application, and report any delays to the committee.	Implemented January 2005.	Recommendation 5
37. Establish timeframes for committee and Advisory Panel processes and use as key performance indicators (KPIs).	Timeliness targets are currently on the website and MSAC timeframes are reducing. Draft KPIs were developed for stakeholder consultation in October/November 2008. The KPIs were reviewed by MSAC in June 2009 and are now awaiting the outcomes of the HTA Review. MSAC provides an annual performance report.	Recommendations 5b, 5c and 9d

Appendix C: Terms of Reference and Scope for the HTA Review

Terms of Reference

The terms of reference of the HTA Review are as follows:

1. simplification and better coordination between the Commonwealth HTA processes (as identified in the Review scope), which includes:
 - 1.1. consideration of a single entry point and tracking system for applications for market registration and funding;
 - 1.2. making time to affordable access as short as possible for new technologies while maintaining or improving the rigour of evaluation processes; and
 - 1.3. 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-dependent¹ and hybrid² technologies.

HTA Review Scope

The Commonwealth HTA processes in-scope for the HTA Review are:

- regulation of therapeutic goods for market entry, currently undertaken by the Therapeutic Goods Administration (TGA);
- approval of funding under the Medicare Benefits Scheme (MBS), currently informed by the Medical Services Advisory Committee (MSAC) and relevant implementation consultative committees;
- listing of prostheses for private health insurance coverage, as currently informed by the Prostheses and Devices Committee (PDC); and
- listing of hybrid and co-dependent technologies, as currently informed by the MSAC, Pharmaceutical Benefits Advisory Committee (PBAC) and PDC.

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 (e.g. a pathology or imaging diagnostic technology) which might more accurately identify patient subsets most likely to gain from the therapy or monitor 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).

Appendix D: HTA Review Governance

Inter Departmental Committee

Key responsibilities:

- a) provide whole-of-government input to inform the development of proposed options and outcomes to address each of the terms of reference; and
- b) provide strategic guidance on the development of policy and options papers for each of the terms of reference.

Chair: Mr David Learmonth, Deputy Secretary, Department of Health and Ageing

Representatives from:

Department of Finance and Deregulation

Department of Health and Ageing

Department of Innovation, Industry, Science and Research

Department of Prime Minister and Cabinet

Department of Veterans' Affairs

National Health and Medical Research Council

The Treasury

Medical Technology Stakeholder Reference Group

Key responsibilities:

- a. discuss issues and concerns with the existing processes for health technology assessment with the Department of Health and Ageing; and
- b. provide comment on the draft Review report for the Department's consideration in finalising a report to the Minister.

Chair: Mr David Learmonth, Deputy Secretary, Department of Health and Ageing

Representatives from:

Ausbiotech

Australian Health Insurance Association

Australian Medical Association

Australian Orthopaedic Association

Australian Private Hospitals Association

Consumers Health Forum of Australia

Department of Finance and Deregulation

Department of Innovation, Industry, Science and Research

Department of Health and Ageing

Department of Prime Minister and Cabinet

Department of Veterans' Affairs

Medical Technology Association of Australia

Medicines Australia

National Health and Medical Research Council

Royal Australasian College of Surgeons

Royal College of Pathologists of Australasia

The Royal Australasian College of Physicians

The Royal Australian and New Zealand College of Radiologists

The Treasury

Appendix E: Review of Health Technology Assessment in Australia – A Discussion Paper

Review of Health Technology Assessment in Australia A Discussion Paper

Review of Health Technology Assessment in Australia – A Discussion Paper

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1. Introduction

The Commonwealth Department of Health and Ageing (the Department) is inviting submissions from interested parties to the Review of Health Technology Assessment in Australia (HTA Review). This paper provides information on the scope and context of the HTA Review to assist in informing submissions, and provides a brief overview of Australian health technology assessment (HTA) processes to identify issues on which the Department is seeking comment. However, submissions may comment on any matters relevant to the HTA Review terms of reference, and are not limited to issues canvassed in this paper.

2. HTA Review in Context

In recent years, a number of reviews (which are listed in **Appendix A**) have highlighted the need for systemic review of current HTA processes in Australia. Specifically, the “Rethinking Regulation – Report of the Taskforce on Reducing Regulatory Burdens on Business, January 2006” (the Banks Review) recommended that:

“The Australian Government should undertake a system-wide, independent and public review of health technology assessment, with the objective of reducing fragmentation, duplication and unnecessary complexity, which can delay the introduction of beneficial new medical technologies. Health technology assessment processes and decisions should also be made more transparent, in line with good regulatory practice.”

As well, the Australian Government is committed to reducing the level of unnecessary or poorly designed regulation and contributing to improved productivity and future living standards.

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, jointly announced the Review of Health Technology Assessment in Australia¹. The HTA Review will be one of the first Better Regulation Ministerial Partnerships to be undertaken by the Australian Government. It is due to report in late 2009. The approved HTA Review terms of reference are at **Appendix B**.

The HTA Review will make recommendations about options for improving process efficiency and reducing regulatory costs 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 outcomes and value for money.

The HTA Review will canvass opportunities for deregulation reform that are consistent with the Government’s policy objectives.

The Minister for Health and Ageing has asked the Commonwealth Department of Health and Ageing (the Department) to coordinate the conduct of the HTA Review.

¹ Ministerial press releases can be found at: <http://www.health.gov.au/internet/ministers/publishing.nsf/Content/mr-yr08-nr-nr187.htm> and http://www.financeminister.gov.au/media/2008/mr_462008_joint.html

Abridged HTA Review Terms of Reference

The Department is seeking submissions from interested parties against the HTA Review terms of reference (which are detailed in full in **Appendix B**) as follows:

1. Simplification and better co-ordination between the 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-dependent² and hybrid³ technologies.

The scope of the HTA Review will include the processes of the Medical Services Advisory Committee (MSAC) and the Prostheses and Devices Committee (PDC), and the Therapeutic Goods Administration's (TGA) regulation of therapeutic goods for market entry in Australia where there is duplication of MSAC and PDC processes. The Pharmaceutical Benefits Advisory Committee (PBAC) processes will also be considered where there is an interface between medical services and devices and pharmaceuticals.

The HTA Review will have regard to the outcomes of earlier reviews at **Appendix A**.

2 Where therapy involving the use of one health technology to directly improve health (eg 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.

3 Where the characteristics of different health technologies (eg a medicine or a medical device or a biologic) are combined in one intervention (eg laser activated medicines such as photodynamic therapy, or drug eluting stents)

3. Importance of Health Technology Assessment

HTA is a multidisciplinary field of policy analysis studying the medical, economic, social and ethical implications of development, diffusion and use of health technology⁴. HTA encapsulates a range of processes and mechanisms that use scientific evidence to assess the quality, safety, efficacy/performance, effectiveness and cost effectiveness of health interventions. HTA processes are commonly applied to medical devices and medical procedures, pharmaceuticals (including vaccines) and to public health interventions, in order to inform both regulatory and public funding decisions.

The purpose of HTA is to provide policy makers and funders, health professionals and health consumers with the necessary information to understand the benefits and relative value of health technologies and interventions to inform either policy, funding or clinical decisions. The key questions that HTA typically aims to answer are:

- is the new health technology safe?
- does it improve health outcomes?
- is it cost effective?

Effective assessment of health technologies includes:

- evaluating their risks and benefits, using clinical evidence of patient safety, efficacy and clinical effectiveness⁵; and
- understanding the aetiology and prevalence of disease and knowledge of best practice treatment pathways.

Important features of effective HTA systems are:

- promoting patient access to cost effective health technologies that positively impact on health outcomes;
- minimising widespread diffusion of technologies that are ineffective or harmful;
- achieving value for money from investment in health technology in the context of limited health care resources;
- keeping pace with international best practice;
- provision of clear information on processes, rules and outcomes to businesses seeking approvals; and
- ensuring the system itself is designed to achieve these outcomes in the most timely, effective, efficient and targeted way.

Health technology is a key driver of both public and private health expenditure as new medicines, devices, procedures and tests continue to be developed. HTA processes use evidence to ensure patient safety, to inform decisions on the value of health expenditure, and to deliver better health outcomes for individuals and the whole community.

Key stakeholders interested in HTA include government decision-makers, regulators, medical and health professionals, industry and consumers.

4 International Network of Agencies for Health Technology Assessment (HTAi). www.HTAi.org

5 'Efficacy' measures how well a technology works in clinical trials or the laboratory whereas 'effectiveness' relates to how well a health intervention works in practice.

4. Health Technology Assessment in Australia

HTA is a key tool for the Australian Government to achieve its overall objective of delivering a safe, effective and efficient health care system that includes sustainable future health expenditure. Australian Government policy regarding access to, and financing of, medical procedures and devices requires demonstrated safety, effectiveness and cost effectiveness to support health funding.

The scope of the HTA Review will focus on those Commonwealth HTA processes that relate to medical services and devices. These processes are managed by a number of agencies and committees within the Commonwealth Health and Ageing portfolio. Each agency or committee has discrete functions and has evolved to respond to different needs. The HTA Review will consider the following:

- the role of the TGA – which is responsible for regulation of therapeutic goods for market entry and for post-market surveillance of therapeutic goods;
- processes leading to Government consideration of funding medical services under the MBS, currently informed by advice from MSAC and relevant implementation consultative committees;
- processes leading to Government consideration of listing of prostheses for private health insurance coverage, as currently informed by advice from the PDC and its expert groups; and
- assessment processes for hybrid and co-dependent technologies as currently informed by the PBAC, MSAC and PDC.

The HTA Review will not examine PBAC processes except where there is an interface between MSAC and PBAC. The HTA Review will not specifically examine processes for regulation or subsidy of blood or blood products or state and territory government HTA processes. A brief outline of the in-scope agencies and committees follows.

Therapeutic Goods Administration (TGA)

Under the *Therapeutic Goods Act 1989*, TGA is responsible for assessing the quality, safety, and efficacy of new therapeutic goods, including medicines and medical devices, before they are entered on the Australian Register of Therapeutic Goods (ARTG) and can be released to the Australian market. A key consideration is timely availability to the Australian community. The medical devices regulations are closely aligned with the internationally harmonised principles established by the Global Harmonisation Task Force.

The TGA regulates the overall supply of therapeutic goods through three main processes:

- pre-market review of therapeutic products at a level commensurate with risk;
- licensing or certification of pharmaceutical manufacturers and certification of medical device manufacturer quality systems; and
- post-market surveillance.

The TGA reviews scientific (including clinical) data provided by product sponsors in making its assessment. Independent statutory committees provide expert advice to TGA to assist with decision making. It has legislated processing timeframes for conformity assessment certification and agreed 'target timeframes' with industry for other processing functions to ensure timely availability of new products on the Australian market. TGA can recall products from the market where there are safety or quality issues associated with the product.

Medical Services Advisory Committee (MSAC)

MSAC advises the Minister for Health and Ageing on evidence relating to the safety, effectiveness and cost-effectiveness of new medical technologies⁶ and procedures. MSAC uses a comparative assessment approach where the safety, effectiveness and cost effectiveness of the new technology is compared against the most commonly used currently funded treatment option/s. This advice informs Australian Government decisions about public funding, most commonly via the MBS.

MSAC conducts an evidence-based assessment from the ground up. This involves commissioning a full HTA including a systematic literature review and modelled economic evaluation conducted by an external evaluator. This is in contrast to the TGA, PDC or PBAC, which all predominantly review evidence provided by the applicant. As well, there are no fees associated with an MSAC application. However, the cost (to the Australian Government) of performing an MSAC assessment is approximately \$250,000.

Prostheses and Devices Committee (PDC)

Under the Private Health Insurance Act 2007, private health insurers are required to pay benefits for a range of prostheses that are provided as part of an episode of hospital or hospital substitute treatment for which a patient has cover and for which a Medicare benefit is payable for the associated professional service. Prostheses include cardiac pacemakers and defibrillators, cardiac stents, hip and knee replacements and intraocular lenses, as well as human tissues such as human heart valves, corneas, bones (part and whole) and muscle tissue.

PDC provides advice to the Minister for Health and Ageing about the prostheses that should be included on the Prostheses List and the appropriate benefits. PDC commissions its own HTA process – via its standing Clinical Advisory Groups – to assess the comparative safety, clinical effectiveness and relative clinical effectiveness of prostheses. It also conducts benefit negotiations through the Prostheses and Devices Negotiating Group (PDNG).

Pharmaceutical Benefits Advisory Committee (PBAC)

PBAC is an independent statutory body established in 1954 under section 101 of the *National Health Act 1953*. PBAC assesses the comparative clinical effectiveness and cost effectiveness of all new medicines as part of the basis for whether to recommend that they be listed on the Pharmaceutical Benefits Scheme (PBS) and thus subsidised by the Australian Government.

In the PBAC assessment model the burden of proof lies with the applicant with the Committee making recommendations based on a critique of the evidence that the applicant has provided.

6 Whereas TGA assesses a medical device to determine safety and performance (does it do what is supposed to do), MSAC assess the safety, effectiveness and cost effectiveness of the medical service when using the device.

5. HTA Challenges – Exploring the HTA Review Terms of Reference

The current HTA framework and the individual processes and interactions between the agencies and committees involved are complex as shown in **Appendix C**. Reviews commenting on HTA in Australia in recent years have identified a range of issues and challenges arising from this framework.

This section provides an overview of current issues in HTA in Australia as they relate to each term of reference including questions to be explored as part of the HTA Review. It is provided to assist those seeking to make a submission to the HTA Review. This paper is intended as a guide only to stimulate discussion and does not seek to give a detailed analysis of current HTA processes or to limit or be prescriptive about possible solutions to identified issues.

The HTA Review is required to 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 safe, effective and cost effective medical services and devices, and the delivery of improved health outcomes and value for money.

In making its recommendations, the HTA Review will need to put forward options that can be sustained within existing funding levels and that are consistent with Government policy objectives, including:

- a. be consistent with the Australian Government policy of regulating the safety, quality and efficacy of therapeutic products;
- b. be consistent with Australian Government policy regarding access to, and financing of, medical procedures and therapeutic products, in particular the requirement for demonstrated safety, effectiveness and cost effectiveness to support public and private funding;
- c. interpret the term 'public funding' to mean direct and indirect funding of health technologies by the Australian Government whether that funding fully or partially covers the cost of the health technology; and
- d. ensure that regulatory processes are effective and efficient by minimising the costs of achieving the desired outcomes, but are also proportionate and targeted – using appropriate risk management frameworks to align the regulatory process with the scale of the regulatory problem and ensuring that regulations impact only on those intended.

The HTA Review will need to balance the competing demands of the different stakeholders (government, industry, health professionals and consumers) who have a vested interest in HTA in Australia and the policy drivers that push for a robust HTA system to inform health financing decisions. This challenge is not unique to Australia, as the international HTA community is also striving to grapple with many of these issues. International activities and initiatives may provide useful insight.

Term of Reference No 1

Simplification and better co-ordination between all Commonwealth health technology assessments, including:

- a. consideration of a single entry point and tracking system for applications for market registration and funding and coverage purposes;
- b. making time to affordable access as short as possible for new technologies while maintaining rigour of evaluation process; and
- c. examination of the feasibility of conducting concurrent assessments for market registration and funding and coverage purposes, noting current work in this area.

There are a number of agencies involved in HTA in Australia. Most sponsors of new medical procedures or devices need to navigate two (TGA and MSAC **or** PDC) and in a small number of cases, three separate HTA processes (TGA, MSAC **and** PDC). That is:

- medical device sponsors must submit an application to the TGA for inclusion of a new device on the ARTG. Once included on the ARTG the device can be supplied to the market. Access to devices not included on the ARTG is available through special access provisions;
- if the device is associated with a new medical procedure for which MBS funding is sought, then an application for assessment of a new medical service is made to MSAC;
- all new products need to be assessed by the PDC before being considered for listing on the Prostheses List and attracting health insurer benefits.

Currently these processes are sequential as the Australian health system links product or device approval for market use to decisions about health funding. Earlier reviews and industry have been critical of these sequential timeframes, and in particular the impact on industry in being able to achieve a return on investment and the potential for device obsolescence due to the speed of technological development.

Often there is tension between adequate, rigorous assessment and evaluation and the time to market for new technologies, particularly for linked technologies (for example, medicine/device or medicine/test combinations). An underlying issue that impacts on the evaluation processes for assessing new health technology applications for medical procedures and devices is the evidence base available, which is often not as well developed as for pharmaceuticals.

To address this issue, MSAC for example, may advise interim funding for applications where results are promising but there is insufficient evidence to support ongoing MBS funding. Where interim funding is approved by Government, applicants are generally expected to provide evidence at a later date to inform a review of the service, but there is often difficulty in collecting the evidence necessary to ultimately enable conclusive advice to Government.

The lack of high quality evidence for new medical procedures and associated devices is a shared problem that affects the medical industry, health professionals, consumers and governments. The HTA Review provides an opportunity to address such issues, for example through links to post-market or post-implementation surveillance.

HTA is well established in the majority of developed health care systems. In a global health care market many new technologies emerge at the same time around the world so that international HTA agencies can be assessing the same health technology at the same time, using the same published evidence base. Generally speaking, HTA agencies across the international community have been reluctant to rely on HTA undertaken in other countries, and Australia is no exception. While informed by international reviews, most current Australian HTA agencies routinely conduct their own full assessment of new technologies. In certain circumstances, the TGA may conduct a full assessment (however, this is the exception rather than the rule).

The key issues to consider in the HTA Review in developing options for simplification and coordination of Commonwealth HTA process include:

- the feasibility of and options for:
 - a. overlapping HTA processing including any likely costs and benefits;
 - b. single application process to cover the HTA processes undertaken by TGA, MSAC and PDC (and to the extent of their involvement in HTA processes for medical services and devices, PBAC);
 - c. most efficient mechanisms for ensuring that HTA are relevant to Australian clinical practice and informed by expert clinicians;
- the identification of practical strategies for stakeholders to work collaboratively to enhance the evidence base for new medical services and devices and items approved for interim funding for example, better use of existing data sources or joint stakeholder funded data collection exercises;
- the development of mechanisms to enable monitoring of medical procedures for take-up, efficacy and effectiveness; and
- the potential to leverage international HTA resources to inform Australian HTA practices and assessments of the evidence based for safety, effectiveness and cost effectiveness.

Key Questions

1. How can the interaction between the different HTA agencies (ie TGA, MSAC and PDC) and their processes for the registration and approval for market entry and public and private health funding of new medical services and devices be improved?
2. How could the administrative processes of each individual HTA agency (ie TGA, MSAC and PDC) be simplified without compromising the scientific rigour underpinning the HTA process?
3. How can HTA undertaken by other countries be used in the Australian context? What are the limitations, risks and opportunities that would need to be considered?
4. How can assessment of cost effectiveness be improved to ensure HTA can inform government decisions in a timely manner?
5. Are there regulatory impediments to enhancing the evidence base for items approved for interim funding, either through collaboration or individually?

Term of Reference No 2

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

Different reviews and the medical devices industry have raised issues about perceived duplication between Australia's discrete HTA processes for drugs, medical services and devices, and the need for better communication and streamlining of these current systems. There is perceived duplication of and overlap in the assessment of applications for market entry and reimbursement/subsidy of therapeutic goods between national HTA bodies (including TGA, MSAC and PDC) and state and territory agencies, with specific concerns about the timeliness, efficiency and transparency of these HTA processes.

For example, once a medical device has been included in the ARTG by TGA it must then undergo a separate assessment to be considered for approval for funding under the MBS and in most instances, one separate assessment to be approved for reimbursement by private health insurers. Where a device does not have an appropriate MBS item and an application is made for the Prostheses List, a MSAC assessment will need to be conducted before the application for the Prostheses List can proceed.

Inclusion in the ARTG is a prerequisite for assessment by PDC and MSAC where there is an associated device. For a medical service involving the use of a new device to be funded, both need to be assessed by two expert advisory committees, with MSAC advising Government on MBS funding for the medical service and PDC advising on private health insurance rebates for the medical device. While each assessment considers safety and effectiveness, their approach and focus to these considerations are different due to different roles. For example, the TGA is concerned with ensuring only safe and effective products are supplied in Australia, MSAC is concerned with ensuring medical services funded under the MBS are safe and effective (including where this involves a device) and the PDC is concerned with effective medical devices being reimbursed by private health insurers (refer to [Section 4](#) of this paper).

A similar situation arises where medical tests and pharmaceuticals are linked for example, the use of diagnostic testing to refine patient selection and eligibility for high cost procedures, devices and particularly drugs, which consequently involves the processes of PBAC. Subsidy/reimbursement processes for assessing co-dependent and hybrid technologies, where it involves more than one HTA body can result in coordination difficulties, confusion and delays in assessing a new technology. This is particularly the case where there is ambiguity or where there are strong linkages between technologies.

Notwithstanding the different approaches to HTA criteria undertaken by each HTA agency or committee, a more detailed and thorough analysis of current HTA processes would be useful to determine if there are areas of duplication and, if so, to provide opportunities for streamlining of processes. Potential opportunities to address duplication and enhance integration and efficiencies in HTA processes could include:

- standardisation of information requirements;
- consolidation of application information;
- alignment of assessment processes;
- alignment of appeals mechanisms across all HTA processes to provide greater consistency and clarity to applicants (noting that MSAC does not have an appeals mechanism);
- clarification of how HTA agencies or committees can work cooperatively and collaboratively to assess combined technologies (eg medical services/devices and drugs/medical devices); and
- the sharing of HTA expertise and experience across all aspects of the Australian HTA system.

Key Questions

1. What HTA roles and functions require clarification?
2. Does duplication and/or overlap of HTA processes occur? If so, where? How could this be resolved?

Term of Reference No 3

Enhancing post marketing surveillance mechanisms to ensure the ongoing safety and efficacy of medical devices.

There are three main components of post-market surveillance activities of medical devices in Australia:

- the manufacturer's post-market surveillance system;
- post-market monitoring of market compliance by the TGA; and
- vigilance programs.

Post market surveillance of medical device performance for clinical safety, efficacy and effectiveness is important because it can provide valuable new evidence on both the risks and benefits of a device to inform policy, funding, clinical and consumer decisions, especially where pre market evidence is limited.

While recognised as an important element of any HTA program, only the TGA has a formalised and systematic process for monitoring and reviewing new technologies once they are introduced into the health care system. This system predominantly relies on manufacturer obligations and sponsor requirements to report problems as a condition of the product being included in the ARTG. However, the TGA does undertake proactive market surveillance. While there are competing interests in managing post market surveillance, all stakeholders (for example, the medical profession, device manufacturers, regulators and quality committees) could play a role.

The key issues to consider in the HTA Review in developing options for improving post market surveillance mechanisms for medical devices include the feasibility and the options for using post market surveillance data to:

- allow monitoring of medical devices in relation to patient safety and health outcomes;
- inform future decisions to continue funding medical services (which are reliant on a medical device) where MSAC recommended interim funding to enable data collection and further evaluation; and
- monitor and review all, or selected, new devices once they are introduced into the health care system to inform for example, utilisation rates for medical devices or improvements in health outcomes, which in turn informs future policy and funding decisions.

It is also important to consider who should be responsible for undertaking and managing a post market surveillance system, who would own the data collected, the costs and benefits involved and critically, how such a system might be funded.

Key Questions

1. What changes, if any, are needed to current HTA arrangements for post market surveillance of health technologies?
2. How could the arrangements for post market surveillance of medical devices for ongoing safety and clinical effectiveness be improved?
3. What additional arrangements for post market surveillance could be considered or implemented?
4. How should post market surveillance be managed?

Term of Reference No 4

Strengthening transparency and procedural fairness in the assessment, decision making and fee negotiation processes through improved communication with stakeholders about processes, methodologies, outcomes and performance against key indicators.

Each HTA body has its own processes and procedures, which may be based on legislative or other administrative requirements, for managing its assessments, communicating with applicants, formulating advice, negotiating fees, and managing appeals mechanisms.

The HTA Review provides an opportunity to review these processes and procedures and make recommendations about improvements required, which may also need to take account of other recommendations within the context of the HTA Review.

Key Questions

1. What aspects of Australia's HTA system are working well in relation to transparency and procedural fairness? Provide specific examples.
2. What could be improved to assist transparency and procedural fairness? Provide specific examples.
3. What key performance indicators could be developed and reported on to improve transparency for HTA processes?

Term of Reference No 5

Enhanced arrangements for assessment of co-dependent⁷ and hybrid⁸ technologies.

As technology advances, and diagnostic and treatment complexity increases, the development of co-dependent and hybrid technologies will present complex challenges for HTA systems in Australia, particularly MSAC and PBAC. The use of diagnostic testing, including genetic testing, to refine patient selection and eligibility for high cost procedures, devices and particularly drugs is likely to continue to develop rapidly in the future.

Currently, assessments of diagnostic test/pharmaceutical combinations and drug/device combinations are undertaken separately through either MSAC or PBAC, following relevant regulatory approval by the TGA. PBAC and MSAC both undertake assessment of the clinical effectiveness and cost-effectiveness of the particular drug or medical technology.

A key difference between the two bodies is the process for submitting the evidence. In the PBAC assessment model, the burden of proof lies with the applicant with PBAC making recommendations based on a critique of the evidence that the applicant has provided. In contrast, MSAC conducts an evidence-based assessment from the ground up which involves commissioning a full HTA, including a systematic literature review and modelled economic evaluation conducted by an external evaluator.

7 Where therapy involving the use of one health technology to directly improve health (eg a medicine or a medical device or a procedure) is improved by the use of another health technology (eg a pathology or imaging diagnostic technology) which might more accurately identify patient subsets

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

The key issues to consider in improving future assessments of co-dependent and hybrid technologies include:

- appropriate methodology for assessment of effectiveness and cost-effectiveness of both components to support Government decision-making regarding funding;
- assessment of co-dependent technologies that takes into account the evidence on accuracy of the diagnostic and health outcomes of treatment predicted by the test;
- assessment processes that are coordinated and reduce unnecessary duplication of efforts and resource use and allow timely decision-making;
- capacity and skill development to assess co-dependent and hybrid technologies in the face of increasing technological developments;
- links to research to develop an adequate evidence base for both technologies;
- input required from industry and the impact that this could have;
- consideration of legislative requirements; and
- timely patient access to approved and evidence based technologies and procedures.

The HTA Review provides an opportunity to consider a more strategic approach to assessment of co-dependent and hybrid technologies.

Key Questions

1. What are the key issues for government, regulators, medical and health professionals, industry and consumers in relation to the assessment of co-dependent and hybrid technologies?
2. What enhancements to current arrangements for assessment of co-dependent and hybrid technologies could be introduced?
3. What are the implications for assessment of clinical effectiveness and cost-effectiveness for hybrid and co-dependent technologies in relation to decision making about funding?

6. Participating in the Review

Effective public consultation is important in ensuring a comprehensive and informed report to the Ministers on the findings of the HTA Review. Interested parties may participate in the HTA Review through the following processes:

- a. **a public submissions process** – the Department is calling for submissions against the HTA Review terms of reference through the Department's website (<http://www.health.gov.au/htareview>);
- b. **focus groups** with stakeholders in major capital cities to provide an opportunity for discussion and clarification of issues to be considered during the Review – notification of venues and dates will be on the HTA Review website at a later date; and
- c. key stakeholders have been invited to participate on a **stakeholder reference group**.

Where required, the Department will hold bilateral discussions with key stakeholders.

How to make a submission

There is no specified format for submissions. However, submissions should provide commentary on one, some or all of the terms of reference. General comments are welcome, but these should be clearly identified as such and provided in a separate part of your submission. Where possible, supporting data and documentation should be provided. This is a public review and the Department seeks to have as much information as possible on the public record.

It is preferred if submissions are sent electronically to htareview@health.gov.au by email as a text document (.txt), a Microsoft Word document (.doc) or similar text format, rather than Adobe Portable Document Format (.pdf), to ensure accessibility by screen readers.

Alternatively, submissions may also be sent by mail as either a hard copy or CD to:

Attn: HTA Review
Department of Health and Ageing
MDP 106
GPO Box 9848
Canberra ACT 2601

The Department will consider all submissions to the HTA Review. The HTA Taskforce will acknowledge receipt of all submissions.

Closing date for submissions: 22 May 2009

Further information

Email contact: htareview@health.gov.au

Review website: <http://www.health.gov.au/htareview>

Confidentiality

It is planned that all submissions will be published on the HTA Review website. If you wish any information contained in your submission to be treated as confidential, please clearly identify that information. Confidential information will not be published.

Recent Reviews – Reform of HTA in Australia

In recent years, a number of reviews have highlighted the need for systemic review of current HTA processes. These reviews and any consequent outcomes will be considered during the HTA Review. They include:

1. *Impacts of Advances in Medical Technology in Australia August 2005* (Productivity Commission)
2. *Rethinking Regulation – Report of the Taskforce on Reducing Regulatory Burdens on Business January 2006* (the Banks Review)
3. Medical Devices Industry Action Agenda (2004 – 2008)
4. *Annual Review of Regulatory Burdens on Business: Manufacturing and Distributive Trades September 2008* (Productivity Commission)
5. *Report of the Review of the Medical Services Advisory Committee May 2005* (MSAC Review)
6. *Report of the Review of the Prostheses Listing Arrangements October 2007* (Doyle Review).

Commonwealth Health Technology Assessment Review – Terms of Reference

The Commonwealth Health Technology Assessment (HTA) Review will be conducted as a Health Technology Assessment Better Regulation Ministerial Partnership by the Minister for Health and Ageing, the Hon Nicola Roxon MP, and the Minister for Finance and Deregulation, the Hon Lindsay Tanner MP.

The HTA Review will 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 HTA Review is to canvas opportunities for reform within existing funding levels and consistent with the Government's policy objectives.

The HTA Review terms of reference are to provide advice to the Minister for Health and Ageing (in consultation with the Minister for Finance and Deregulation). The HTA Review is to report on the following matters:

1. Simplification and better co-ordination between the 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-dependent⁹ and hybrid technologies¹⁰.

Review Scope

The Commonwealth HTA processes in-scope for the HTA Review are:

- regulation of therapeutic goods for market entry, currently undertaken by the Therapeutic Goods Administration (TGA);
- approval of funding under the Medicare Benefits Scheme (MBS), currently informed by the Medical Services Advisory Committee (MSAC) and relevant implementation consultative committees;
- listing of prostheses for private health insurance coverage, as currently informed by the Prostheses and Devices Committee (PDC); and
- listing of hybrid and co-dependent technologies as currently informed by the MSAC, Pharmaceutical Benefits Advisory Committee (PBAC) and PDC.

⁹ Where therapy involving the use of one health technology to directly improve health (eg a medicine or a medical device or a procedure) is improved by the use of another health technology (eg a pathology or imaging diagnostic technology) which might more accurately identify patient subsets most likely to gain from the therapy or monitors therapy response.

¹⁰ Where the characteristics of different health technologies (eg a medicine or a medical device or a biologic) are combined in one intervention (eg laser activated medicines such as photodynamic therapy, or drug eluting stents)

Out of scope

While internal PBAC processes are not specifically in scope, the interface between MSAC and PBAC will be addressed as part of the Review. The Review will not specifically examine processes for regulation or subsidy of blood or blood products.

Review Process

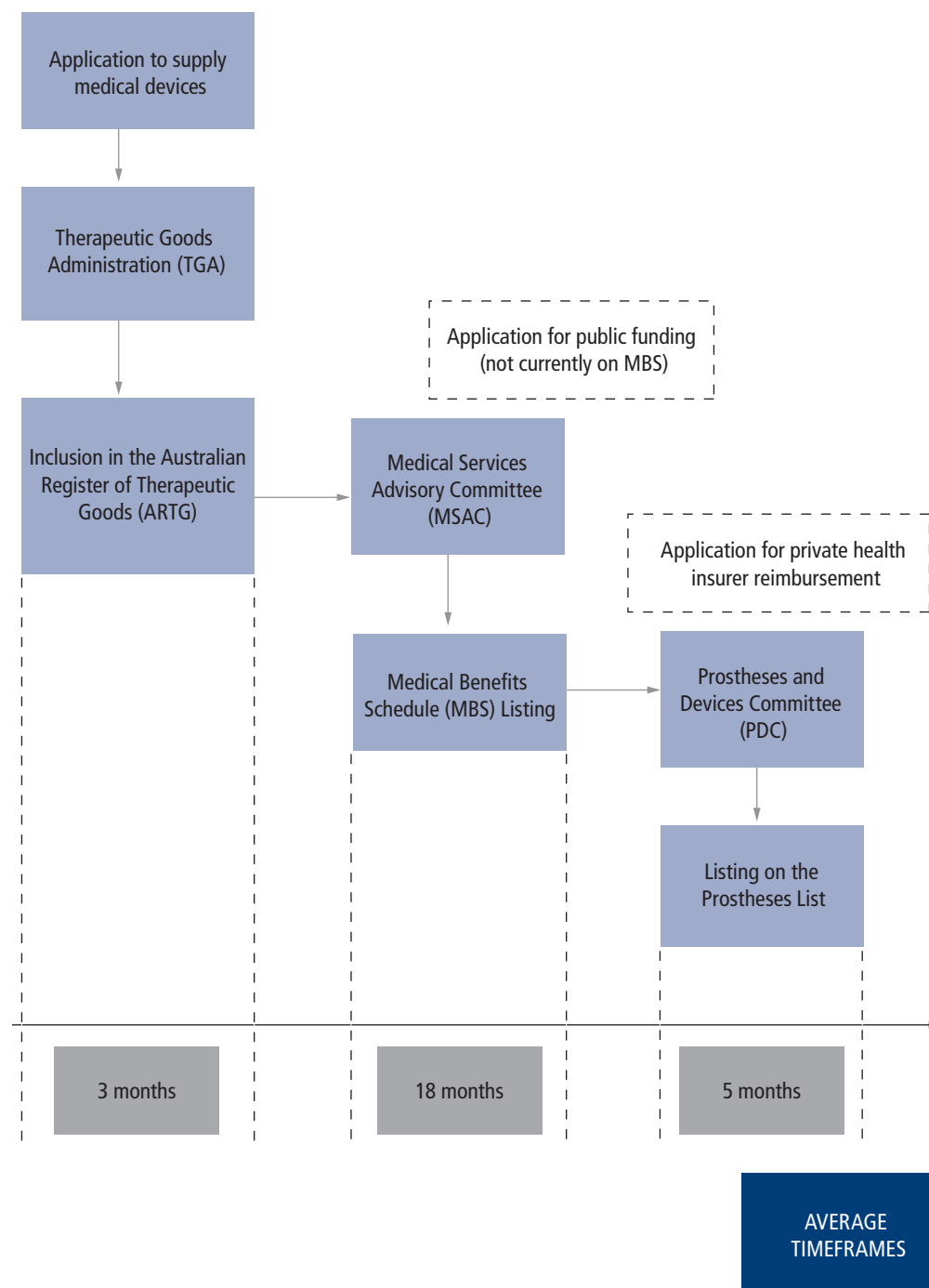
The HTA Review will be conducted by the Department of Health and Ageing, informed by a stakeholder reference group and public submissions process. The HTA Review will result in a report to the Minister for Health and Ageing and the Minister for Finance and Deregulation. The report will identify process improvements and broader HTA policy reforms in line with the Review terms of reference. The report is expected to be delivered in late 2009.

Stakeholder consultation

A call for submissions against the HTA Review terms of reference will be advertised on the Department's website.

The Department will also write to key stakeholders formally advising them of the HTA Review and inviting them to make a submission.

Current HTA Processes in Australia



Appendix F: Submissions to the HTA Review

The individuals and organisations that provided submissions to the HTA Review are listed below. Some submissions or parts thereof were provided on a confidential basis. The HTA Review has sought permission from all individuals and organisations to publish their submission. The HTA Review also received correspondence and materials relating to its work. The HTA Review thanks all correspondents.

Adelaide Health Technology Assessment
Advanced Biomedical Pty Ltd
Allergan Australia Pty Ltd
Australian Safety and Efficacy Register of New Interventional Procedures -Surgical
AusBiotech Ltd
Australasian Podiatry Council
Australasian Society for HIV Medicine
Australasian Tissue and Biotherapeutics Forum
Australian and New Zealand Association of Physicians in Nuclear Medicine
Australian and New Zealand Hyperbaric Medicine Group
Australian Association of Private Radiation Oncology Practices
Australian Commission on Safety and Quality in Health Care
Australian Federation of AIDS Organisations Inc
Australian Health Insurance Association
Australian Healthcare and Hospital Association
Australian Medical Association
Australian National Musculoskeletal Research Institute
Australian Orthopaedic Association
Australian Physiotherapy Association
Australian Private Hospitals Association
Australian Unity
Back Up
Barwon Biomedical Research
Baxter Healthcare
Bermaci Health Care
Bio21 Cluster
Blamey, Dr Stephen
Boston Scientific Australia New Zealand

Bupa Australia Group
Cancer Voices NSW Inc
Catholic Health Australia
Cell and Tissue Therapies WA
Centre for Health Economics Research and Evaluation
Colorectal Surgical Society of Australia and New Zealand
Consumers' Health Forum of Australia
Cook Australia
Department of Health and Human Services, Tasmania
Department of Health, Western Australia
Department of Innovation, Industry, Science and Research
Device Technologies Australia Pty Ltd
Electrophysiology and Pacing Council of the Cardiac Society of Australia and New Zealand
Fisher, Mr Frank
Garvan Institute of Medical Research
Generic Medicines Industry Association Pty Ltd
Genzyme Australasia Pty Ltd
Glaxo SmithKline Australia Pty Ltd
Health Technology Analysts Pty Ltd
Healthscope Limited
IMS Health Australia Pty Ltd
Johnson & Johnson
Medibank Private Limited
Medical Device Evaluation Committee
Medical Intelligence
Medical Services Advisory Committee
Medical Technology Association of Australia
Medicines Australia
Medtronic Australasia Pty Ltd
Meniere's Australia
N Stenning & Co. Pty Ltd
National Association of People living with HIV/AIDS
National Coalition of Public Pathology

National Health and Medical Research Council
National Hepatitis B Alliance
NHMRC Clinical Trials Centre
NSW Health
Orthotech Holdings Pty Ltd
Parkinson's Australia
Perth Bone and Tissue Bank Inc.
Pfizer Australia
Pharmaceutical Benefits Advisory Committee
Pharmaceutical Society of Australia
Prostheses and Devices Committee
Queensland Health
Reynolds, Mr M
School of Medicine, Griffith University
South Australian Department of Health
Spine Society of Australia
St Jude Medical Australia Pty Ltd
Standards Australia
Stephen (surname withheld at author's request)
The Royal Australian and New Zealand College of Ophthalmologists
The Royal Australian and New Zealand College of Radiologists
The Royal College of Pathologists of Australasia
Therapeutic Goods Administration

Appendix G: Analysis of Current Commonwealth HTA Processes

The matrix was prepared during the issues development stage of the Review of Health Technology Assessment in Australia (HTA Review) for the Medical Technology Stakeholders Reference Group's consideration. The matrix provides an overview of how Commonwealth HTA is currently managed by the Department of Health and Ageing with a focus on comparing how each of the HTA functions are executed, and comments received during the HTA Review and previous reviews.

The first page of the matrix provides a summary of key elements of Commonwealth HTA. These elements have been grouped into:

- *HTA Framework* – Provides a high level description of the legislative, policy and program arrangements for each HTA function. It includes the role of the expert committee in the decision making process, and the Departmental resources assigned to run the function.
- *Implementation of HTA Functions* – Provides a high level description of how the HTA functions are implemented. This includes how each of the responsible areas communicate with stakeholders and manage their applications.

Subsequent pages of the matrix provide greater detail of the elements (with the groups as above) and include:

- A description of how each element is implemented by the responsible areas
- Current reform activities for the element (if any)¹
- Issues raised in previous reviews and as identified through internal analysis
- Issues raised in the submissions to the HTA Review
- Implications for option development

¹ PBAC is within scope for the HTA Review to the extent that there is an interface with MSAC around co-dependent and hybrid technologies. It has been included in the matrix for comparative purposes because it performs one of the HTA functions undertaken by the Department and also provides a framework which may be a model for reform of the other HTA functions.

Commonwealth Health Technology Assessment (HTA) in Australia

	Market entry	Public funding/subsidy Medical Benefits Schedule (MBS)	Private health insurance funding Prostheses List (PL)	Public funding/subsidy Pharmaceutical Benefits Scheme (PBS) National Immunisation Program (NIP)
HTA Framework – summary				
HTA Function	Regulation of market entry of therapeutic products	Determination of public subsidy of medical services with or without a medical device	Determination of private health insurance reimbursement of surgically implantable medical devices	Determination of public subsidy of pharmaceutical products and vaccines
Framework for HTA processes	Legislation Therapeutic Goods Act 1989 and subordinate regulations	Guidelines Funding for new medical technologies and procedures: application and assessment guidelines	Guidelines Prostheses List – Guide to listing and setting benefits for prostheses	Legislation National Health Act 1953 and subordinate regulations
Establishment of HTA processes	Parliament – legislative framework TGA Officer – include products in ARTG	Minister – creation of expert committee and inclusion of items on MBS	Minister – creation of expert committee Delegate – inclusion of products in PL	Parliament – legislative framework Delegate – inclusion of products in PBS/NIP
HTA Criteria	Safety, quality, efficacy (perform as intended by the manufacturer)	Safety, comparative clinical effectiveness, comparative cost effectiveness	Comparative clinical effectiveness and cost relative to clinical effectiveness	Comparative clinical effectiveness, comparative cost effectiveness
HTA Program Guidelines	Guidelines – plain English explanation of market entry processes defined in legislation.	Guidelines – arrangements for assessment of medical services for public subsidy. None for implementation of MSAC advice.	Guidelines – processes for private health insurance reimbursement.	Guidelines – plain English explanation of public subsidy processes for pharmaceuticals and vaccines defined in legislation
Departmental Administration of HTA	TGA (medical devices program) Staff with administrative and technical skills process ~2000 applications/annum. Program operates on full cost recovery from the regulated industry	MBD Staff with administrative, secretariat and policy skills process ~16 MSAC applications/annum. Departmental funding	ACD Staff with administrative, secretariat and policy skills process ~1000 applications/annum. Program operates on full cost recovery from the prostheses sponsors	PBD Staff with administrative, secretariat and policy skills process ~250 applications/annum. Administered funding, but full cost recovery to be implemented soon.
HTA Expert Committee	MDEC – advises the Minister and TGA on safety, quality and performance of medical devices supplied in Australia	MSAC – advises the Minister on evidence relating to the safety, effectiveness and cost-effectiveness of new medical technologies and procedures.	PDC – makes recommendations to the Minister on appropriate listing and benefits of prostheses.	PBAC – provides expert advice to the Minister on listing of products on the PBS & NIP.

	Market entry	Public funding/subsidy Medical Benefits Schedule (MBS)	Private health insurance funding Prostheses List (PL)	Public funding/subsidy Pharmaceutical Benefits Scheme (PBS) National Immunisation Program (NIP)
HTA Decision-maker	Secretary with delegation to TGA	Minister for Health and Ageing	Minister with delegation to ACD	Minister with delegation to PBD
Public Communication	Primarily through a website which does not inform how it fits into broader DoHA HTA responsibility.	Primarily through a website which does not inform how it fits into broader DoHA HTA responsibility.	Primarily through a website which does not inform how it fits into broader DoHA HTA responsibility.	Primarily through a website which does not inform how it fits into broader DoHA HTA responsibility.
HTA Information Management system	Full electronic application and tracking system (Notes based system)	Uses Access database to manage applications No electronic tracking	Uses Access database to manage applications No electronic tracking	Uses Delphi database to manage applications No electronic tracking
Frequency of applications/inclusion in Schedule/List/Register	Applications – daily Inclusion in ARTG – daily	Applications – daily Update to MBS – every six months	Applications – every six months Update to Prostheses List – every six months	Applications – daily Update to PBS – monthly
HTA process – Application phase	Multiple assessment pathways based on existing overseas approvals and/or materials of device	Single assessment pathway that includes full evaluation	Three assessment pathways – new applications, applications to amend or duplicate and applications to expand, compress or transfer.	Two assessment pathways – major and minor applications
HTA process – Assessment phase	Assessment undertaken by internal staff Evidence for assessment supplied by applicant	Assessment undertaken by external experts Evidence collected during assessment phase	Assessment undertaken by external experts Evidence for assessment supplied by applicant	Assessment undertaken largely by internal staff Evidence for assessment supplied by applicant
HTA process – Benefit/fee negotiation phase	NO	Undertaken by separate committee to MSAC	Undertaken by PDC and PDNG	Undertaken by Department with PBPA advice
HTA process – Approval for listing phase	TGA Officers decides if a product should be included in the ARTG	Minister approves listing on MBS	Delegate creates Rules to give effect to the Prostheses List	Delegate creates legislative instruments to give effect to the PBS/NIP.
HTA process – Post market surveillance	YES	NO	NO	YES

HTA Framework

HTA Function	Market entry	Public funding/subsidy Medical Benefits Schedule (MBS)	Private health insurance funding Prostheses List (PL)	Public funding/subsidy Pharmaceutical Benefits Scheme (PBS) National Immunisation Program (NIP)
Overview	<p>The purpose of the HTA function is for regulation of market entry of new therapeutic products (including, pharmaceuticals, devices and diagnostic tests) to ensure that they are safe, perform as intended and are produced using appropriate quality controls for supply in Australia.</p> <p>This is a regulatory mechanism and involves a range of assessment and monitoring activities with the aim of ensuring that the Australian community has access, within a reasonable time, to therapeutic advances.</p> <p>TG Act amended in 2002 to introduce new, internationally harmonised regulatory framework for medical devices based on the principles of the Global Harmonisation Task Force GHTF.</p>	<p>The purpose of the HTA function is to inform Australian Government decisions about whether new medical services + / – a device should receive public funding (such as a Medicare benefit).</p> <p>New health technologies and medical services for which funding is sought under the MBS are assessed for safety, effectiveness and cost-effectiveness against an MBS funded comparator, while taking into account other issues such as access and equity.</p> <p>MSAC established 1998.</p>	<p>The purpose of the HTA function is to determine which medical devices should be included on the Prostheses List, compelling private health insurers to pay a benefit for the prosthesis.</p> <p>Medical devices are assessed for clinical effectiveness, comparative clinical effectiveness and cost relative to clinical effectiveness.</p> <p>Prostheses arrangements revised in 2005 to implement evidence-based assessment and centralised benefit negotiation.</p> <p>100% cost recovery introduced on 1 April 2007.</p>	<p>The purpose of the HTA function is to inform Australian Government decisions about whether a drug should receive a pharmaceutical benefit.</p> <p>The key role is to assess the cost effectiveness of these medicinal products compared to alternative therapies.</p> <p>Established 1954.</p>
Current reform activities	Nil	Nil	Nil	Cost recovery will be introduced in the near future.
Issues – Department Analysis	Nil	<p>While MSAC has a broad remit to act as a gatekeeper to the MBS through its TOR, it currently only assesses medical services involving a new procedure, device or diagnostic test.</p>	<p>Stakeholders support this HTA function:</p> <ul style="list-style-type: none"> • sponsors – provides certainty of reimbursement • PHI – caps financial risk • hospitals – insulation from price movements • clinicians – secondary product safety 	

HTA Function	Market entry	Public funding/subsidy Medical Benefits Schedule (MBS)	Private health insurance funding Prostheses List (PL)	Public funding/subsidy Pharmaceutical Benefits Scheme (PBS) National Immunisation Program (NIP)
Issues – Submissions	<ul style="list-style-type: none"> Support TGA's existing regulatory function and object to duplication of TGA safety assessments. Critical of functional transparency, including roles, responsibilities and interrelationships of DoHA HTA functions. Concerned that regulatory aspects are too strict eg. regarding international CE marked goods. Claim that HTA processes are "siloed" and confusing. 	<ul style="list-style-type: none"> Critical of functional transparency, including roles, responsibilities and interrelationships of DoHA HTA functions and especially timeliness. Some express caution about consolidation of the regulatory, HTA and reimbursement function. Many claim that MSAC should become a reimbursement body only and a separate HTA body do HTA assessment. 	<ul style="list-style-type: none"> Critical of functional transparency, including roles, responsibilities and interrelationships of DoHA HTA functions. Critical of duplication of the TGA's safety assessments. Claim that HTA processes are "siloed" and confusing. 	<ul style="list-style-type: none"> Some claim that there should be one agency that does regulation and reimbursement while others express caution about consolidation of the regulatory, HTA and reimbursement function. Support for reform activities of the Access to Medicines Working Group
Implications for option development	The Department is responsible to Government for the legislation, policy and program administration for the HTA functions of market entry, public funding (including MBS and PBS reimbursement) and private health insurance reimbursement. This should facilitate communication and management of a "seamless" process.			

Framework for HTA Processes	Market entry	Public funding/subsidy Medical Benefits Schedule (MBS)	Private health insurance funding Prostheses List (PL)	Public funding/subsidy Pharmaceutical Benefits Scheme (PBS) National Immunisation Program (NIP)
Overview	<p><i>Therapeutic Goods Act 1989</i> and associated Regulations</p> <ul style="list-style-type: none"> • Defines medical device, manufacturer, compliance with the essential principles etc • Outlines application requirements • Specifies conformity assessment procedures • Provides for medical device classifications • Outlines the application process to apply for a CA certificate and other administrative requirements • Provides for inclusion of medical devices in the ARTG, and suspension and cancellation of the inclusion • Provides for the exemption of some devices from inclusion on the ARTG (but not exemption from application of the relevant conformity assessment procedure) • Provides for the Secretary to seek information from various parties and outlines penalties for false or misleading information • Provides for the Secretary to recover devices that do not comply with requirements or cannot be lawfully supplied. 	HTA processes not established through legislation	HTA processes not established through legislation	<p>PBAC is an independent statutory body established on 12 May 1954 under s101 of the National Health Act 1953. Its primary role is to recommend to the Health Minister which drugs and medicinal preparations should be subsidised by the Australian Government under the PBS.</p> <p>PBAC is required by the Act to consider both the effectiveness and cost of the proposed drugs and medicinal preparations.</p> <p>Since the beginning of 2006, PBAC has also been required under the Act to recommend to the Health Minister vaccines for funding under the National Immunisation Program (NIP).</p>
Basis for eligibility	s41BD(1) of TG Act defines a medical device (See Attachment A1)	<i>Health Insurance Act 1973</i> Part 1 Preliminary Section 3 defines a professional service for the purposes of the MBS (See Attachment A2)	s72-1 of the <i>Private Health Insurance Act 2007</i> defines the mandatory criteria for listing a product on the PL. (See Attachment A3)	S9B of the National Health Act defines a vaccine, where s85 determines pharmaceutical benefit. (See Attachment A4)
Current reform activity	Nil	Nil	Nil	Nil

Framework for HTA Processes	Market entry	Public funding/subsidy Medical Benefits Schedule (MBS)	Private health insurance funding Prostheses List (PL)	Public funding/subsidy Pharmaceutical Benefits Scheme (PBS) National Immunisation Program (NIP)
Issues – Department Analysis	<p>The legislative framework sets expectations and predictability about the prescribed functions, program area performance (including timelines), and provides for transparency of processes, procedures and requirements.</p> <p>Changes to legislation require rigorous analysis and comprehensive consultation and are less responsive to emerging requirements.</p>	<p>The Act identifies eligible services for MBS listing for MSAC to assess, but does not provide any guidance or certainty around how to conduct the assessment.</p> <p>This provides the Minister with the ability to respond quickly to new and emerging medical services and technologies.</p> <p>MSAC HTA processes are defined through administrative guidelines approved in DoHA.</p>	<p>The Act identifies mandatory criteria for the PL. It neither defines prosthesis nor provides guidance or certainty around how assessments should be conducted.</p> <p>This enables the Minister to respond quickly to new and emerging medical devices.</p> <p>PDC HTA processes are defined through administrative guidelines prepared by DoHA.</p>	<p>The legislative framework sets expectations and predictability about the prescribed functions and provides for transparency of processes, procedures and requirements.</p> <p>Changes to legislation require rigorous analysis and comprehensive consultation and are less responsive to emerging requirements.</p> <p>Legislation provides arm's length decision making for the Minister.</p>
Issues – Submissions	<ul style="list-style-type: none"> Concern at lack of international harmonisation and acceptance of internationally approved technologies. Concern at poor guidance on regulation around 3rd party conformity assessment. 	<ul style="list-style-type: none"> Concerns at long average timeframes for MSAC and lack of prescribed timeframes. Concerns at lack of transparency of process. 	<ul style="list-style-type: none"> Concerns at lack of transparency of process. Concern at delays with sequential TGA, MSAC and PDC approval processes. 	Nil
Implications for option development	Legislation can provide a prescriptive framework for HTA such that all stakeholders have clarity and transparency around each function, process, timeline and outcome but maybe less responsive to emerging needs.			

Establishment of HTA Processes	Market entry	Public funding/subsidy Medical Benefits Schedule (MBS)	Private health insurance funding Prostheses List (PL)	Public funding/subsidy Pharmaceutical Benefits Scheme (PBS) National Immunisation Program (NIP)
Overview	The Parliament approved the legislation which underpins the TGA and its operations, including the establishment of MDEC and its sub-committees.	<p>The Minister:</p> <ul style="list-style-type: none"> established MSAC in 1998 to advise on evidence relating to the safety, effectiveness and cost-effectiveness of new medical technologies and services to inform Australian Government decisions about public funding (MBS) for new, and in some cases existing, medical procedures; and approved TOR (Attachment B) <p>DoHA approved Guidelines and operating procedures and formation of sub-committees.</p>	<p>The Minister:</p> <ul style="list-style-type: none"> has discretion to include additional eligibility criteria for PL; established the PDC on 14 July 2004 to provide advice on the listing of no gap and gap permitted prostheses and the benefits payable for them. 	The Parliament approved the legislation which underpins the PBS and the establishment of PBAC and its sub-committees.
Current reform activity	Nil	Nil	Nil	Nil
Issues – Department Analysis	Nil	<ul style="list-style-type: none"> Government policy determines how and what should be assessed by MSAC for inclusion on the MBS. The Minister is able to change the scope of MSAC's HTA functions and operations via its TOR to meet changing government policy requirements. TOR provide for HTA of 'new' and 'existing' technologies and procedures, but current practice focuses on new technologies and procedures. Not all new technologies are assessed by MSAC. TOR are subject to interpretation by changing committees and administrations and/or program guidelines intended to guide MSAC HTA functions. Broad TOR do not provide certainty or predictability to stakeholders about how this function is interpreted and what can and cannot be assessed through MSAC. Minister is responsible for the final decision to list on the MBS based on MSAC advice, but does not have to accept this advice (either for or against). Minister is the final decision maker and can be lobbied by stakeholders seeking a desired outcome. 	<ul style="list-style-type: none"> Previous Health Minister agreed additional criteria for the PL specifying that only surgically implanted medical devices or medical devices integral to the use of an implantable medical device would be eligible. Some stakeholders are pressing to increase scope of the PL to include other products that do not meet the additional criterion eg non-implantable devices. Current Health Minister has also requested that Insulin Pumps remain on the PL even though they are not surgically implanted devices. This causes potential inconsistency about which devices are eligible for the PL which may already be funded by other means (eg contracts between hospitals and PHI and theatre banding). Some products already on the PL do not meet current listing criteria, while new applications that do not meet the criteria are being declined, creating potential inequity of access. 	Nil

Establishment of HTA Processes	Market entry	Public funding/subsidy Medical Benefits Schedule (MBS)	Private health insurance funding Prostheses List (PL)	Public funding/subsidy Pharmaceutical Benefits Scheme (PBS) National Immunisation Program (NIP)
Issues – Submissions	Nil	Nil	<ul style="list-style-type: none"> Concerns expressed about eligibility for the PL being limited to implantable devices Concerned that the PL excludes high cost single use medical devices. Lack of implementation of the outstanding Doyle Review recommendations. Some did not support implementing recommendation 9. Some support for concurrent application for ARTG and PL listing (Rec 2, Doyle) 	Nil
Implications for option development	The Ministerial approval process which determines committee/advisory functions through TOR act as a gateway to access to the MBS and PL and need to be clear and consistent to ensure policy and procedural interpretation and fairness. As MSAC, PDC and PBAC all perform similar HTA functions, execution of these functions should be consistent where appropriate.			

HTA Criteria	Market entry	Public funding/subsidy Medical Benefits Schedule (MBS)	Private health insurance funding Prostheses List (PL)	Public funding/subsidy Pharmaceutical Benefits Scheme (PBS) National Immunisation Program (NIP)
Safety	<p>Taken from Australian/International Standard AS ISO 14971 – <i>Medical Devices – Application of risk management to medical devices – a standard endorsed in the regulatory framework, and defined as ‘freedom from unacceptable risk’</i></p> <p>Not explicitly defined in the regulatory framework, but by complying with the essential principles outlined in Schedule 1 to the <i>Therapeutic Goods (Medical Devices) Regulations 2002</i>, a judgement is made that the product is safe.</p> <p>The essential principles:</p> <ul style="list-style-type: none"> • Set out requirements relating to the safety and performance characteristics of devices • may define results to be achieved, performance levels, hazards to be addressed, or issues to be considered • do not necessarily specify how the principles can be satisfied or complied with. 	<p>Not explicitly defined, but the MSAC’s ToR require MSAC to assess the strength of the evidence for safety as defined in the guidelines, “<i>MSAC – Funding for new medical technologies and procedures: application and assessment guidelines</i>” and “<i>Guidelines for assessment of diagnostic technologies</i>”.</p> <p>MSAC assesses the safety of a generically described medical service (ie the use in clinical practice of either the specific device or a range of similar devices – safety is based on all available data for assessing adverse outcomes of a medical service – a judgement is made regarding the likely balance of benefits and harms which can be expected if the intervention is widely used in Australian patients.</p>	<p>Elements of safety are currently considered by the PDC process. When assessing the clinical comparisons of products by the PDC and its supporting clinicians, it is difficult to ignore safety.</p>	<p>Not explicitly defined, but PBAC undertakes a comparative assessment of safety, which is outlined in the <i>Guidelines for Preparing Submissions to the Pharmaceutical Benefits Advisory Committee (Version 4.3)</i>. This involves assessing overall harms and benefits of pharmaceutical benefit items.</p> <p>A judgement is made regarding the likelihood that the drug is more effective and/ or less toxic than the comparator.</p>
Quality	<p>Manufacturing quality is assessed in the context of the Quality Management System implemented by the device manufacturer, and those systems are assessed against Australian/International Standard AS ISO 13485 – <i>Medical devices – Quality management systems – requirements for regulatory purposes</i></p>	<p>The safety and clinical effectiveness dimensions of quality are assessed</p>	<p>The PDC process does consider quality of products as this is a relevant factor in conducting comparative assessments.</p>	<p>Optional assessment: The Quality Use of Medicines (QUM) is additionally assessed when data is provided. QUM includes judicious selection of management options, appropriate choice of medicines and safe and effective use as outlined in the Guidelines.</p>
Efficacy (ie performs as intended)	<p>As above for safety.</p>	<p>Not assessed</p>	<p>The PDC process does consider efficacy as fitness for purpose is a key determinant of whether the PDC recommends a product is listed.</p>	<p>Not assessed</p>

HTA Criteria	Market entry	Public funding/subsidy Medical Benefits Schedule (MBS)	Private health insurance funding Prostheses List (PL)	Public funding/subsidy Pharmaceutical Benefits Scheme (PBS) National Immunisation Program (NIP)
Clinical effectiveness	The safety and effectiveness of all medical devices must be supported by clinical evidence, and that evidence may be assessed before appropriate certification is issued.	<p>Comparative clinical assessment is assessed in accordance with the "NHMRC Designation of levels of evidence for studies of clinical effectiveness".</p> <p>A consideration of the quality and strength of evidence in relation to a medical service, as well as the magnitude of the effect and relevance of the evidence to Australian practice compared with a currently MBS funded procedure or current clinical practice.</p> <p>This is based on MSAC's consideration of a contracted report from an expert advisory panel which includes the contracted evaluators' systematic literature review, and analysis of the applicant's response and contracted evaluator's rejoinder as well as an independent presentation to MSAC, a critique by the Economics Sub-committee and MSAC's own expertise.</p>	<p>Determined by clinicians' assessment of:</p> <ul style="list-style-type: none"> information provided by sponsors available clinical evidence; and their experience and expertise. <p>Clinicians consider how effectively it achieves, or is likely to achieve, treatment outcome(s) for its indication. Assessment may be relative to other products on the PL that treat the same clinical condition. Clinicians assess a product to determine its level of clinical effectiveness when compared with comparators.</p>	<p>Comparative assessment of the clinical place and overall effectiveness of the proposed drug with already listed medicines, or with standard medical care.</p> <p>PBAC considers evidence presented by a sponsor that demonstrates superiority, or non-inferiority (equivalence), to a relevant comparator.</p> <p>A judgement is made regarding the likelihood that the drug is more effective and/ or less toxic than the comparator.</p>
Cost effectiveness	Not assessed.	<p>MSAC Economic Guidelines are available on the MSAC website. Economic evaluation entails a set of formal quantitative methods used to compare alternative strategies (or treatments) with respect to their resource use and their expected outcomes.</p> <p>Normally once clinical effectiveness and safety of a medical service has been established on the basis of adequate data an economic analysis is undertaken. The types of economic evaluation undertaken are advised by the Economics Sub-committee of MSAC.</p>	<p>Cost effectiveness is not assessed but a determination of cost relative to clinical effectiveness is made.</p>	<p>PBAC assesses the cost effectiveness of a medicine by considering the economic evaluation provided by the sponsor of a medicine and assess the degree to which new drugs represent 'value for money' for the Australian community.</p> <p>The primary focus of an economic evaluation is to make a comparative assessment of the extra cost required to achieve additional health outcomes with the new therapy compared with existing therapies.</p>

HTA Criteria	Market entry	Public funding/subsidy Medical Benefits Schedule (MBS)	Private health insurance funding Prostheses List (PL)	Public funding/subsidy Pharmaceutical Benefits Scheme (PBS) National Immunisation Program (NIP)
Fee/Benefit Negotiation	Not assessed	<p>The fee for an MBS service is based on the time and complexity of the service compared to currently funded procedures.</p> <p>Fee negotiations are performed by DoHA in consultation with the medical craft groups utilising the MSAC assessment report.</p> <ul style="list-style-type: none"> The Government pays a Medicare rebate at one of three levels: <ol style="list-style-type: none"> 75% of the Schedule fee: <ol style="list-style-type: none"> for professional services rendered to a private patient as part of an episode of hospital treatment (other than public patients). for professional services rendered as part of an episode of hospital-substitute treatment, and the patient who receives the treatment chooses to receive a benefit from a private health insurer. 100% of the Schedule fee for non-referred attendances by general practitioners to non-admitted patients and services provided by a practice nurse or registered Aboriginal Health Worker on behalf of a general practitioner. 85% of the Schedule fee, or the Schedule fee less \$68.10 (November 2008 figure which is indexed annually), whichever is the greater, for all other professional services.. 	<p>The benefit for a product is based on its relative clinical effectiveness compared with comparable products. Benefit negotiations are performed by PDNG (on behalf of PDC) and focus on similarities (or differences) in clinical effectiveness, product features and relevant clinical outcomes. Products having similar clinical effectiveness should be listed with similar benefits.</p>	<p>The Pharmaceutical Benefits Pricing Authority (PBPA) is an independent non-statutory body that makes recommendations to the Minister on prices for new items that have been recommended for listing on the PBS by PBAC. PBPA makes its recommendations for prices of new listings and extensions and changes to listings based on the trade name, sponsor, proposed price, overseas prices (UK and New Zealand), alternatives listed on the PBS and their prices, estimated expenditure, cost of goods and margin, price calculations and PBAC advice.</p> <p>One of the main mechanisms to determine the initial listing of new products is the advice of PBAC arising from the cost effectiveness information supplied by the sponsor and evaluated by the Pharmaceutical Evaluation Section, and the Drug Utilisation Sub-Committee (DUSC) and the Economics Sub-Committee (ESC) of PBAC. PBAC is required by legislation to consider both the clinical and cost effectiveness of therapy in making its recommendations.</p>

HTA Criteria	Market entry	Public funding/subsidy Medical Benefits Schedule (MBS)	Private health insurance funding Prostheses List (PL)	Public funding/subsidy Pharmaceutical Benefits Scheme (PBS) National Immunisation Program (NIP)
Current reform activities	<p>TGA is currently reviewing its third party conformity assessment (TPCA) arrangements including consultation with industry.</p> <p>TGA is currently reviewing the risk based classification of major orthopaedic joints with a view to increasing the level of review prior to approval for marketing – a consultation paper has been prepared, but is yet to be distributed to stakeholders.</p>	<p>Guidelines and approach for economic evaluation are currently being reviewed including against PBAC approach to ensure consistency.</p> <p>Guidelines for preparing MSAC Assessment Reports are being reviewed to ensure that appropriate information to inform the development of MBS item descriptors for the proposed MBS service is contained in the evaluation report.</p>	<p>Workshop with TGA scientists and PDC clinicians scheduled for August 2009 will explore the apparent duplication of safety assessment and ultimately the definition of safety and role clarity of both functions regarding the safety assessment needs resolution.</p>	<p>Nil</p>
Issues – Department Analysis	<p>For many devices, the TGA accepts certification issued by external Conformity Assessment Bodies (CABs) indicating they have examined, and are accepting of, the manufacturer's evidence (including clinical evidence) to support the safety of the device.</p> <p>For higher risk devices, the TGA reviews assessment reports generated by these CABs that support their issue of certification.</p> <p>For a select group of the highest risk devices, the TGA examines the evidence generated by the manufacturer to support the safety of the device.</p>	<ul style="list-style-type: none"> MSAC assesses the safety of a generically described medical service (ie the use in clinical practice of either the specific device or a range of similar devices – a judgement is made regarding the likely balance of benefits and harms which can be expected if the intervention is widely used in Australian patients, which is different to that of TGA but similar to the PBAC assessment of safety. The economic evaluation does not take into account potential out-of-pocket costs eg. Medicare Safety Net and patient out-of-pocket costs. MSAC report and advice may not be specific in relation to appropriate restrictions on the service that may be funded on the MBS. The fee negotiation process is conducted after the initial MSAC advice to the Minister by another section of DoHA. The process has been criticised as informal, ad hoc, lacking transparency, and untimely. There are different approaches to costing items scheduled on the MBS which may result in inconsistent costing outcomes. 	<p>Stakeholders claim that PDC also undertakes a safety assessment function (which is performed by TGA) when assessing clinical effectiveness is supported in the PL Guide:</p> <p><i>"In making its recommendations, the PDC considers the safety, clinical effectiveness and cost relative to the clinical effectiveness of other products."</i> In relation to clinical evidence:</p> <p><i>"This evidence includes reports of any relevant clinical trials and/or studies, safety data and reports of any adverse events associated with the use of a product, most of which can be identified by a literature search."</i> In relation to the use of NJRR data: "The NJRR data will complement orthopaedic surgeon expert knowledge and literature provided by sponsors regarding the safety and efficacy of prostheses...."</p> <p>In addition, to their primary role of assessing clinical effectiveness and comparative clinical effectiveness, clinician members of the CAGs see their role as assessing safety as a secondary safeguard for the Australian public.</p> <p>Some PDC members also believe that the safety assessment conducted by the TGA for some categories of devices is inadequate.</p>	<p>Nil</p>

HTA Criteria	Market entry	Public funding/subsidy Medical Benefits Schedule (MBS)	Private health insurance funding Prostheses List (PL)	Public funding/subsidy Pharmaceutical Benefits Scheme (PBS) National Immunisation Program (NIP)
Issues – Submissions	<ul style="list-style-type: none"> Many submissions argued that TGA should be the sole Cth arbiter of the safety of medical devices. Industry concerned at the lack of harmonisation or acceptance of internationally approved technologies. 	<ul style="list-style-type: none"> Some called for the costings involved in the cost effectiveness analysis to be used as the basis for fee setting. Cost effectiveness should be derived from both a societal perspective and an individual payer perspective (government/consumer) and include indirect costs. Some question the fairness of the comparative assessment approach – this poses a significant challenge to new technologies which have no ideal (or no) comparator. Concerned that levels of evidence required is inappropriate and impossible to collect for medical technologies pre-market. 	<ul style="list-style-type: none"> Call for specific health economics expertise to be shared across the HTA committees. Some submissions called for more cost effectiveness analysis for PDC. Several expressed concerns about duplication in assessment of safety (vis a viz clinical effectiveness). Concern at low levels of knowledge of CAG members. Concerned that levels of evidence required is inappropriate and impossible to collect for medical technologies pre-market. Concern at the limited criteria for listing. 	<p>Lack of certainty about the interface between MSAC and PBAC functions for co-dependent and hybrid technologies.</p>
Implications for option development	<p>The definitions of the different HTA criteria need to be clearly articulated. The information sought from applicants to inform assessment of each criterion across each function needs to be consistent where appropriate, or the rationale for requesting different information needs to be articulated. Visual mapping of the total process or an easily searched web address would assist applicants identify which component of the pathway is most appropriate to their needs.</p>			

HTA Program Guidelines	Market entry	Public funding/subsidy Medical Benefits Schedule (MBS)	Private health insurance funding Prostheses List (PL)	Public funding/subsidy Pharmaceutical Benefits Scheme (PBS) National Immunisation Program (NIP)
Overview <ol style="list-style-type: none"> Approved by? Consultation? Program elements ie what's included eg timeframes How often are the guidelines updated? 	<ol style="list-style-type: none"> Delegated Officers within the Office of Devices, Blood & Tissues Public consultation with all stakeholders and consultation with stakeholders on program guidelines TGA Guidelines are intended to provide a plain English explanation of TGA functions defined in legislation and include: <ul style="list-style-type: none"> An overview of the system Details of application audits Clinical evidence requirements Obligations and requirements of medical device manufacturers and sponsors Device-medicine boundary products The guidelines are updated as required. 	<ol style="list-style-type: none"> Department – cleared at HTMSG Executive level Consultation with MSAC and advice from contracted evaluators, with any major changes communicated to the Minister. Publicly available guidelines include Application and Assessment Guidelines covering: Part 1: Background to the current arrangements and Part 2: Application Guidelines. Guidelines for the Assessment of Diagnostic Technologies based on the above guidelines have also been prepared. There are also Supplementary Economic Guidelines for economic evaluation. Not publicly available are the MSAC Administrative Guidelines and Advisory Panel Chair and Member Guidelines. These explain the role of the Committee and Advisory panels and how they operate. Annual review updated as required. 	<ol style="list-style-type: none"> Department – no formal clearance processes, noted by PHIB AS when application forms are approved. Consultation with MTAA and other industry stakeholders. Guidelines are in two parts with a matrix of key events and include: <ul style="list-style-type: none"> Background to the current arrangements Outline of the Prostheses List Overview of the PDC Overview of clinical assessment and benefit negotiation How to complete the application forms Guidelines and application forms are updated prior to each cycle. PDC issues a bulletin on occasion throughout the prostheses listing cycle to update stakeholders on new policy decisions that may be implemented for the next cycle. 	<ol style="list-style-type: none"> PBAC and PBAC Chair Members of the PBAC and its sub-committees, a range of contributors from industry, government, academia and the community (PBAC Guidelines Working Group) Guideline for Preparing Submissions to the Pharmaceutical Benefits Advisory Committee (Version 4.3) include: <ul style="list-style-type: none"> Role of PBAC Introduction to the guidelines Types of submissions Rationale and basis for the economic evaluation Organisation of a major submission Lodging a major submission Subject to regular review

HTA Program Guidelines	Market entry	Public funding/subsidy Medical Benefits Schedule (MBS)	Private health insurance funding Prostheses List (PL)	Public funding/subsidy Pharmaceutical Benefits Scheme (PBS) National Immunisation Program (NIP)
Current reform activity	On-going review and revision of published guidance documentation	Options for targeted assessments are currently being considered eg triaging of applications according to complexity, available evidence and so on. Recent changes to separation of advice from contracted MSAC reports and new ESC TOR will necessitate a review of all documentation. Next version of the Guidelines will be updated to reflect changes at the prelodgement to allay stakeholder concerns around transparency, clarity and accountability	The Guide and Forms used for each cycle are reviewed. This exercise has just been completed for the February 2010 cycle and consultation occurred with the MTAA.	Currently reviewing several technical issues within the guidelines.
Issues – Department Analysis	Nil	MSAC program guidelines define how MSAC performs its HTA function. Stakeholders are critical of MSAC's approach to assessing applications due to the "one-size fits all" approach to evaluation and the need to establish and review the evidence base from the ground up regardless of the level of evidence provided by the applicant. There is currently no targeting of assessment effort based on an application's alignment with health priorities and potential for improved clinical outcomes. MSAC program guidelines are silent on timeframes and internal departmental processes, particularly for implementation of MSAC advice (MBS descriptor and fee) once noted by the Minister. This is a consistent area of stakeholder criticism about lack of transparency, clarity and accountability (see reform activity above).	Prostheses List Guide define how PDC performs its HTA function.	Nil

HTA Program Guidelines	Market entry	Public funding/subsidy Medical Benefits Schedule (MBS)	Private health insurance funding Prostheses List (PL)	Public funding/subsidy Pharmaceutical Benefits Scheme (PBS) National Immunisation Program (NIP)
Issues – Submissions	Generally supported	<ul style="list-style-type: none"> Some claimed that the guidelines are too general. Some claim the guidelines need to be clearer about how different types of technologies are assessed. Lack of criteria and guidelines for economic evaluation and data requirements. Lack transparency. 	<ul style="list-style-type: none"> Written guidelines are too general. Lack of guidance of benefit setting parameters. Lack transparency. 	Developed consultatively and generally well accepted.
Implications for option development	In the absence of legislation, program guidelines provide the framework for administration of the program upon which stakeholders rely to make an application for government HTA. Where MSAC and PDC perform a similar HTA function to PBAC (prescribed in legislation) there may be benefits in aligning program guidelines with PBAC requirements (where appropriate) as a basis for ensuring a consistent departmental approach.			

Departmental Administration of HTA	Market entry	Public funding/subsidy Medical Benefits Schedule (MBS)	Private health insurance funding Prostheses List (PL)	Public funding/subsidy Pharmaceutical Benefits Scheme (PBS) National Immunisation Program (NIP)
Overview a. Division b. Role c. Staffing – skills d. Financing e. How many applications per year	a. TGA b. Two sections: Application Entry & Coordination (AECs) Assesses and processes applications for entry of medical and therapeutic devices onto ARTG Medical Devices Assessment (MDAS) Undertakes the assessment process for high-risk medical devices and other therapeutic goods including disinfectants and in vitro diagnostic devices for HIV and Hepatitis C. Conducts the conformity assessments of Australian manufacturers for both the Australian market and for the European market under the Australia-EC/EFTA Mutual Recognition Agreements (MRA) c. Administrative and technical skills to assess medical device applications d. Cost recovery for medical devices program and administered funds to provide policy advice to Government e. 2000 applications pa	a. MBD b. MSAC Secretariat (HTMSG) provides secretariat support to MSAC including: <ul style="list-style-type: none"> secretariat support to MSAC and its sub-committees; management of applications (including pre-lodgement meetings) and evaluation processes; publish MSAC reports and public summary documents on MSAC website Various MBD sections implement MSAC advice (staff as required) c. Secretariat, project management and administrative skills. Clinical advice provided by various MBD Medical Advisers. Implementation activities require policy, administrative, secretariat and financial analysis, as well as health economics skills. d. Departmental funds. e. 16 applications pa (MSAC)	a. ACD b. The Prostheses Section: <ul style="list-style-type: none"> provides secretariat support to PDC and its supporting committees; develops policy on private health insurance funding of prostheses provides advice about legislation, regulation and other government programs (eg MBS) that impact the use and funding of prostheses; maintains and publishes Prostheses List; processes sponsors' applications to list new products and amendments to existing listings; coordinates internal reviews of PDC recommendations; coordinates implementation of Doyle Report recommendations; provides advice to stakeholders about prostheses arrangements; and facilitates communication and discussion between individuals and external stakeholders. c. Administrative and policy skills d. Cost recovery for prostheses arrangements e. 1000 applications pa plus amendments to existing products (can be thousands)	a. PBD b. The Pharmaceutical Evaluation Branch: <ul style="list-style-type: none"> provides secretariat support to PBAC and its sub-committees; manages applications to PBAC and their evaluation; publishes PBAC outcomes and public summary documents on departmental website negotiates pricing and other reimbursement conditions for listing of medicines maintains the Schedule of Pharmaceutical Benefits c. Secretariat, technical, administrative and policy skills. The majority of staff supporting PBAC are pharmacists and health economists. Clinical advice provided by PBD Senior Medical Adviser. Post-PBAC implementation activities require policy, administrative, secretariat and financial analysis skills. d. Administered funds. e. 250 applications pa

Departmental Administration of HTA Current reform activity	Market entry On-going implementation of Business Process Review undertaken in 2007/08	Public funding/subsidy Medical Benefits Schedule (MBS) MSAC is discussing options with craft groups and colleges about improving time to establish advisory panels.	Private health insurance funding Prostheses List (PL) Staffing and internal processes have been adjusted in anticipation of workload for the next cycle.	Public funding/subsidy Pharmaceutical Benefits Scheme (PBS) National Immunisation Program (NIP) Cost recovery will be implemented in the near future.
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Departmental Administration of HTA	Market entry	Public funding/subsidy Medical Benefits Schedule (MBS)	Private health insurance funding Prostheses List (PL)	Public funding/subsidy Pharmaceutical Benefits Scheme (PBS) National Immunisation Program (NIP)
Issues – Department Analysis	<p>There is:</p> <ul style="list-style-type: none"> • a lack of transparency in conveying policy decisions and new application rules to industry • a lack of accessibility of TGA officers • inconsistency in decision making and advice • a lack of clarity with regard to the reasons or justification for certain decisions. 	<p>Stakeholders have criticised MSAC for its administrative arrangements and processing (which are provided by DoHA) including:</p> <ul style="list-style-type: none"> • establishment of expert advisory panels is unacceptably slow (eg can take up to six months); • this delays commencement of assessment phase; • MSAC is slower, more cumbersome, less flexible and possibly less consistent in its recommendations than other Commonwealth HTA models; • the scientific and economic expertise of the MSAC Secretariat to manage HTA function; • visibility of MSAC functions is through the MSAC Secretariat; However, stakeholders claim that the implementation of their approved application is not transparent (eg applicant has no involvement in this phase), slow and are also critical of the informal processes for implementing MSAC advice. 	<p>The high volume workload, serial nature of the process and current manual processing adversely impacts on staff and results in a reactive rather than proactive approach to managing the PL.</p> <ul style="list-style-type: none"> • Due to 100% cost recovery, industry expects performance measured against KPI and accountability of outcomes. 	<p>Nil</p>

Departmental Administration of HTA	Market entry	Public funding/subsidy Medical Benefits Schedule (MBS)	Private health insurance funding Prostheses List (PL)	Public funding/subsidy Pharmaceutical Benefits Scheme (PBS) National Immunisation Program (NIP)
Issues – Submissions	Concerns at lack of harmonisation and acceptance of internationally approved technologies.	<ul style="list-style-type: none"> • Criticise delays in processing applications especially in convening advisory panels. • Call for greater HTA and health economics expertise in the secretariat. • Call for increased HTA skills of secretariat staff. • Lack of communication with stakeholders. • Assessment not conducted by an independent, non government body. 	<ul style="list-style-type: none"> • Question the expertise of the PDC secretariat to manage HTA function. • Call for greater HTA and health economics expertise in the secretariat. • Recent timeframe slippages. • Low number of cycles per year (prefer rolling or increased number of cycles). • Concerns at strict and early cut-off date for applications, and requirement of ARTG registration. • Assessment not conducted by an independent, non government body. 	<ul style="list-style-type: none"> • Has appropriate expertise for HTA function. • Assessment not conducted by an independent, non government body.
Implications for option development	MSAC – Look at ways of strengthening the applications to provide alternative to full contracted evaluation and analysis of existing evidence from applicant. A limiting factor for establishment of panels is the time taken by the Consumer Health Forum's nomination process to provide nominees for advisory panels.			

HTA Expert Committee	Market entry	Public funding/subsidy Medical Benefits Schedule (MBS)	Private health insurance funding Prostheses List (PL)	Public funding/subsidy Pharmaceutical Benefits Scheme (PBS) National Immunisation Program (NIP)
Overview a. ToR b. Operating procedures c. Who appoints the committee? d. Role e. Chair – full/part f. Membership g. Remuneration h. Meetings i. Sub-committees – relationship to main committee, how appointed, expertise, role, accountability, confidentiality, representational vs expert, ToR	MDEC a. Specified in the <i>Therapeutic Goods Regulations 1990</i> . See Attachment B1 b. Not available on website c. Minister appoints the Committee on advice from DoHA d. Provides independent medical and scientific advice to the Minister and TGA on the safety, quality and performance of medical devices supplied in Australia including issues relating to pre-market conformity assessment and post market monitoring. e. Part time Chair – appointed for 3 years, may serve up to 3 consecutive terms, but no more than 5 terms total f. Comprises 12 core members and up to 20 associate members with expertise in a broad range of disciplines including: <ul style="list-style-type: none"> • general medicine practice • gastroenterology • cardiology • anaesthesia • orthopaedics • plastic & reconstructive surgery • neurosurgery • gynaecology/obstetrics • ophthalmology • vascular & transplant surgery • restorative dentistry • biomedical engineering • in vitro diagnostic devices • medical device manufacture • consumer issues. 	MSAC a. See Attachment B2. b. Administrative Guidelines MSAC; Guidelines for Chairs of MSAC Advisory Panels; Guidelines for Members of MSAC Advisory Panels. c. The Minister on advice from DoHA d. Advise the Minister on evidence relating to the safety, effectiveness and cost-effectiveness of new medical technologies and procedures – this informs decisions about public funding for new, and in some cases existing, medical procedures. e. Part-time chair – appointed for two year term f. Currently, comprises 20 individuals with a mix of clinical expertise including: <ul style="list-style-type: none"> • general practice • pathology • colorectal surgery • cardiology • medical oncology • trauma and emergency medicine • thoracic medicine • nuclear medicine • radiology • genetics • public health • research including health research • health economics • consumer representation • CMO is an ex-officio member • AHMAC representative • Appointed for two years 	PDC a. See Attachment B3. b. Appendix B to Part 1 of the PL Guide c. The Minister on advice from DoHA d. PDC makes recommendations to the Minister on appropriate listing and benefits of prostheses. e. Part time Chair – appointed for four years, may serve no more than two terms f. Committee consists of: <ul style="list-style-type: none"> • Four clinicians • Four health insurers • One industry • One private hospitals • One catholic hospitals • One consumer • One DVA (ex officio) g. Appointed for four years, may serve no more than two terms h. Prep and sitting fees paid as per Schedule B of Rem Tribunal Determination 2008/07 i. Meet between weeks 8 and 18 of the cycle as many times as necessary to progress business – usually 6 times	PBAC a. See Attachment B4 b. Underpinned by legislation c. The Minister with reference to Cabinet on advice from DoHA d. Provides independent, expert advice to the Minister e. Full-time chair f. Membership prescribed under the Act and comprises a chair and at least 11 (but not more than 17) other members with 2/3 of PBAC selected from: <ul style="list-style-type: none"> • Consumers • health economists • practising community pharmacists • general practitioners • clinical pharmacologists • specialists • other nominees with appropriate qualifications or experience g. As determined by Remuneration Tribunal h. Meets 3 times per year, working on a 17 week cycle.

HTA Expert Committee	Market entry	Public funding/subsidy Medical Benefits Schedule (MBS)	Private health insurance funding Prostheses List (PL)	Public funding/subsidy Pharmaceutical Benefits Scheme (PBS) National Immunisation Program (NIP)
	<p>Members appointed for 3 years, may serve up to 3 consecutive terms, but no more than 5 terms total</p> <p>i. As per Schedule B of Rem Tribunal Determination 2008/07.</p> <p>j. Meet four times in a year.</p> <p>k. Subcommittees:</p> <p>MDIRC – Medical Device Incident Review Committee</p> <p>IMDTS – Implantable Medical Device Tracking Subcommittee</p> <p>BBC – Biomaterials and Bioengineering Subcommittee</p> <p>OEWG – Orthopaedic Expert Working Group</p> <p>CEWG – Cardiac Expert Working Group</p> <p>The role of these Subcommittees is to examine and provide advice on queries or issues in their specialised areas of expertise, referred to them by the TGA or the MDEC.</p>	<p>g. Per Schedule A of the Rem Tribunal 2008/07 - Professional Committee (includes a stipend for Chair).</p> <p>h. MSAC meets four times pa, MSAC Executive (Includes Chair and Deputy Chair(s)) meets monthly. Advisory panels meet as required, for each assessment.</p> <p>i. Subcommittees:</p> <p><i>MSAC Executive</i>: agree eligibility for assessment on advice from DoHA, approve membership of advisory panels and monitor MSAC work plan.</p> <p><i>MSAC Advisory Panels</i>: are established on an ad hoc basis, are an essential part of the MSAC process, and provide expert and consumer advice during the contracted assessment process and report on their findings to MSAC. Remuneration is through sitting and assessment fees.</p> <p>MSAC Executive approves and appoints:</p> <ul style="list-style-type: none"> • a MSAC member as Chair and a second member as deputy chair; • clinicians nominated by (but not representative of) relevant medical colleges for their expertise; • consumer representing the CHF; and • consideration of an applicant nominated members to the panel and DoHA medical or other. 	<p>j. Supporting groups:</p> <p><i>Clinical Advisory Groups & Panel of Clinical Experts</i> clinically assess products and amendments (where required) and reports on their findings to PDC.</p> <p>PDC appoints CAG and Panel members from nominees provided by relevant medical colleges for their expertise. Remuneration is through sitting and assessment fees.</p> <p><i>Prostheses and Devices Negotiating Group</i> (PDNG) – negotiates benefits with the sponsor of new products and renegotiates benefits for listed prostheses on behalf of PDC.</p> <p>PDC appoints PDNG from nominees provided by AHIA, APHA and CHA for their negotiating expertise. PDNG members are contracted by the nominating organisation.</p> <p><i>Advisors</i> – from PHIB and a departmental medical advisor assist the PDC in its procedures, especially in the provision and explanation of data.</p>	<p>i. Sub-committees:</p> <p><i>Economics Sub-Committee</i> (ESC): PBAC established ESC in December 1993 s101A of the <i>National Health Act 1953</i> to:</p> <ul style="list-style-type: none"> • review and interpret economic analyses of drugs submitted to the PBAC; • advise the PBAC on these analyses; and • advise the PBAC on technical aspects of requiring and using economic evaluations. <p><i>Drug Utilisation Sub-Committee</i> (DUSC): PBAC established DUSC in 1988 s101A of the <i>National Health Act 1953</i> to:</p> <ul style="list-style-type: none"> • collect and analyse data on drug utilisation in Australia for use by the PBAC; • make inter country comparisons of drug utilisation statistics; and • assist in generating information relating to rational use and prescribing of medicines. <p>The DUSC secretariat is responsible for publishing the Australian Statistics on Medicines on an annual basis.</p>

HTA Expert Committee	Market entry	Public funding/subsidy Medical Benefits Schedule (MBS)	Private health insurance funding Prostheses List (PL)	Public funding/subsidy Pharmaceutical Benefits Scheme (PBS) National Immunisation Program (NIP)
		<p>MSAC Evaluators are directed by the Advisory Panels to develop an evaluation protocol (including research questions) and undertake a systematic literature review for analysis of the strength of the evidence for safety and effectiveness and economic evaluation. Contracted by DoHA.</p> <p><i>The Economics Sub-committee (ESC)</i></p> <p>Appointed by the MSAC Executive to provide advice to the Advisory Panel on the economic evaluation and critiques the economics of the final report to MSAC. Includes clinical expertise and consumer perspectives.</p> <p>currently supports an MSAC* and AHMAC initiative – the Australia and New Zealand Horizon Scanning Network (ANZHSN) to undertake horizon scanning functions.</p> <p>Includes two MSAC members and jurisdictional representatives. This Committee is being more formally aligned under AHMAC.</p> <p>* As of 1 July 2009 – HealthPACT reports to AHMAC and CTEPC and is no longer a sub-committee of MSAC.</p>		
Current reform activity	Nil	Closer alignment of ESC advice early in assessment process	A proportion of PoCE items are to be moved to a CAG structure to better deal with their ongoing assessment and review activity.	Nil

HTA Expert Committee	Market entry	Public funding/subsidy Medical Benefits Schedule (MBS)	Private health insurance funding Prostheses List (PL)	Public funding/subsidy Pharmaceutical Benefits Scheme (PBS) National Immunisation Program (NIP)
Issues – Department Analysis	Nil	<ul style="list-style-type: none"> DoHA has been criticised for its management of the administrative arrangements for Advisory Panels eg delays in establishment. Stakeholders say MSAC is slower, more cumbersome, less flexible and possibly less consistent in its recommendations than other Commonwealth HTA models. Establishing and reviewing the evidence base for MSAC applications lies with MSAC and not the applicant. The general lack of evidence provided with applications coupled with a “one-size fits all” approach to evaluation has been criticised as inefficient resource use DoHA and MSAC have been criticised for lack of transparency during the assessment and implementation phases 	<ul style="list-style-type: none"> Stakeholders are concerned that representation on PDC is unbalanced given competing interests in the prostheses listing arrangements eg currently PDC has four health insurers and one sponsor member. PDC decisions are consensus based with the Chair holding a casting vote. There must be a quorum of members (three PHI and three clinicians) present for a recommendation to be effective. The lack of clinical expertise on PDNG limits the level of debate that occurs during the benefit negotiation process and introduces process inefficiencies. Sponsors are concerned that PDNG are employed by the insurers and act on their behalf during negotiations. 	Nil
Issues – Submissions	Nil	<ul style="list-style-type: none"> Concerns about theopaqueness of selection of advisory panel members Criticism of the slowness in establishing advisory panels Some want MSAC to have a broader multi-disciplinary membership 	<ul style="list-style-type: none"> Question the independence of PDNG members. Concerns at the membership of the committees being unpublished. Concerns about the balance of expertise on PDC and CAG. 	Nil
Implications for option development	In the current HTA arrangements, advisory committees play an important role in providing advice to assist with government decision making. Going forward, how these committees are structured, appointed, and remunerated will determine how effectively they function and the ability of decisions to respond to different stakeholder needs. Consideration needs to be given to ensuring a level of consistency and integration between how these committees work, as appropriate and required.			

HTA Decision Maker	Market entry	Public funding/subsidy Medical Benefits Schedule (MBS)	Private health insurance funding Prostheses List (PL)	Public funding/subsidy Pharmaceutical Benefits Scheme (PBS) National Immunisation Program (NIP)
Who?	Secretary	Minister	Minister	Minister
Delegation?	Delegated Officers within the Office of Devices, Blood & Tissues	No	Assistant Secretary	Assistant Secretary
Decision to be made	To list on ARTG	Minister makes three decisions: 1. <u>notes</u> advice from MSAC. If Minister accepts advice, MBD commences implementation process including: i) item descriptor and fee negotiation; ii) MBS utilisation and cost modelling; iii) agree costings with DOFD; 2. <u>approves</u> item and costings for inclusion on MBS (costings over \$10 million Cabinet must approve). Concurrently, MBD prepares drafts for Office of Legislative Drafting and Publishing to amend the Health Insurance Regulations; 3. <u>approves</u> Health Insurance Regulations; Health Insurance Regulations are sent to Executive Council for consideration. Once the Amendment Regulations are approved they are registered on the Federal Register of Legislative Instruments. It is a disallowable instrument until such time as it passes through both houses of parliament	Include products on PL and determine their benefit.	Advice and listing on PBS DoFD has agreed the PBS costings process up to \$10 million/annum for new items – the Minister notes the costings. If the cost for PBS listing is over \$10 million/annum DoFD must agree costings and Minister and Cabinet must approve.
Effect of decision	Immediate – ARTG is updated daily	On updating of MBS – annual remake in November, otherwise as required.	On date of effect of the PL which is 10 working days after the PL is published.	On updating of PBS.
Current reform activity	Nil	Current activity to resolve DoHA HTA decision making about co-dependent and hybrid technologies	Nil	Current activity to resolve DoHA HTA decision making about co-dependent and hybrid technologies

HTA Decision Maker	Market entry	Public funding/subsidy Medical Benefits Schedule (MBS)	Private health insurance funding Prostheses List (PL)	Public funding/subsidy Pharmaceutical Benefits Scheme (PBS) National Immunisation Program (NIP)
Issues – Department Analysis	<ul style="list-style-type: none"> No financial implication of decision as long product meets safety, quality and efficacy criteria. Decisions are advised through advice to stakeholder and through listing on ARTG 	<ul style="list-style-type: none"> Minister does not have to accept MSAC advice Minister's decision has financial and policy implications for Government Minister may be exposed to pressure from stakeholders to make a decision PBAC/MSAC interface for decisions about co-dependent and hybrid technologies Stakeholders and consumers have been critical about the transparency of decision making subsequent to MSAC's advice to the Minister Applicants are critical of lack of involvement in the implementation process, noting that the Minister's decision to list the technology on the MBS is only advised through listing on MBS Stakeholders are critical about the impact that the lack of system integration has on applications and decisions throughout the HTA process 	<p>The Minister's delegate does not have to accept PDC's advice, is responsible for the decision ultimately so is in a position to be lobbied.</p> <p>The delegate's decision:</p> <ul style="list-style-type: none"> has no direct financial implications for Government; has financial implications for PHI <p>Stakeholders are critical about the impact that the lack of system integration has on applications and decisions throughout the HTA process</p>	<ul style="list-style-type: none"> Minister's decision has financial and policy implications for Government PBAC/MSAC interface for decisions about co-dependent and hybrid technologies
Issues – Submissions	Nil	<ul style="list-style-type: none"> Delays in seeking Ministerial approval and implementation. 	Nil	Nil
Implications for option development	The decision making processes and decisions made vary across the DoHA HTA continuum. Improved system integration is required to provide greater transparency and clarity to applicants and other interested stakeholders.			

Public Communication	Market entry	Public funding/subsidy Medical Benefits Schedule (MBS)	Private health insurance funding Prostheses List (PL)	Public funding/subsidy Pharmaceutical Benefits Scheme (PBS) National Immunisation Program (NIP)
Website	<p>Contains (main page):</p> <ul style="list-style-type: none"> • Safety information • About the TGA • Information for...[different stakeholder types] • Regulation • News • ARTG • Hot Topics • Other information <p>Comment:</p> <ul style="list-style-type: none"> • has a formal application tracking component • is tailored for different groups (eg health professionals, consumers etc) 	<p>Contains:</p> <ul style="list-style-type: none"> • Background to MSAC. • TOR. • Guidelines. • Advisory Panel Membership. • Details of applications status • Assessment Reports. • Simple Links to other relevant websites (Australian and international) <p>Comment:</p> <ul style="list-style-type: none"> • links to TGA home page but not to specific HTA function and does not explain importance to MSAC process • has a low level tracking component • electronic contact and phone details listed. 	<p>Contains:</p> <ul style="list-style-type: none"> • Background to PL • Information on IFC • Feb 09 PL (current list) • Key dates for Aug 09 List (next list) • Guide and Forms • Background on fees • Contact details • Simple links to other relevant websites (external and internal stakeholders) <p>Comment:</p> <ul style="list-style-type: none"> • links to TGA home page but not to specific HTA function and does not explain importance to PDC process • links to MSAC website but does not explain importance to PDC process 	<p>Contains:</p> <ul style="list-style-type: none"> • Background information on PBS and processes involved in listing medicines and applicable fees • Information for industry, consumers and health professionals • List of medicines on the Schedule of Pharmaceutical Benefits including relevant applicable restrictions and charges • PBAC outcomes • PBAC agendas for public comments <p>Comment:</p> <ul style="list-style-type: none"> • PBS website tailored for different groups (eg health professionals, consumers etc).
Current reform activity	Nil	Developing a more efficient search facility and regular communiqués from MSAC.	Nil	Ongoing development of website
Issues – Department Analysis	<ul style="list-style-type: none"> • is not consistent with DoHA format • does not inform stakeholders or clients about how TGA functions fit into the broader DoHA HTA functional responsibility 	<ul style="list-style-type: none"> • is not consistent with DoHA format • does not link to PDC website • does not link to MBS on-line website • is not tailored for different groups (eg health professionals, consumers etc) • does not inform stakeholders or clients about how MSAC functions fit into the broader DoHA HTA functional responsibility 	<ul style="list-style-type: none"> • does not have an application tracking component (i.e. status of an application at any point in time) • is not tailored for different groups (eg health professionals, consumers etc) • does not inform stakeholders or clients about how PDC functions fit into the broader DoHA HTA functional responsibility 	<ul style="list-style-type: none"> • does not have an application tracking component (i.e. status of an application at any point in time) • does not inform stakeholders or clients about how PBAC functions fit into the broader DoHA HTA functional responsibility

Public Communication	Market entry	Public funding/subsidy Medical Benefits Schedule (MBS)	Private health insurance funding Prostheses List (PL)	Public funding/subsidy Pharmaceutical Benefits Scheme (PBS) National Immunisation Program (NIP)
Issues – Submissions	Nil	<ul style="list-style-type: none"> Concerns about difficulties in finding information about the different HTA processes and how they link together. Lack of communication and provision of information to stakeholders. 	<ul style="list-style-type: none"> Concerns about difficulties in finding information about the different HTA processes and how they link together. No ability to track applications. Lack of communication and provision of information to stakeholders. 	Nil
Implications for option development	Future business case development for DoHA external communications about its HTA functions should consider options for providing integrated, interactive and inter-connected web-space (including a cost benefit analysis) to enhance its ability to communicate effectively with stakeholders.			

HTA Information Management	Market entry	Public funding/subsidy Medical Benefits Schedule (MBS)	Private health insurance funding Prostheses List (PL)	Public funding/subsidy Pharmaceutical Benefits Scheme (PBS) National Immunisation Program (NIP)
Overview	<p>TGA has a fully electronic application and tracking system with capacity for electronic input and output from the system including:</p> <ul style="list-style-type: none">• Web based application system with interactive forms which change according to responses and is updated automatically as TGA processes the application• Applications feed from web into a Lotus Notes database which TGA staff use to track applications (workflow system)• Workflow system allows assignment of different pathways (i.e. activities) depending on which assessment will occur• Can also assign tasks to individual TGA staff members• Workflow system contains form letters which can be automatically generated• System includes “stop clocks” for requests to sponsors• Outcome of assessment (if positive) feeds from workflow system into an Oracle database which is the ARTG.• The content of the Oracle database feeds onto TGA’s website to allow public viewing of the ARTG.• Sponsors can log onto TGA’s application system at any time to determine application status	<p>MSAC:</p> <ul style="list-style-type: none">• does not have an electronic application system• uses an Access database to store application information and process applications.• requires application data to be entered manually from paper forms into the database.• Applicants and members can check application progress from the MSAC website which is regularly updated.• MSAC utilises its website as a secure portal for MSAC members to access relevant Committee documents.• Recent MSAC agreement to have “stop clock” for on hold applications. <p>MBS Items and fees are stored on a stand-alone database. Information from the database is uploaded to MBS on-line as required to update the MBS. The MBS database also produces a file to update Medicare Australia’s IT systems for administration of Medicare. As well as private health insurers.</p> <p>Database information is up-loaded to MBS on-line as required in the implementation process – the MBS on-line website is produced out of an Oracle database</p>	<p>PDC:</p> <ul style="list-style-type: none">• does not have an electronic application system• uses an Access database to store application information and process applications.• requires application data to be entered manually from paper forms into the database.• can use the data base to track application progress, but in a very low level, unsophisticated way.• uses the Access database to produce the various formats of the Prostheses List.	<p>PBAC:</p> <ul style="list-style-type: none">• does not have an electronic application system – it receives very large submissions including extra information provided on discs.• uses a Delphi database to store application information – the database can track progress of applications and is largely used in-house (as applications are commercial-in-confidence).
Current reform activity	Nil	<p>Working towards an electronic application form emailed to dedicated mailbox for direct upload into the MSAC access database.</p> <p>Further extension to the secure portal facility will be provided to Advisory Panel and evaluators during the assessment phase – this will be time limited.</p>	<p>The Department’s Business Group has been engaged to review the IT needs of the Prostheses Section with a needs analysis about 75% complete. Particular focus has been on assessment database requirements and the implementation of electronic applications and lodgement.</p>	Nil

HTA Information Management	Market entry	Public funding/subsidy Medical Benefits Schedule (MBS)	Private health insurance funding Prostheses List (PL)	Public funding/subsidy Pharmaceutical Benefits Scheme (PBS) National Immunisation Program (NIP)
Issues – Department Analysis	The TGA's system is not interactive or compatible with MSAC, PBAC and PDC systems.	<ul style="list-style-type: none"> MSAC uses electronic systems to store application information but does not have capacity for electronic input and output to/from other systems. MSAC's system is not interactive or compatible with TGA, PBAC, PDC or MBS database or MBS on-line. 	<ul style="list-style-type: none"> PDC uses electronic systems to store application information but does not have capacity for electronic input and output to/from other systems. PDC system does not interact with those of MSAC or TGA. it is a difficult and time consuming process to determine the status of any application or amendment at a particular point in the Prostheses Listing cycle. The creation of a Prostheses List is time consuming, due to the limited functionality of the current database that is used to create the List. 	<ul style="list-style-type: none"> PBAC uses electronic systems to store application information but does not have capacity for electronic input and output to/from other systems. PBAC system does not interact with those of MSAC or TGA.
Issues – Submissions	Concerns about information sharing and especially decisions that impact across agencies	Concerns that officers within the same agency do not communicate with each other	<ul style="list-style-type: none"> Lack of a tracking system. Concerns about information sharing. 	Nil
Implications for option development	Future business case development for DoHA information management systems to support its HTA functions should consider options for providing integrated, interactive and inter-connected web-space (including a cost benefit analysis) to enhance its ability to communicate effectively with stakeholders.			

Frequency of Applications/ Inclusion in Schedule/List/ Register	Market entry	Public funding/subsidy Medical Benefits Schedule (MBS)	Private health insurance funding Prostheses List (PL)	Public funding/subsidy Pharmaceutical Benefits Scheme (PBS) National Immunisation Program (NIP)
Overview <ol style="list-style-type: none"> application frequency update to list/schedule/register what is the format of the output? 	<ol style="list-style-type: none"> Applications accepted daily ARTG is updated daily The ARTG is an electronic database and is available via the TGA's website. 	<ol style="list-style-type: none"> Applications accepted daily There is a general remake of the MBS in November, but updates can be made as required. MBS is tabled as Regulations in Parliament. MBS is converted to electronic formats for public use. 	<ol style="list-style-type: none"> Applications accepted six monthly List published February/August, but can be updated as required. PL is tabled as Rules (disallowable instrument) in Parliament. PL is converted to electronic formats for public use. 	<ol style="list-style-type: none"> Applications accepted daily; however there is a deadline to reach the meeting. PBAC meets three times per year; major and minor submissions must be made 17 and 11 weeks, respectively, prior to each meeting. Schedule of Pharmaceutical Benefits is updated monthly, however the prices can only change three times a year. Legislative instruments.
Current reform activity	Nil	Nil	Nil	Nil
Issues – Department Analysis	Nil	Stakeholders would prefer more regular updates to the MBS because this would improve patient access to new services/procedures.	<ul style="list-style-type: none"> Stakeholders claim that the biannual application process is too infrequent for products that have a lifecycle of only a few years. Especially where other HTA processes (eg ARTG or MBS listing) can adversely delay a sponsor's listing by a further six months. Hospital representatives are concerned about the level of administration required to implement the PL at the hospital level. Any changes to the PL require hospitals to update their systems and contact doctors. A system of "real-time" approval would be administratively unsustainable. Some stakeholders have expressed difficulty in using the PL to identify comparable products despite different formats. 	Nil

Frequency of Applications/ Inclusion in Schedule/List/ Register	Market entry	Public funding/subsidy Medical Benefits Schedule (MBS)	Private health insurance funding Prostheses List (PL)	Public funding/subsidy Pharmaceutical Benefits Scheme (PBS) National Immunisation Program (NIP)
Issues – Submissions	Nil	Concerns that delays in listing can preclude patients access to new procedures	<ul style="list-style-type: none"> Concern at only 2 listing per annum. Delays due to sequential TGA and PDC processes. Concern at the early cut-off dates for applications. Note that the cyclical nature of the PL means that sponsors are assured of an outcome, but that if key deadlines are missed, products may not appear until the next PL. Increasing errors made by PDC and unfair rejections which are not rectified for a whole cycle. 	Nil
Implications for option development	In determining how frequently a List/Schedule/Register is updated, there is a need to consider the impact (i.e. workload) on stakeholders who use these, and the perceived advantage of more frequent updates.			

HTA Process – Application Phase	Market entry	Public funding/subsidy Medical Benefits Schedule (MBS)	Private health insurance funding Prostheses List (PL)	Public funding/subsidy Pharmaceutical Benefits Scheme (PBS) National Immunisation Program (NIP)
Overview a. Who can make an application? b. Pre-requisites for applications c. Assessment pathway(s) d. Implication of the choice of assessment pathway e. What information is collected during the application phase? f. What is the format of an application and supporting data? g. Number of copies required h. Pre-meeting with applicants?	a. Conformity Assessment Certificate – Manufacturer ARTG Entry – Sponsor b. Nil c. Multiple assessment pathways to accommodate existing overseas approvals and the materials of the medical device. d. The assessment pathway determines what supporting information is required and the length of time for market authorisation. e. May include: <ul style="list-style-type: none"> • Evidence to support overseas approvals • Essential Principles checklist • Product information • Risk management report • Clinical evidence f. Electronic application, paper supporting data g. Many applications are reviewed 'on-screen' and no supporting documentation is required. Two copies where supporting documentation is required h. Pre-submission meetings between sponsors and/or manufacturers are encouraged for both ARTG applications and conformity assessment applications, particularly to resolve any lack of clarity for either party before a submission is lodged.	a. Anyone, but typically medical colleges or the device industry b. ARTG Number or proof of TGA exemption c. Single assessment pathway that includes a full contracted evaluation. d. N/A e. May include: <ul style="list-style-type: none"> • Description of the service • Estimated utilisation of the service • Comparators for the service • Clinical evidence – literature search, • Economic information f. Paper application and supporting data (electronic version where possible) g. two copies h. conducts a pre-lodgement meeting	a. Sponsor of a prosthesis b. ARTG Number and MBS Item c. Three assessment pathways: <ul style="list-style-type: none"> • new applications • applications to amend and applications to duplicate • expand, compress or transfer existing products d. New applications require clinical assessment and benefit negotiation. e. Applications to amend an existing product may or may not require clinical assessment. Applications to duplicate or transfer an existing product do not require clinical assessment or benefit negotiation. Applications to expand or compress an existing product will require clinical assessment and benefit negotiation. Irrespective of the pathway chosen, all products (if approved) will appear on the Prostheses List at same time. Supporting information changes according to the pathway chosen. May include: <ul style="list-style-type: none"> • Clinical evidence – safety and efficacy data, credible clinical trials, comparable clinical evidence • Surgical technique • Product information • Indications of the product • paper application and supporting data • five copies • pre-meetings not held 	a. Anyone can make a submission to PBAC for listing of a medicine; however, the sponsor of the medicine is in the best position to provide information regarding cost-effectiveness. The sponsor decides whether to proceed with listing and provides relevant information to DoHA. b. TGA delegate's written proposal to add to ARTG. c. Applications can be assessed at three levels: <ul style="list-style-type: none"> • evaluation by the Pharmaceutical Evaluation Section • review by subcommittee members • review by PBAC members. d. The assessment pathway is determined by the type of submission including major and minor submissions, listing of generic equivalents and resubmissions. The type of submission determines what supporting information is required as outlined in the Guidelines. e. May include: <ul style="list-style-type: none"> • Details of the proposed drug and its intended use on the PBS • Pharmacological class and action • Indications and requested restrictions • Treatment details • Main comparator and differences between proposed drug • Clinical evaluation including literature search where applicable • Economic evaluation • Estimated extent of use and financial implications f. Main body of submission must be a separate bound document including key reports of relevant trials. Other information may be provided as attachments or technical documents. Applications must be submitted in hard copy (also electronically on disc). g. 12 copies of the main submission and attachments – three copies of the references. h. With the applicant, when requested by the applicant.

HTA Process – Application Phase	Market entry	Public funding/subsidy Medical Benefits Schedule (MBS)	Private health insurance funding Protheses List (PL)	Public funding/subsidy Pharmaceutical Benefits Scheme (PBS) National Immunisation Program (NIP)
Timeframe to accept an application	Immediate for ARTG applications Within 30 days for conformity assessment applications	Eligibility 70 days: includes sign off by TGA that appropriate TGA listing is in place (currently longest time in eligibility process). Also includes consultation with DoHA Medical Advisers regarding nature of service and with policy areas for consistency with Government policy. MSAC Executive agrees eligibility and advisory panel membership.	Ten working days	Immediate
Current reform activity	TGA is currently reviewing its third party conformity assessment (TPCA) arrangements including consultation with industry.	<ul style="list-style-type: none"> Will be seeking to formalise TGA advice through regular scheduled meeting. Targeted assessments 	ACD is currently redefining its clinical evidence requirements for new applications. This includes escalation requirements depending on whether the product is a me-too item, a low risk item or a high risk item.	Investigating 2 pilot projects (through AMWG): <ol style="list-style-type: none"> enhanced pre-submission meetings early and extended evaluations

HTA Process – Application Phase	Market entry	Public funding/subsidy Medical Benefits Schedule (MBS)	Private health insurance funding Prostheses List (PL)	Public funding/subsidy Pharmaceutical Benefits Scheme (PBS) National Immunisation Program (NIP)
Issues – Department Analysis	<ul style="list-style-type: none"> Domestic manufacturers contend that choice of TPCA body would reduce regulation timeframes and costs and create a level playing field with overseas manufacturers. Concerns were raised about excessive timeframes for the processing of applications for registration of higher risk devices. It is an industry 'claim' that there is insufficient recognition of overseas regulatory approval processes and assessments but is not supported by the evidence: <ul style="list-style-type: none"> 90% of applications are accepted solely on the basis of overseas evidence of prior assessment, 8% are accepted on the basis of a review of reports generated by overseas assessment bodies Only 2% are subject to conformity assessment by the TGA 	<ul style="list-style-type: none"> MSAC Secretariat accepts applications of varying quality (including referrals from within DoHA). If eligible, applications are all processed through one assessment pathway. MSAC evaluations are funded by DoHA and are currently at a commitment of approximately \$7 million over three years to mid 2010 	<ul style="list-style-type: none"> Prostheses Section accepts applications of varying quality Individual CAGs have come to differing views on what constitutes acceptable evidence of clinical effectiveness Sponsors argue that some of these requirements are difficult to meet, and are probably excessive for applications for products that are simply a new version of an existing model or a "me-too" version of a product from another manufacturer. Insurers propose that items should not be included on the PL unless they have undergone clinical trials for two years The PL Guide provides information on application processing activities and time frames. This is not replicated in the application forms or on the website. 	Nil
Issues – Submissions	<ul style="list-style-type: none"> Industry claims that the same evidence for clinical assessment is requested for at least two of the processes (TGA and PDC). Lack of harmonisation meaning that TGA approval is required for internationally approved goods. 	<ul style="list-style-type: none"> Some claim that pre-lodgement meetings need to be more prescriptive about the information to be included in an application to give greater certainty of success. Applications should be triaged according to complexity and level of risk. 	<ul style="list-style-type: none"> Industry claims that the same evidence for clinical assessment is requested for at least two of the processes (TGA and PDC). Applications for listing on the PL cannot be processed without TGA registration at the cut-off date for the publication of the PL. Some would like to see greater use of a pre-lodgement meeting. Concerns at delays caused by sequential assessment processes. 	Lack of streamlining between TGA approval and PBAC deadlines.
Implications for option development	Future development of DoHA HTA application guidelines and forms could be standardised to ensure applicants are provided with the necessary information to understand how the HTA functions interrelate including consideration of electronic processing.			

HTA Process – Assessment Phase	Market entry	Public funding/subsidy Medical Benefits Schedule (MBS)	Private health insurance funding Prostheses List (PL)	Public funding/subsidy Pharmaceutical Benefits Scheme (PBS) National Immunisation Program (NIP)
Overview <ol style="list-style-type: none"> Purpose of the assessment Information sources for the assessment Who does the assessment? What happens with the assessment outcome? Seeking further information from the applicant during the assessment process 	<ol style="list-style-type: none"> Determine if product is safe, performs as intended and produced using appropriate quality controls – approval for entry to the Australian market. Evidence provided by the applicant TGA staff have expertise in relevant areas (eg engineering, material science, clinical practice). However, MDEC reviews and provides expert advice to TGA on more complex conformity assessment applications, or applications introducing new treatment modalities or technologies. TGA takes this advice into account when deciding whether a conformity assessment application should be approved. An assessment report is considered by the delegate (TGA Officer) who will decide if application is approved. During the assessment process, the coordinating assessor will correspond with the applicant under s41JA of the TG Act to seek clarification or further information to assist further progression of the application. 	<ol style="list-style-type: none"> Advise the Minister on the strength of the evidence after a comparative assessment of the evidence for safety, efficacy, clinical effectiveness and cost-effectiveness of the medical service leading to approval for a Medicare rebate. Application is assessed in conjunction with the contracted evaluators and the expert advisory panel. Evidence is provided by the applicant however a contracted systematic literature review and an analysis of the strength of the evidence for safety, effectiveness and cost-effectiveness is provided to MSAC along with the applicant's comment on the report and evaluators rejoinder. Contracted evaluators guided by an expert advisory panel managed by DoHA produce a written report. MSAC provides advice to the Minister based on the written report and its own expert opinion. Assessment report is considered by MSAC and advice is sent to the Minister. Applicant is notified of MSAC's advice 	<ol style="list-style-type: none"> Comparative assessment of clinical effectiveness to inform benefit negotiations. Once completed, advice is provided to Minister (delegate) on what products should be included on the List and at what benefit. Evidence provided by the applicant. Independent clinicians undertake the clinical assessment. Clinical assessment is considered by PDC who will recommend (or not) that a product be included on the PL. Application (if recommended) is referred to PDNG for benefit negotiation. Once the benefit is agreed between the sponsor and PDNG, PDC considers the benefits and recommends to the Minister (delegate) that the product be listed at a particular benefit. If PDC recommends that a product is declined for listing, the applicant is sent a letter with reasons and provided with one opportunity to respond with clarification information ("initial decline letter"). 	<ol style="list-style-type: none"> Assesses the value for money of a proposed drug. PBAC considers the clinical place, overall effectiveness, cost and cost-effectiveness of a proposed drug compared with other drugs already listed in the PBS for the same, or similar, indications. Where there is no listed alternative, PBAC considers the clinical place, overall effectiveness, cost and cost-effectiveness of the proposed drug compared with standard medical care. Evidence provided by the applicant Clinical, economic and financial assessment is performed by evaluators in conjunction with the ESC and the DUSC. The sponsor is invited to provide comment on these assessments. PBAC makes recommendations based on the evidence provided by the applicant. Positive recommendations are sent to the Minister... On an as-needs basis as identified by the Department. Applicants are provided two opportunities to comment on the assessment – once the Department completes its review and after the PBAC Subcommittee completes its review.

HTA Process – Assessment Phase	Market entry	Public funding/subsidy Medical Benefits Schedule (MBS)	Private health insurance funding Prostheses List (PL)	Public funding/subsidy Pharmaceutical Benefits Scheme (PBS) National Immunisation Program (NIP)
Current reform activity	TGA is currently reviewing its third party conformity assessment (TPCA) arrangements including consultation with industry.	<ul style="list-style-type: none"> The Department is investigating the possibility of an application based assessment or applicant making a presentation to MSAC about their service Currently the MSAC ESC is working with the Department to improve aspects of implementation including relevant economic information and clinical descriptors within the contracted reports. Targeted assessments 	Workshop with TGA scientists and PDC clinicians scheduled for August 2009 to review current requirements for safety and clinical effectiveness assessments.	Nil
Issues – Department Analysis	<ul style="list-style-type: none"> Uses internal expertise to undertake assessment – the advantage of this is that there is greater control over the timing of assessment activities. The potential disadvantage is that over time, unless further training occurs, the experience of the staff becomes less relevant and therefore may be subject to greater scrutiny by stakeholders 	<ul style="list-style-type: none"> Assessment process is outsourced to contracted external HTA expertise with agreed timeframes and deliverables. Process relies on good contract management and capacity to ensure deliverables meet MSAC requirements. MSAC cost effectiveness evaluations may be more thorough and require greater levels of evidence than other HTA processes because all MSAC advice is taken into the implementation phase by the Minister requires detailed costing and modelling for DoFD endorsement of the listing cost to Government. The link between MSAC advice and MBS fees and descriptors agreed by consultative committees may be less robust than for other HTA bodies. 	<ul style="list-style-type: none"> Assessment process is outsourced to expert clinicians paid by DoHA from the cost recovery pool. Concerns have been expressed that the PDC clinical assessment process includes consideration of product safety, which has been assessed by TGA. Limited opportunities are provided to sponsors to comment on assessments Outcomes of PDC and CAG meetings are not provided on DoHA website which has raised concerns about process transparency. Applicants have commented that the reasoning provided in the initial decline letter is inadequate and does not provide sufficient information to understand why the application was declined. 	Uses internal and external expertise to assess applications

HTA Process – Assessment Phase	Market entry	Public funding/subsidy Medical Benefits Schedule (MBS)	Private health insurance funding Prostheses List (PL)	Public funding/subsidy Pharmaceutical Benefits Scheme (PBS) National Immunisation Program (NIP)
Issues – Submissions	Some stakeholders suggest that they should have a choice of certification body for conformity assessment	<ul style="list-style-type: none"> Assessment phase is too long, with lack of clarity about how different technologies are assessed. Lack of clear criteria and assessment approaches and evidentiary requirements. Lack of communication with sponsors. Not enough information or warning provided for rejection. 	<ul style="list-style-type: none"> Most agree with the government decision to sort prostheses into groups to inform benefit negotiations. Lack of communication with sponsors. Not enough information or warning provided for rejection. 	Nil
Implications for option development	Quality HTA expertise – whether sourced externally or internally – is key to ensuring that HTA assessments are conducted in accordance with advisory committee requirements and consistently across the different HTA functions, where appropriate.			

HTA Process – Benefit/Fee Negotiation Phase	Market entry	Public funding/subsidy Medical Benefits Schedule (MBS)	Private health insurance funding Prostheses List (PL)	Public funding/subsidy Pharmaceutical Benefits Scheme (PBS) National Immunisation Program (NIP)
Overview <ol style="list-style-type: none"> When does it occur? Who does it? What happens? 	Not applicable	<ol style="list-style-type: none"> Fee negotiation occurs as part of the implementation phase. MBD in conjunction with craft group See approval for listing phase – next major heading. 	<ol style="list-style-type: none"> Before delegate approval PDNG (on behalf of the PDC) Once PDC has recommended a product should be listed, it is referred to PDNG for negotiation of a benefit. PDNG negotiates the benefit with the sponsor. Generally negotiations will have two rounds – an initial offer from PDNG and a revised offer from PDNG based on the sponsor's response. Sponsors have 10 working days to respond to the initial offer and five working days to respond to the second offer. The same procedure applies when the benefit of an existing product on the List is reviewed. The benefit negotiation process occurs after clinical assessment is completed. Recently, clinical assessment has been delayed resulting in insufficient time to conduct benefit negotiations within the above timeframes. Consequently, PDC introduced an "abridged negotiation process" in which a sponsor could either accept an offer (which they may not agree with) and be included in the subsequent PL pending the formal benefit negotiation process in the subsequent cycle, or not list the product at all. 	<ol style="list-style-type: none"> Following positive recommendation from PBAC PBPA advises Departmental Officers who negotiate with applicant PBPA Secretariat provides advice to Minister (or delegate) who determines the outcome.
Current reform activity	Nil	Closer interaction between MBD area responsible for implementation and MSAC Secretariat is proposed to improve relevant information capture in applications and in the subsequent MSAC report and MSAC advice.	Policy and procedure work is continuing with the PDC to implement Review by Exception. A draft paper will be released to stakeholders shortly for comment.	Implementation of a deed of agreement. Ongoing work on risk sharing arrangements within these deeds

HTA Process – Benefit/Fee Negotiation Phase	Market entry	Public funding/subsidy Medical Benefits Schedule (MBS)	Private health insurance funding Prostheses List (PL)	Public funding/subsidy Pharmaceutical Benefits Scheme (PBS) National Immunisation Program (NIP)
Issues – Department Analysis	Nil	Nil	<p>Abridged benefit negotiation process:</p> <ul style="list-style-type: none"> Leads to some sponsors not choosing to list as they are not happy with the benefit Adds workload to next cycle as benefit needs to be properly negotiated in the next cycle <p>Benefit negotiation process:</p> <ul style="list-style-type: none"> Sponsors – not a true negotiation as no bargaining between equal parties occurs Sponsors – criticise the “punitive” pricing policy, in some instances the PDC will recommend a lower benefit than the PDNG offered Hospitals – concern that sponsors add freight charges as these are not covered by the benefit <p>Australian manufacturers:</p> <ul style="list-style-type: none"> Premium should be offered for Australian made or benefit determined on basis of design, not clinical data <p>Gaps:</p> <ul style="list-style-type: none"> Not a concern as sponsors waive gaps, hospitals do not supply gap products or hospitals absorb gaps Exist as a safety valve to allow sponsors to list products, even if not satisfied with offered benefit Should be at least one gap item per MBS item, however some MBS items only have one suitable prosthesis – result is monopoly pricing 	Nil

HTA Process – Benefit/Fee Negotiation Phase	Market entry	Public funding/subsidy Medical Benefits Schedule (MBS)	Private health insurance funding Prostheses List (PL)	Public funding/subsidy Pharmaceutical Benefits Scheme (PBS) National Immunisation Program (NIP)
Issues – Submissions	Nil	<ul style="list-style-type: none"> Some assume that MSAC's consideration of the inputs for cost effectiveness should inform benefit negotiations. Delays at this stage. Lack of transparency around final MBS item price. Lack of fee negotiation following rejections. 	<ul style="list-style-type: none"> Lack clarity around how reimbursement amounts are selected for prostheses or why, the principle of comparable product group prices is not consistently maintained. Concerns at fairness of fee negotiations and low fee increases. Call to decrease gaps, whilst reserving the right to charge gap fees. Inequities whereby the public system may get reimbursement for a product that the private system does not. 	Nil
Implications for option development	When setting fees/benefits, there is a need to ensure that determination of these is made such that they can be justified without question.			

HTA Process – Approval for Listing Phase	Market entry	Public funding/subsidy Medical Benefits Schedule (MBS)	Private health insurance funding Prostheses List (PL)	Public funding/subsidy Pharmaceutical Benefits Scheme (PBS) National Immunisation Program (NIP)
Overview <ol style="list-style-type: none"> who does it? what happens with approval? advice to applicants on the outcome of the assessment appeal provisions 	<ol style="list-style-type: none"> Secretary, delegated to Officers within TGA Product is entered onto the ARTG via electronic system. Applicant can monitor application progress and decision online. Applicant is also notified by letter and certificate of inclusion. <p>If application is rejected, applicant is notified by letter including reasons for rejection and advice about appeal processes.</p> <ol style="list-style-type: none"> s60 of the TG Act provides capacity to appeal a decision. The appeal is heard by (usually) TGA's Principal Medical Advisor who is not involved in the original decision. 	<ol style="list-style-type: none"> Minister – notes MSAC's advice. To prepare for listing: <ul style="list-style-type: none"> Once the Minister has noted MSAC's advice, the MSAC Secretariat liaises with the appropriate MBD implementing section about developing an item descriptor, negotiating a fee for the service based on the MSAC report and in consultation with the medical profession. Costings are developed and must be agreed with DoFD. Once costings are agreed with DoFD, the proposed MBS item descriptor, fee and costings are forwarded to the Minister for approval. Once approval is given the Health Insurance Regulations are drafted and sent to the Minister for approval and finally to EXCO for registration on the federal register of legislative instruments. Applicants and Advisory Panel are advised in writing within two weeks of the Minister noting MSAC's advice on the outcome of the assessment and a debrief is offered. There are no formal appeal provisions regarding the outcome of the assessment. 	<ol style="list-style-type: none"> Delegated to officer within Department (AS) To prepare for delegate to sign the Prostheses Rules, the following activities occur: <ul style="list-style-type: none"> Delegate grants new application and seeks payment of initial listing fees (sponsors are allowed 14 calendar days in which to pay) Applicants are also advised of which applications have not been granted. Payment status of ongoing listing fees is confirmed – twice during a calendar year, sponsors are levied a fee to maintain existing products on the PL. If this is unpaid, then the product(s) will be removed from the subsequent PL. Draft list is created in Access and sent to sponsors for checking Final list is prepared and attached to a Minute to the PHIB and also includes the Prostheses Rules which are signed – this gives rise to the PL. Signed Prostheses Rules are given to FRU for registration to take effect as law. Once FRU has registered the Rules, various electronic versions of the PL are published on DoHA's website. Stakeholders are advised of the PL availability via PHI Circular. <p>The Prostheses Rules take effect 10 working days after they are registered to allow insurers and hospitals to update their payment systems.</p> After the delegate has granted and not granted new applications, applicants are advised in writing. The non granting letters provide a statement of reasons and are the trigger for an internal review of the process. Internal Review is used to determine if process to reach a recommendation (list or not) or benefit negotiation process adhered to guidelines. The Internal Review application is made to the ACD FAS, but is conducted by the Attorney General's Department Internal Reviews can also be triggered by the publication of the Prostheses List. 	<ol style="list-style-type: none"> Cabinet/The Minister/delegate The Minister for Health and Ageing authorises the listing of items on the Schedule of Pharmaceutical Benefits by the tabling of legislative instruments which are registered on the Federal Register of Legislative Instruments. The listing is then published in the <i>Schedule of Pharmaceutical Benefits</i> <p>Publishing, Industry Liaison and Listing Section (PILLS) publish the <i>Schedule of Pharmaceutical Benefits</i>, provide a range of services to the pharmaceutical industry and manage processes concerned with product availability on the Pharmaceutical Benefits Scheme (PBS).</p> <ol style="list-style-type: none"> The applicant will receive a formal letter advising that the listing is approved approximately one month prior to the listing date. Independent Review Mechanism for most major submissions to PBAC. An application for procedural review may be made to the Federal Court.

HTA Process – Approval for Listing Phase	Market entry	Public funding/subsidy Medical Benefits Schedule (MBS)	Private health insurance funding Prostheses List (PL)	Public funding/subsidy Pharmaceutical Benefits Scheme (PBS) National Immunisation Program (NIP)
Current reform activity	Nil	<p>Improving alignment of information in applications, reports and advice to requirement for listing. Introduction of MSAC Chair's regular communiqué which includes advice regarding recent listings based on MSAC advice.</p>	Nil	Nil
Issues – Department Analysis	Nil	<ul style="list-style-type: none"> Timeliness around the implementation of the MSAC advice on the item/procedure onto the MBS is affected by the need to consult with DoFD and the medical profession and subsequent approval by the Minister (who provides policy approval for implementation and final approval for listing). The link between MSAC's conclusions and the MBS fees and descriptors agreed by the Consultative Committees is less robust than for other HTA bodies. Lack of formal appeal process. 	<ul style="list-style-type: none"> The IT systems used to create the PL require considerable time and manual input. This leads to errors. Depending on the nature of the errors, if they are not discovered prior to the Rules being signed by the delegate and registered with FRLJ, an amended List may need to be prepared. This involves similar processes as the original Rules. In recent cycles sponsors have been asked to pay the initial listing fees quicker than the 14 days to ensure that the products are included in the PL in time for its agreed publication. Hospitals and health insurers suggest that 10 working days from the date of publication to the date of effect of the PL is too short to upload the List and sort out informed financial consent issues. Reconciliation of the payment of initial and ongoing listing fees is a manual process and time consuming. Even if the internal review appeal is upheld, the original decision by the Minister's delegate will normally stand until the following List is produced, when amendments are made if appropriate.. 	Nil

HTA Process – Approval for Listing Phase	Market entry	Public funding/subsidy Medical Benefits Schedule (MBS)	Private health insurance funding Prostheses List (PL)	Public funding/subsidy Pharmaceutical Benefits Scheme (PBS) National Immunisation Program (NIP)
Issues – Submissions	Nil	<ul style="list-style-type: none"> • Lack of formal appeal process. • Rationale for decisions is not always clearly understood, particularly the evidentiary methods. • No publication of meeting minutes, discussions and decisions. • Lack of information about implementation of an application once MSAC has provided its advice to the Minister. 	<ul style="list-style-type: none"> • Lack of appeal process based on merit. Appeals based on error delay listing and cost. • No publication of meeting minutes, discussions and decisions. 	Concerned regarding appeal processes.
Implications for option development	Two of the four HTA functions commit Government funds, and this has an impact on which parties (i.e. Minister/DoFD/Cabinet) are involved in the approval and implementation phases.			

HTA Process – Post Market Surveillance	Market entry	Public funding/subsidy Medical Benefits Schedule (MBS)	Private health insurance funding Prostheses List (PL)	Public funding/subsidy Pharmaceutical Benefits Scheme (PBS) National Immunisation Program (NIP)
<p>Overview (includes Organised Disinvestment, Coverage with Evidence)</p>	<p>The TGA's post market arrangements are defined in legislation and guidance.</p> <p>Legislative requirements:</p> <ul style="list-style-type: none"> Manufacturers must hold and make available, technical documentation that demonstrates conformity of products with the essential principles and evidence that an appropriate conformity assessment procedure has been applied. Sponsors must have access to this evidence and be able to provide it on request. <p>Three components of TGA's post-market:</p> <ol style="list-style-type: none"> The manufacturer's post-market surveillance system; Post-market monitoring of market compliance by the TGA; and Vigilance programs. 	<p>Post market surveillance is not formally included in the MBS arrangements</p> <p>MSAC's TOR include provision for interim public funding and this can be construed as a form of post market activity.</p> <p>MSAC has on over 20 occasions recommended interim MBS funding for promising services / technologies. Mostly over a set period of time to collect data.</p> <p>The Department and Minister can refer MBS listed services and non-MBS listed services for Review by MSAC.</p> <p>MSAC has also undertaken evaluations for Nationally Funded Centres under the HealthPact AHMAC* arrangements.</p> <p>* As of 1 July 2009 Health Pact reports to AHMAC and CTEPC it is no longer a sub-committee of MSAC</p>	<p>Post market surveillance is not formally included in the prostheses arrangements.</p> <p>However, in recent cycles, the PDC Chair has advised the TGA of safety concerns with products being assessed for the PL. Product will not be included in the PL until TGA has resolved the safety concerns.</p> <p>PDC has agreed guidelines for use of NJRR data in the prostheses arrangements, specifically that the data will feed into the benefit negotiation process through CAGs grouping products according to NJRR performance, and establishing more detailed groupings and suffixes following their consideration of the data.</p>	<p>The Pharmaceutical Benefits Advisory Committee (PBAC) established the DUSC in 1988 under section 101A of the National Health Act 1953 to:</p> <ul style="list-style-type: none"> collect and analyse data on drug utilisation in Australia for use by the PBAC; make inter country comparisons of drug utilisation statistics; and to assist in generating information relating to rational use and prescribing of medicines. <p>The DUSC secretariat is responsible for publishing the Australian Statistics on Medicines on an annual basis.</p>
<p>Current reform activity</p>	<p>Nil</p>	<p>Implementation of the 2009-10 Budget Measure "Medicare Benefits Schedule – A framework for reviewing services"</p> <p>Implementation date 1 January 2010</p>	<p>2009/10 Budget measure to recover the cost of the NJRR from industry.</p>	<p>AMWG is currently reviewing the post market surveillance arrangements for the PBS/NIP.</p>

HTA Process – Post Market Surveillance	Market entry	Public funding/subsidy Medical Benefits Schedule (MBS)	Private health insurance funding Prostheses List (PL)	Public funding/subsidy Pharmaceutical Benefits Scheme (PBS) National Immunisation Program (NIP)
Issues – Department Analysis	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 being developed and implemented.	<ul style="list-style-type: none"> MBS Review is not systematic (see current reform activity). MSAC is generally not used to review existing MBS items. MBS interim funding has not routinely been reviewed by the Department. 	<p>A formal mechanism to report safety concerns to TGA would be supported by PDC members. Review of existing products against Criteria for Listing:</p> <ul style="list-style-type: none"> Was a key recommendation of Doyle Occurring for mandatory criteria with non-mandatory criteria to follow. <p>NJRR:</p> <ul style="list-style-type: none"> Data demonstrates new prostheses do not perform as well as older ones; Contrary view is that registry had promise but too early to draw definitive conclusions Would be helpful if the concept of the NJRR could be extended to other products ACSQH working to coordinate improvement in the quality and consistency of registry information. 	Nil
Issues – Submissions	<ul style="list-style-type: none"> Post market surveillance is currently too ad-hoc and passive As no pre market assessment process is 100% conclusive, it is important that post market monitoring is via clinical registries is in place Lack of consumer input. Lack of clarity around the responsibility of industry to report adverse events. Lack of enforcement of PMS pathways, eg. referring safety concerns to the TGA. 	<ul style="list-style-type: none"> The establishment of clinical registries would assist in informing evidence development for promising novel devices. Lack of Medicare item numbers for PMS. 	<ul style="list-style-type: none"> Strong support for the NJRR, and that this model be broadened to other prostheses. Lack of systematic PMS for prostheses (apart from the NJRR). 	Nil
Implications for option development	Going forward, a post market surveillance system should be part of all components of the HTA system and include such features as Coverage with Evidence and Organised Disinvestment.			

Attachment A1

Definition of a medical device (s41BD(1) of Therapeutic Goods Act 1989)

41BD What is a medical device

(1) A medical device is:

- (a) any instrument, apparatus, appliance, material or other article (whether used alone or in combination, and including the software necessary for its proper application) intended, by the person under whose name it is or is to be supplied, to be used for human beings for the purpose of one or more of the following:
 - (i) diagnosis, prevention, monitoring, treatment or alleviation of disease;
 - (ii) diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap;
 - (iii) investigation, replacement or modification of the anatomy or of a physiological process;
 - (iv) control of conception; and that does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but that may be assisted in its function by such means; or
- (b) an accessory to such an instrument, apparatus, appliance, material or other article.

Note: Declarations under subsection (3) exclude articles from the scope of this definition. Declarations under section 7 can also have this effect: see subsection 7(4).

(2) For the purposes of paragraph (1)(a), the purpose for which an article is to be used is to be ascertained from the information supplied, by the person under whose name the article is or is to be supplied, on or in any one or more of the following:

- (a) the labelling on the article;
- (b) the instructions for using the article;
- (c) any advertising material relating to the article.

(3) The Secretary may, by order published in the *Gazette*, declare that a particular instrument, apparatus, appliance, material or other article, or that a particular class of instruments, apparatus, appliances, materials or other articles, are not, for the purposes of this Act, medical devices.

Note: A declaration under this section does not stop articles from being therapeutic goods.

(4) A declaration under this section takes effect on the day on which the declaration is published in the *Gazette* or on such later day as is specified in the order.

Attachment A2

Definition of a professional service (Part 1, Preliminary Section 3 of Health Insurance Act 1973)

Professional service means:

- (a) a service (other than a diagnostic imaging service) to which an item relates, being a clinically relevant service that is rendered by or on behalf of a medical practitioner; or
- (b) a prescribed medical service to which an item relates, being a clinically relevant service that is rendered by a dental practitioner approved by the Minister in writing for the purposes of this definition; or
- (ba) a service specified in an item that is expressed to relate to a professional attendance by an accredited dental practitioner, being a clinically relevant service that is rendered by an accredited dental practitioner to a prescribed dental patient; or
- (c) a service specified in an item that is expressed to relate to a professional attendance by a participating optometrist, being a clinically relevant service that is rendered by an optometrist, being a participating optometrist or an optometrist acting on behalf of a participating optometrist; or
- (d) a pathology service that is rendered by or on behalf of an approved pathology practitioner pursuant to a request made in accordance with subsection 16A(4) by:
 - (i) a treating practitioner; or
 - (ii) another approved pathology practitioner to whom the treating practitioner has made a request for the service; or
- (e) a pathology service (other than a service referred to in paragraph (d)) that is a clinically relevant service rendered by or on behalf of an approved pathology practitioner other than a medical practitioner; or
- (f) a diagnostic imaging service that is rendered by or on behalf of a medical practitioner pursuant to a subsection 16B(1) request; or
- (g) a diagnostic imaging service (other than a service referred to in paragraph (f)) that is a clinically relevant service rendered by or on behalf of a medical practitioner.

Attachment A3

Benefit requirements for a product (Eligibility criteria for the Prostheses List – s72-1 of Private Health Insurance Act 2007)

72-1 Benefit requirements

- (1) An insurance policy that *covers *hospital treatment meets the benefit requirements in this Division if:
 - (a) the policy meets the requirements in the table in subsection (2); and
 - (b) the policy meets any requirements specified in the Private Health Insurance (Complying Product) Rules to be benefit requirements; and
 - (c) the policy does not provide benefits for:
 - (i) the cost of care and accommodation in an aged care service (within the meaning of the *Aged Care Act 1997*); or
 - (ii) a charge for a pharmaceutical benefit supplied under Part VII of the *National Health Act 1953*, unless the circumstances of the charge are covered by section 92B of that Act; or
 - (iii) any other treatment specified in the Private Health Insurance (Complying Product) Rules as a treatment for which benefits must not be provided; and
 - (d) the *rules of the private health insurer that issues the policy meet the rules requirement in section 72-5.
- (2) These are the requirements that a policy must meet for the purposes of paragraph (1)(a):

Requirements that a policy that * covers *hospital treatment must meet		
Item	There must be a benefit for ...	The amount of the benefit must be ...
1	any part of *hospital treatment that is one or more of the following: (a) psychiatric care; (b) rehabilitation; (c) palliative care; if the treatment is provided in a *hospital and no *medicare benefit is payable for that part of the treatment.	at least the amount set out, or worked out using the method set out, in the Private Health Insurance (Benefit Requirements) Rules as the minimum benefit, or method for working out the minimum benefit, for that treatment.
2	*hospital treatment *covered under the policy for which a *medicare benefit is payable.	(a) if the charge for the treatment is less than the *schedule fee for the treatment—so much of the charge (if any) as exceeds 75% of the schedule fee; and (b) otherwise—at least 25% of the schedule fee for the treatment.
3	if the policy * covers *hospital-substitute treatment— hospital-substitute treatment covered under the policy for which a *medicare benefit is payable.	(a) if the charge for the treatment is less than the *schedule fee for the treatment—so much of the charge (if any) as exceeds 75% of the schedule fee; and (b) otherwise—at least 25% of the schedule fee for the treatment; but the benefit must not be provided if a medicare benefit of an amount that is at least 85% of the schedule fee is claimed for the treatment.
4	(a) *hospital treatment *covered under the policy; and (b) if the policy covers *hospital-substitute treatment— hospital-substitute treatment covered under the policy; that is the provision of a prosthesis of a kind listed in the Private Health Insurance (Prostheses) Rules in circumstances: (c) in which a *medicare benefit is payable; or (d) set out in the Private Health Insurance (Prostheses) Rules for the purposes of this table item.	(a) at least the amount set out, or worked out using the method set out, in the Private Health Insurance (Prostheses) Rules as the minimum benefit, or method for working out the minimum benefit, for the prosthesis; and (b) if the Private Health Insurance (Prostheses) Rules set out an amount, or a method for working out an amount, as the maximum benefit, or method for working out the maximum benefit, for the prosthesis—no more than that amount or the amount worked out using that method.
5	any treatment for which the Private Health Insurance (Benefit Requirements) Rules specify there must be a benefit.	at least the amount set out, or worked out using the method set out, in the Private Health Insurance (Benefit Requirements) Rules as the minimum benefit, or method for working out the minimum benefit, for that treatment.

Note: If a private health insurer provides an insured person with, or arranges for an insured person to be provided with, treatment, it is treated as a benefit for the purposes of this Division (see subsection 69-5(3)).

Attachment A4

Definition of a vaccine (s9B of National Health Act 1953)

9B Provision of vaccines

(1) The Minister may provide, or arrange for the provision of:

- (a) designated vaccines; and
- (b) goods or services that are associated with, or incidental to, the provision or administration of designated vaccines.

Designated vaccines

(2) The Minister may, by legislative instrument, determine that a specified vaccine is a *designated vaccine* for the purposes of this Act.

Note: For variation and revocation, see subsection 33(3) of the Acts Interpretation Act 1901.

(3) A vaccine may be specified by reference to any or all of the following:

- (a) brand;
- (b) formulation;
- (c) active ingredient;
- (d) strength;
- (e) number and timing of doses in a course of immunisation.

(4) Subsection (3) does not limit the ways in which a vaccine may be specified.

(5) In addition to specifying a vaccine, a determination under subsection (2) may specify the circumstances in which the vaccine may be provided.

(6) If any such circumstances are specified, subsection (1) only authorises the provision of the vaccine in those circumstances.

(7) A vaccine must not be specified in a determination under subsection (2) unless:

- (a) the Pharmaceutical Benefits Advisory Committee has recommended to the Minister that the vaccine be a designated vaccine; or
- (b) at any time during the 60-day period ending immediately before the commencement of this subsection, the vaccine was provided under repealed section 9B of this Act.

(8) Before:

- (a) revoking a determination under subsection (2); or
- (b) varying a determination under subsection (2) in such a way that a vaccine ceases to be a designated vaccine; the Minister must obtain the written advice of the Pharmaceutical Benefits Advisory Committee in relation to the proposed revocation or variation.

(9) An advice under subsection (8) is to be tabled in each House of the Parliament with the revocation or variation to which the advice relates.

(10) This section does not limit the vaccine-related powers conferred on the Minister by the Quarantine Act 1908.

Determination of a pharmaceutical benefit (s85 of National Health Act 1953)

85 Pharmaceutical benefits

(1) Benefits shall be provided by the Commonwealth, in accordance with this Part, in respect of pharmaceutical benefits.

Note: The Commonwealth may also provide the drugs and medicinal preparations covered by subsection 100AA(1) under special arrangements made under section 100.

(2) Subject to subsection (3), the drugs and medicinal preparations in relation to which this Part applies are:

- (a) drugs and medicinal preparations that are:
 - (i) declared by the Minister, by legislative instrument, to be drugs and medicinal preparations to which this Part applies; or
 - (ii) included in a class of drugs and medicinal preparations declared by the Minister, by legislative instrument, to be a class of drugs and medicinal preparations to which this Part applies; and
- (b) medicinal preparations composed of:
 - (i) one or more of the drugs and medicinal preparations referred to in paragraph (a), being a drug or medicinal preparation that is, or drugs and medicinal preparations that are, included in a class of drugs and medicinal preparations declared by the Minister, by legislative instrument, to be a class of drugs and medicinal preparations to which this paragraph applies; and
 - (ii) one or more of such additives as are declared by the Minister, by legislative instrument, to be additives to which this paragraph applies.

(2A) The Minister may, by legislative instrument:

- (a) determine that a particular pharmaceutical benefit is to be a relevant pharmaceutical benefit for the purposes of section 88A; and
- (b) specify the circumstances in which a prescription for the supply of the pharmaceutical benefit may be written.

(2AA) The Minister may, by legislative instrument, revoke or vary a declaration under subsection (2) in relation to a drug or medicinal preparation.

(2AB) If:

- (a) under subsection (2AA), the Minister proposes to revoke or vary a declaration under subsection (2) in relation to a drug or medicinal preparation; and
- (b) the drug or medicinal preparation would cease to be a listed drug on and after the day the revocation or variation comes into force; then, before making the revocation or variation, the Minister must obtain the advice in writing of the Pharmaceutical Benefits Advisory Committee in relation to the proposed revocation or variation.

(2AC) An advice under subsection (2AB) shall be laid before each House of the Parliament with the declaration under subsection (2AA) to which the advice relates.

(3) The Minister may, by legislative instrument, determine, by reference to strength, type of unit, size of unit or otherwise, the form or forms of a listed drug.

(4) A form of a listed drug as determined by the Minister under subsection (3) may be such as to require the addition of a substance or substances to the drug so that it will be suitable for administration in a particular manner or at a particular strength.

(5) The Minister may, by legislative instrument, determine the manner of administration of a form of a listed drug, being a form of the drug in relation to which a determination under subsection (3) is in force.

(6) The Minister may, by legislative instrument, determine a brand of a pharmaceutical item.

Attachment B1

Terms of Reference of MDEC (s35 of Therapeutic Goods Regulations 1990)

35 Medical Devices Evaluation Committee

- (1) The Medical Devices Evaluation Committee is established.
- (2) The functions of the Committee are:
 - (a) to give medical and scientific advice to the Minister or the Secretary in relation to any medical device that the Minister or the Secretary refers to it; and
 - (b) to give medical and scientific advice to the Minister or the Secretary in relation to any medicines that the Minister or the Secretary refers to it; and
 - (c) to give medical and scientific advice to the Minister or the Secretary in relation to any other therapeutic goods that the Minister or the Secretary refers to it; and
 - (d) to give advice to the Minister or the Secretary about the importation into, exportation from, and manufacture, distribution and supply in Australia, of therapeutic goods that have been assessed by the Committee; and
 - (e) to give advice that has been given to the Minister or the Secretary under paragraph
 - (d) to persons or bodies as the Minister may direct.

Attachment B2

Terms of Reference of MSAC

Advise the Minister for Health and Ageing on the strength of evidence pertaining to new and emerging medical technologies and procedures in relation to their safety, effectiveness and cost-effectiveness and under what circumstances public funding should be supported.

Advise the Minister for Health and Ageing on which new medical technologies and procedures should be funded on an interim basis to allow data to be assembled to determine their safety, effectiveness and cost-effectiveness.

Advise the Minister for Health and Ageing on references related either to new and/or existing medical technologies and procedures.

Undertake health technology assessment work referred by the Australian Health Ministers' Advisory Council (AHMAC) and report its findings to the AHMAC.

Attachment B3

Terms of Reference of PDC

The PDC makes recommendations to the Minister on appropriate listing and benefits of prostheses. In making recommendations, the PDC considers advice, and recommendations provided by:

- Clinical Advisory Groups;
- Panel of Clinical Experts;
- Prostheses and Devices Negotiating Group; and
- Sponsors of prostheses.

The PDC will consider and recommend the listing of products in a timely manner and draw to the attention of the Department possible amendments to the Prostheses List. The PDC may also report on any other issues it may wish to draw to the attention of the Minister.

Attachment B4

Terms of reference of PBAC (s101 of National Health Act 1953)

101 Functions of Pharmaceutical Benefits Advisory Committee

Functions relating to drugs and medicinal preparations

- (3) The Pharmaceutical Benefits Advisory Committee shall make recommendations to the Minister from time to time as to the drugs and medicinal preparations which it considers should be made available as pharmaceutical benefits or special pharmaceutical products under this Part and shall advise the Minister upon any other matter concerning the operation of this Part referred to it by the Minister.
- (3AA) The Pharmaceutical Benefits Advisory Committee must make recommendations to the Minister from time to time about what should be specified in a determination under subsection 84AAA(2).
- (3AB) Subsection (3AA) does not limit subsection (3).
- (3A) For the purpose of deciding whether to recommend to the Minister that a drug or medicinal preparation, or a class of drugs and medicinal preparations, be made available as pharmaceutical benefits or special pharmaceutical products under this Part, the Committee shall give consideration to the effectiveness and cost of therapy involving the use of the drug, preparation or class, including by comparing the effectiveness and cost of that therapy with that of alternative therapies, whether or not involving the use of other drugs or preparations.
- (3B) Without limiting the generality of subsection (3A), where therapy involving the use of a particular drug or medicinal preparation, or a class of drugs and medicinal preparations, is substantially more costly than an alternative therapy or alternative therapies, whether or not involving the use of other drugs or preparations, the Committee:
 - (a) shall not recommend to the Minister that the drug, preparation or class be made available as pharmaceutical benefits or special pharmaceutical products under this Part unless the Committee is satisfied that the first-mentioned therapy, for some patients, provides a significant improvement in efficacy or reduction of toxicity over the alternative therapy or therapies; and
 - (b) if the Committee does recommend to the Minister that the drug, preparation or class be made available as pharmaceutical benefits or special pharmaceutical products under this Part, the Committee shall include in its recommendation a statement that the Committee is satisfied as mentioned in paragraph (a).
- (3BA) If the Committee is of the opinion that a drug or medicinal preparation should be made available as a pharmaceutical benefit under this Part, the Committee must, in its recommendation under subsection (3), specify whether the drug or medicinal preparation and another drug or medicinal preparation should be treated as interchangeable on an individual patient basis.
- (3C) Where the Committee is of the opinion that a drug or medicinal preparation, or a class of drugs and medicinal preparations, should be made available as pharmaceutical benefits or special pharmaceutical products under this Part, but only in certain circumstances, the Committee shall, in its recommendation

under subsection (3), specify those circumstances.

- (4) A drug or medicinal preparation shall not be declared, pursuant to paragraph 85(2)(a), to be a drug or medicinal preparation in relation to which this Part applies unless:
 - (a) the drug or medicinal preparation was, immediately before the commencement of this subsection, a pharmaceutical benefit; or
 - (b) the Committee has recommended to the Minister that it be so declared.
- (4A) A class of drugs or medicinal preparations, or of drugs and medicinal preparations, shall not be declared, pursuant to paragraph 85(2)(a), to be a class of drugs or medicinal preparations, or of drugs and medicinal preparations, in relation to which this Part applies unless:
 - (a) each member of that class was, immediately before the commencement of this subsection, a pharmaceutical benefit; or
 - (b) the Committee has recommended to the Minister that the class be so declared.

Function relating to Minister's determination of therapeutic groups

- (4AA) If the Committee is of the opinion that the Minister should, or should not, determine a therapeutic group, the Committee must advise the Minister accordingly.

Function relating to Minister's determination about exempt items

- (4AB) If the Committee is of the opinion that the following circumstances exist in relation to a pharmaceutical item:
 - (a) the listed drug in the pharmaceutical item represents suitable therapy for a particular patient population;
 - (b) the pharmaceutical item is suitable for use by a particular subgroup of that population because of either or both of the form and manner of administration of the drug in the item;
 - (c) no other pharmaceutical item that has that drug is suitable for use by that subgroup because of either or both of the form and manner of administration of the drug in that other item; the Committee must advise the Minister that those circumstances exist in relation to the pharmaceutical item.

Function relating to Minister's decisions about prices of combination items

- (4AC) If the Committee is satisfied that therapy involving a combination item provides, for some patients:
 - (a) a significant improvement in patient compliance with the therapy; or
 - (b) a significant improvement in efficacy or reduction in toxicity; over alternative therapies, then the Committee must advise the Minister accordingly.

Functions relating to vaccines

- (4B) The Pharmaceutical Benefits Advisory Committee must:
 - (a) make recommendations to the Minister from time to time about the vaccines it considers should be designated vaccines (see section 9B); and
 - (b) advise the Minister about any other matter concerning the operation of section 9B referred to it by the Minister.
- (4C) For the purpose of deciding whether to recommend to the Minister that a vaccine be a designated vaccine, the Committee must give consideration to the effectiveness and cost of immunisation involving the use of the vaccine, including by comparing the effectiveness and cost of immunisation involving the use of the vaccine with the effectiveness and cost of alternative options, whether or not involving the use of other vaccines.
- (4D) If immunisation involving the use of a particular vaccine (the first vaccine) is substantially more costly than an alternative vaccine:
 - (a) the Committee must not recommend to the Minister that the first vaccine be a designated vaccine unless the Committee is satisfied that the first vaccine, for some individuals, provides a significant improvement in efficacy or reduction of toxicity over the alternative vaccine; and
 - (b) if the Committee recommends to the Minister that the first vaccine be a designated vaccine—the Committee must include in its recommendation a statement that the Committee is satisfied as mentioned in paragraph (a).
- (4E) Subsection (4D) does not limit subsection (4C).
- (4F) If the Committee is of the opinion that a vaccine should be a designated vaccine, but should only be provided under subsection 9B(1) in certain circumstances, the Committee must, in its recommendation under subsection (4B), specify those circumstances.

Appendix H: Report of Stakeholder Focus Groups – Issues Identification Phase

Review of Health Technology Assessment in Australia

Report of Stakeholder Focus Groups

18 June – 24 July 2009

Issues Identification Phase

Review of Health Technology Assessment in Australia, Report of Stakeholder Focus Groups, 18 June – 24

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1. Background to the HTA Review

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, jointly announced the Review of Health Technology Assessment (HTA) in Australia. The HTA Review is one of the first Better Regulation Ministerial Partnerships to be undertaken by the Australian Government. It is due to report in late 2009.

The HTA Review will make recommendations about options for improving process efficiency and reducing regulatory costs that can act as impediments to medical innovation, without compromising timely and affordable patient access to medical services and devices that:

- are demonstrated to be safe, effective and cost effective; and
- deliver improved outcomes and value for money.

The HTA Review, co-ordinated by the Commonwealth Department of Health and Ageing (the Department) will canvass opportunities for deregulation reform that are consistent with the Government's policy objectives, against the following (abridged) Terms of Reference:

1. Simplification and better co-ordination between the Commonwealth HTA processes (as identified in the Review scope), which includes:
 - consideration of a single entry point and tracking system for applications for market registration and funding;
 - making time to affordable access as short as possible for new technologies while maintaining or improving the rigour of evaluation processes; and
 - 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 and hybrid technologies.

The scope of the HTA Review includes the processes of the Medical Services Advisory Committee (MSAC) and the Prostheses and Devices Committee (PDC), and the Therapeutic Goods Administration's (TGA) regulation of therapeutic goods for market entry in Australia where there is duplication of MSAC and PDC processes. The Pharmaceutical Benefits Advisory Committee (PBAC) processes will also be considered where there is an interface between medical services and devices and pharmaceuticals.

The HTA Review will have regard to the outcomes of earlier reviews of HTA in Australia.

2. Background to the Focus Groups and this Report

Effective public consultation is an essential component of the HTA Review. Interested parties have had the opportunity to participate in the HTA Review to date through the following processes:

- **public submissions** against the HTA Review Terms of Reference through the Department's website;
- **a stakeholder reference group** involving key stakeholders meeting at key points during the HTA Review; and
- **a series of focus groups with stakeholders in major capital cities and by teleconference** to provide an opportunity for discussion and clarification of issues and priorities to be considered by the HTA Review.

A second round of focus groups will be held later in the year to explore options for change and improvement of HTA processes identified through stakeholder consultation and other research and analysis.

In addition, the Department has held bilateral discussions with key stakeholders and peak bodies and will hold another round of bilateral meetings later in the Review to test options to address the Review terms of reference and issues raised during the public consultation activities.

Between 18 June 2009 and 24 July 2009, 102 participants representing 90 different organisations participated in a total of 9 Focus Groups held in Canberra, Melbourne and Sydney and by teleconference from Perth, Melbourne and Sydney. Sessions were facilitated, and this Report prepared, by Origin Consulting.

Participation was by open invitation and an attempt was made to accommodate participants from the various sectors with an interest in HTA: industry, health professionals, health insurers and health consumers.

It should be noted however that the Department has initiated a separate process for gaining consumer input through the Consumers' Health Forum. This is currently underway and includes consideration of an issues paper on consumer concerns in regard to HTA at a one-day workshop. To some extent this separate process resulted in a reduced participation level in the Focus Groups by representatives of that sector. Nonetheless, consumer representatives did make an important contribution to the sessions in small numbers and the interests and perspectives of consumers of health technology were often raised by participants representing the other sectors.

While an effort was made to bring together stakeholders from the same sector in each Focus Group session, this goal was generally waived in the interest of ensuring that as many organisations as possible were able to participate by nominating a session that would suit their schedules. A diversity of participants in each session had the advantage of generating valuable discussion from different perspectives, often drawing out alternative viewpoints on particular issues. On the other hand, the mixing of various sectors of stakeholders also made it more difficult to clearly delineate the differences in the views of each group.

Discussion in the Focus Groups was structured around the following four key areas (and associated prompting questions) based on the HTA Review Terms of Reference.

1. Problems and areas for improvement in the operation of the current HTA system

- Do you think that the roles of the various agencies and participants taking part in the system are clear, well-defined and well-understood? Where is the greatest lack of clarity?
 - Do you see problems with duplication or co-ordination between HTA agencies and processes? Where are these problems most severe? What changes would make the most difference?
- Do you think HTA processes need to be simplified and if so how would you simplify them? What are the priority changes you would make?
- What do you think is the impact of problems or shortcomings in the current system and what would be the benefits and the risks of making changes or improvements?

2. Transparency and procedural fairness in the current system

- Do you think that there is enough public information about the rules and guidelines governing HTA and the steps in the processes? Are you confident that you can see into the workings and methods of the system at an appropriate level?
- Do you feel confident in the procedural fairness of the system? Do you think that the guidelines and rules are applied fairly and consistently, and that the processes operate reliably according to the rules?
- Do you feel you understand enough about how the HTA system performs overall, and if not, what are the information gaps? What do you want to know that you currently cannot find out? How would it help you to know more about the operation and impact of the system?

3. Post-market surveillance of medical devices

- Do you think current arrangements for post market surveillance of the ongoing safety and efficacy of medical devices are adequate?
- If not, what are the shortcomings and what would you like to see changed or improved?
- Who should be responsible for post market surveillance?

4. HTA in hybrid and co-dependent technologies

- What do you think are the challenges for HTA posed by the growth in co-dependent and hybrid technologies?
- In your opinion, how well do current HTA processes deal with these technologies?
- If enhancements are needed to HTA processes, what should they be?

Participants were asked for their viewpoints, opinions, experiences, observations and ideas about the current system, with the aim of identifying the key issues and priorities they felt should be addressed in the HTA Review. Although the focus of these sessions was to identify issues in the current system, as to be expected a number of options for change and forward directions emerged in discussions. These were captured in the recording and will also be reflected in the report below.

The following Report attempts to synthesise the main themes and issues emerging from the Focus Group sessions, highlighting priority concerns and noting areas of consensus or tension and contested views where they arose. While viewpoints or ideas will not be ascribed to individual participants or their organisations in this Report, the basis of participation in the sessions was an acknowledgement that participant input was not confidential.

3. Findings from the Focus Group Sessions

3.1 Introduction

There are three important caveats to the findings outlined in the Report below.

Firstly, Commonwealth Public Servants from the following Departments also attended the sessions strictly as observers and provided the rare point of clarification on request from participants:

- Department of Health and Ageing
- Department of Finance and Deregulation
- Department of Innovation, Industry, Science and Research

Given their observer status, the presence of Government representatives in the sessions does not imply Government agreement with the views or perspectives outlined below in this Report. The aim of the sessions was to capture the perceptions and views about the current HTA system in Australia from the perspective of the key stakeholder groups, without discussions influenced by input from Departmental officers.

Given that Departmental officers did not contribute unless they were expressly requested by participants to clarify an issue, they did not intervene, even in matters of fact where they believed that participants misunderstood current HTA processes, rules or arrangements or were describing them inaccurately or incorrectly. Some of the participant viewpoints contained in this report may be based on inaccurate understandings of the workings of some aspects of the current system. Nonetheless, all commonly expressed viewpoints have been included in order to convey the perceptions held by participants, whether or not they are based on accurate understandings of the system.

Secondly, it should be noted that as participation in the Focus Group sessions was by self-selection, the views expressed cannot be assumed to be 'representative' of the various stakeholder groups. Some participants may have been motivated to attend by holding particularly strong views on some aspect of HTA, and some may have chosen to come because they had not made a written submission while others did not attend because they had already submitted their views in writing.

Thirdly, it is important to note that, given the limited time available in the Focus Groups, questions and prompts concentrated on eliciting stakeholder views about problems or areas needing improvement in the current HTA system which the Review should address. Stakeholder feedback about the strengths of the system was sought only peripherally. This approach has therefore skewed Focus Group outcomes towards findings that are critical of the system.

A number of participants expressed the overarching view that the current Australian HTA system is sound and has a number of strengths. Nonetheless, they are pleased that the Review provides the opportunity to address some pressing problems in, and future requirements of the system. Participants also offered positive feedback about particular aspects of the system, and where relevant, these comments are included below but should not be assumed to be the only positive views about the system held by stakeholders.

3.2 Problems and areas for improvement in the current HTA System

This component of the Focus Group discussions considered the HTA system from the point of view of role clarity, duplication and co-ordination of processes, simplification needed and the impact of these issues. A number of other issues and areas for improvement in the current system that emerged in discussions are included at the end of this section.

Role clarity

The predominant view among participants in the Focus Group sessions was that the roles of and boundaries between individual HTA agencies are unclear. Many examples were given by sponsors of their confusion about where to enter the system and failed attempts to gain clarity about roles, responsibilities and boundaries from HTA agencies. Participants expressed concern about the current system's capacity to manage the growing demands of assessing hybrid and co-dependent technologies given these fundamental problems (see Section 3.5 below for more discussion of this issue).

There was a small number of participants who felt that role delineation between the agencies was clear, but it is probably fair to say that in general they had had close or long involvement with the agencies, sometimes in advisory roles, and therefore had gained greater insight into the workings of the system.

Of the agencies involved in HTA, TGA's role was best understood by participants. This was attributed to its clear focus on safety in terms well understood by participants and its clear processes, ground rules and predictable timelines. It was also generally considered to be the entry point or foundation for HTA, with participants looking for clear delineation of and rationale for the roles of the other agencies vis a vis the TGA and often finding this lacking.

MSAC's role, boundaries and workings were much less clear to participants.

In general, there was a view – particularly strongly held by a number of industry representatives – that safety assessment by MSAC was a straightforward duplication of the TGA's efforts. This view seemed often to be based on the argument that sponsors were being asked to supply MSAC with exactly the same information and evidence regarding safety of the applicant technology that they had been required to provide to TGA, therefore leading to the conclusion that the same assessment was being repeated.

In general, participants considered safety assessment to be TGA's role and there was limited understanding about the nature of MSAC's cost effectiveness methodologies and the role of safety assessment in evaluation of clinical effectiveness and how this might differ from the market entry safety assessment undertaken by TGA. The common participant view was that MSAC took an unacceptably long time to complete an assessment which was partly accounted for by its duplication of activity already conducted by the TGA.

PDC's role was the least understood of the agencies by Focus Group participants, with the exception of private health insurance representatives, who, understandably, had a stronger grasp of what the PDC does and why. PDC's role was expressed as a rationing gateway and some stated that it was operating effectively in this role with the previously rapid growth in the cost of prostheses in the hospital system coming under control.

There was widespread frustration expressed by participants – particularly industry sponsors – that PDC was also assessing the safety of medical technologies. Stakeholder uncertainty about the role of PDC was exacerbated by a perceived lack of transparency in the Committee's processes and decision-making.

In addition to confusion about the roles of various players in regard to technology assessment, there was also much uncertainty about the responsibilities for reimbursement. For example, participants were unclear about the roles of MSAC and PDC separately, and in particular where their reimbursement interests overlapped. Few were aware of the relationships between these bodies and the Minister.

Duplication and co-ordination

Participants argue that the problems generated by lack of role clarity are intensified by HTA agencies operating as "silos" with poor, if any, coordination or communication, making navigation between them fraught for the participant.

The assessment of safety was considered by many participants to be the most important area of duplication in the system. There was general participant consensus that safety assessment should only be undertaken once, or if there really are different forms of safety assessment for different purposes they need to be much more clearly defined and communicated. Participants also generally held the view that if there is a good reason for MSAC or PDC undertaking safety assessment from a different angle to TGA, surely the same inputs should not be required from the sponsor all over again, but rather one arm of the system ought to be able to provide them to the other arm.

While most participants considered TGA to be the appropriate agency to assess safety given its regulatory authority, its well-established processes and its good record, there was a small minority voice in the Focus Groups that questioned the quality of some TGA assessment and did not wish to see all safety assessment undertaken under its aegis.

Other areas of duplication, highlighted particularly by sponsors, included: the requirement to submit multiple applications containing similar information, when more than one agency is involved in assessing a device; and repeated, full re-assessment of the same basic technology if a small aspect of its composition changes (eg the type of glue or screws).

Simplification

Strong support existed in the Focus Groups for a single entry point to HTA in Australia, but not necessarily a 'one-stop-shop' or super-agency. On balance, participants generally recognised the merits of separate processes (in particular the separation of market entry assessment from reimbursement processes and decisions).

However, participants advocated very strongly for significant improvements in the streamlining and co-ordination of processes if agencies remain separate in the future. They want automatic movement of applications along clear, explicit pathways through relevant processes, rather than sponsors having to navigate their application through the system, the component parts of which currently do not join up.

There was also very strong support amongst participants for the capacity to seek parallel or linked approvals where appropriate, particularly in the context of hybrid or co-dependent technologies.

There was no consensus among participants as to whether the TGA should be the portal for a single entry point in the future. Some participants felt that TGA was not strictly speaking an HTA agency and pointed to the fact that it did not assess procedures. The majority of participants, however, saw TGA as the natural pathway into the system.

A number of participants advocated strongly that the Australian HTA system should draw more on international better practices and methodologies in order to improve, simplify and streamline practices. This approach was expanded by some participants to include support for the adoption of prior-approvals of health technologies by other countries. Proponents of this position generally considered Australian standards to be unjustifiably tougher than those of counterpart nations. However, this proposal was generally contested when raised in the Focus Groups. There was a strong theme running through all discussions that safety and efficacy of technologies should be the primary concern of the HTA system. They argued that often the context for using a device was crucial and that where Australia had higher standards in these matters they should prevail.

Impacts

The consensus between participants was that the most important impact of the current problems in the HTA system outlined above is lack of timely decisions, particularly from MSAC. This results in frustration, additional financial costs and planning difficulties for sponsors and lost or delayed opportunities for timely access for patients to beneficial procedures, devices and services.

In addition, some stakeholders believed that the current practice of extra levels of safety review by MSAC and PDC leads to:

- a higher level of safety for private patients than public patients; and
- private patients receiving delayed access to health technologies already in the public system.

Finally, while current HTA arrangements were considered usually to keep unproven, dangerous or inferior technology out, they were also thought by some participants to exclude some beneficial technology.

Other Issues Raised

In the course of discussions a number of other concerns with the current system were raised that do not fit neatly into the Focus Group question structure. They are as follows:

- A common theme was that there is a lack of consumer input and involvement in HTA, contributing to the lack of a holistic-care approach in HTA.
- Participants often argued that there is insufficient preparedness in the system to meet the challenges of future trends in technology for example, there is a lack of horizon scanning capacity and practice.
- Participants regularly raised concern about the inadequate capacity in the system to manage 'disinvestment' in technologies either proven ineffective or less effective than other technologies.
- Participants generally believe that a lack of consistency and predictability in the current system makes it hard for all parties to plan, with the main problems being a lack of
 - defined and predictable timelines in parts of the system
 - appropriate guidance in some agencies and some processes
 - explicit decision-making criteria, and
 - an apparent link between sponsor inputs and final outcomes.
- In regard to assessment methodologies some key complaints were made about
 - PDC's requirement for years of data
 - MSAC's perceived focus on level-1 evidence and meta analyses
 - perceived blurring of safety and efficacy issues, and
 - evaluators using comparators when they should not, and sponsors unable to proceed when there are no comparators.
- The PDC -monthly cycle was seen by small sponsors as generating serious cash flow and planning challenges for their businesses, while hospitals prefer the predictability of the current cycle and argue that more frequent lists would be administratively unworkable for them.
- Some participants raised a concern with the way current prostheses arrangements are leading to an increasing number of prostheses that lack a 'no gap' alternative.

A few suggestions were also made about options for high level approaches to a future HTA system.

- Some stakeholders suggested the need for something like a Charter for HTA to define roles, processes, governance and goals as a way of addressing current fragmentation and confusion about the system.
- Strong support existed among participants for a more holistic appraisal methodology addressing the full costs and benefits of the entire package of procedure, device and service, as well as the non-health costs and benefits of particular technologies.

- A number of participants (but not all) supported a risk-based approach to HTA which directs the main resources of the system to intensive assessment of higher risk, new technologies and avoids over-investing in the assessment of low risk technologies. The proponents of this approach viewed it as essential for speeding up timeliness and reducing cost in the system. The caveat that always accompanied this discussion, however, was that such an approach should not undermine safety standards and outcomes in any way.
- Participants generally supported the identification of explicit guiding principles for a future system.

3.3 Transparency and fairness

This discussion focused on the level and appropriateness of public information available about the HTA system, procedural fairness and system performance information.

Level and appropriateness of public information available on HTA

While a small number of participants felt that adequate information about the system was publicly available, the great majority of participants expressed the view that the basis for both HTA assessment and reimbursement decisions is not transparent in the Australian system. The assessment process is seen as more transparent (although not adequately so) than the reimbursement process. Some participants, (particularly those with a clinical background) felt the latter to be opaque and inadequately defined.

TGA is generally seen by the participants as having good guidance and explicit processes, but the assessment processes and methodologies in MSAC and PDC were generally viewed as a 'black box' by most participants. Guidelines, rules, decision-making criteria and evaluation methodologies were all viewed as missing or inadequate, or poorly communicated to stakeholders.

An often repeated concern was the lack of clarity about evidence requirements. Many participants felt that the amount and type of evidence required in the application process was not explicit and they were unable to elicit this information despite repeated attempts to gain direction and feedback. In this regard, participants overwhelmingly supported greater use of pre-lodgement and face-to-face meetings before, during and after the evaluation process. A number of participants were under the impression that there was no process for correcting or clarifying matters in applications during the evaluation in MSAC and PDC and consequently felt this to be a particularly inefficient practice.

MSAC and PDC decisions are considered to be poorly documented, explained and communicated. A number of sponsor participants expressed strongly negative viewpoints on this matter arising from their experience of receiving short, uninformative, form-letter notifications on the success or failure of an application. This 'black hole', as many saw it, was a key factor in undermining participant confidence in both the evaluation and decision-making processes.

A key complaint from some participants was that they were aware that MSAC evaluator advice on cost effectiveness and reimbursement levels is sometimes not reflected in the final funding decision, with a different payment level or structure emerging without explanation from later decision-making. The reason and processes behind these variations is unknown to stakeholders and considered unjustified.

In regard to process and decision-making transparency, PBAC was often cited as providing a good model, where: guidelines, rules and processes are clear and explicit; opportunity exists for pre-lodgement meetings and for sponsors to make corrections to applications during the evaluation process; and decisions are well documented and well explained.

Procedural fairness

A commonly expressed view in the Focus Group discussions was that participants did not feel in a position to make a judgement about whether or not procedural fairness is a feature of the current HTA system, given the lack of transparency in the system and generally underdeveloped stakeholder understanding of the rules and guidelines governing the system. Nonetheless, there was a degree of suspicion and lack of confidence expressed about fairness in the HTA system, reinforced by what some participants considered to be poor responsiveness to their queries about both processes and decisions and the provision of inconsistent advice, particularly from the PDC Secretariat, to queries from some stakeholders.

The absence of an appeal process in MSAC and limited appeal processes in PDC is a source of indignation to a number of participants. The view was often expressed that no-one gets it right all the time, and the UK experience of a significant proportion of appeals upheld was often cited. In addition, many participants felt that this was an area in which the HTA system significantly lagged behind Government better practice in Australia in other fields and was an aspect of denial of natural justice to sponsors. Participants also generally held the view that sponsors should be able to appeal decisions on both process and merit grounds, with the possibility of substitution of a new decision emerging from appeal.

Conflict of interest was a topic of intensive discussion in most of the Focus Group sessions. Conflicts of interests were perceived to be poorly managed in the HTA system, with the view that this is an extensive problem in MSAC Advisory Panels and more especially in the Prostheses and Devices Negotiating Group (PDNG). This debate was linked to two related issues.

Firstly, some participants strongly felt that the identity of evaluators and advisors should be public as an essential component of natural justice. However, there was an alternative view expressed by a minority of participants that anonymity of these experts was necessary to protect them from pressure from sponsors and other stakeholders. Further, there was a concern that given the tight supply of HTA evaluators and advisors, exposing them to possible controversy or stakeholder pressure might make it more difficult to attract professionals to the sector.

Secondly, some participants forcefully expressed the view that the individuals appointed as advisors to the MSAC Advisory Panels and the PDC Clinical Advisory Groups were sometimes not the appropriate people in the field in terms of knowledge and expertise. A number of instances were cited where particular participants believed the obvious candidate for advisor was passed over for the position, even when recommended by the appropriate clinical association. Related to this complaint was the view held by some participants that sometimes input was sought from an inappropriate craft group or medical college.

Another recurring theme expressed by industry-based participants was that the presence of four private health insurers on the PDC as opposed to a single industry member, and the absence of industry representatives altogether on the PDNG, undermine the fairness of the negotiation process and the sustainability of funding recommendations.

Strong support was also expressed by most participants for a separation of HTA evaluation functions from reimbursement and funding decisions, as an essential component of fairness in the system.

Information on system performance

There was a general perception among participants that there are currently no substantial, publicly available data on the performance of the system. There was strong support for the use and reporting of Key Performance Indicators (KPIs) in the system, for the purposes of accountability, improvement and benchmarking against other national systems.

Participants believed that KPIs for the system as a whole and each of the component parts were most crucially needed in regard to:

- Timeliness;
- % applications approved/rejected; and
- % applications granted interim funding.

3.4 Post market surveillance

Current shortcomings

There was strong support from participants for robust post market surveillance of health technologies and general agreement that post market surveillance is currently poor in Australia. Participants acknowledged that TGA undertakes some degree of surveillance in its role as the regulator of the safety of devices, but (with some dissenting views) generally considered TGA activity in this area to be relatively weak given its passive nature. Some participants saw the TGA as waiting for adverse events to occur and hoping that they are reported. The voluntary and partial (addressing only the inherent safety of the device without regard to the safety of the procedures associated with the use of that device) nature of existing TGA post market surveillance is also considered by some participants to be a weakness in the system.

The key barrier to effective post market surveillance identified by participants is the lack of readily available, reliable and comprehensive data. Improvements in data sources, data collection, linkages between databases such as the MBS and PBS and analysis of trends are seen as the essential pre-conditions for a robust post market surveillance system. A number of participants did, however, acknowledge that reliance on clinician agreement and participation to provide case information was both a key to its success and a major risk, given the difficulties ensuring consistent participation by individual clinicians.

Taking a broader view on this issue, some participants believe that there should be the ability to commission research linked to post market surveillance, but were of the view that the NHMRC, as the most likely sponsor, is not interested in funding this sort of research. The absence of a sponsor for these types of research projects has, according to some participants, resulted in Australia being unable to participate in major international reviews of particular health technologies with other countries.

Participants supported the development of a framework for post market surveillance that clarifies its purpose(s), for example whether it is supporting one or all of the following:

- regulatory safety surveillance;
- comparative safety and efficacy of similar technologies;
- interim funding arrangements for new technologies (known as 'coverage with evidence'); and/or
- broader health service planning.

The Registry Model of post market surveillance was generally very strongly supported by participants, with repeated reference to the National Joint Replacement Registry as an example of best practice. Some participants did, however, identify perceived shortcomings with the model which decision-makers need to be clear about, including the following:

- data from Registries are designed for use by doctors to inform their clinical practice and therefore may not be suitable for other uses;
- the data in Registries may be incomplete as it depends on voluntary submission of information by clinicians and hospitals;
- funding of Registries by industry is seen by some to undermine credibility to some extent;
- Registries take a long time to deliver useable data;
- Registries are viewed as primarily supporting relative efficacy analysis, and not cost effectiveness or reimbursement decisions; and
- some participants argued that Registry data cannot be a substitute for good trials.

Responsibility for Post Market Surveillance

- The main stakeholder view on this issue was that a co-ordinated approach involving all relevant parties was crucial, but noted the key role of clinicians.

3.5 Challenges of co-dependent and hybrid technologies

Current challenges and suggested enhancements

There was widespread lack of confidence among Focus Group participants in the capacity of the current HTA system to efficiently and effectively assess co-dependent and hybrid technologies. Participants broadly acknowledged that assessing these types of health technologies already presents major methodological and administrative challenges. They expect these problems to intensify with the imminent growth in these technologies (including multi-combinations, tissue implants and the trend to personal medicine and genetic testing) and acknowledge that there is no easy answer. It was also recognised that Australia is not alone in facing this challenge and that other national systems are also struggling with the issue.

However, participants generally considered the inflexible, fragmented, uncoordinated and 'siloed' nature of the current Australian HTA system to be unsuitable for assessing hybrid and co-dependent technologies. There was widespread participant concern about the lack of clarity around roles and responsibilities for assessing these technologies and how a decision in one agency or process connects to/impacts upon a process or decision in another part of the system which is considering the related device or procedure.

Sponsor participants in particular gave examples of negative experiences when applying for assessment of these types of technologies, including not knowing where to enter the system and not being able to find guidance on this matter from the agencies. Sponsors expressed the strong view that it should not be their responsibility to engage in trial and error to work out how and where to enter the system with applications for hybrid and co-dependent technologies.

MSAC and PBAC are viewed by some as unable to work together (based on a perceived absence of channels of communication and their different cycles and processes for HTA). Improvements in these arrangements are generally considered by participants to be a pre-condition for assessing hybrid and co-dependent technologies if the agencies remain separate entities in a future HTA system.

A number of participants also suggested that the terms and definitions currently used in HTA are already out of date and will become more so in the light of the growth of hybrid and co-dependent technologies, and as such, need to be overhauled.

Finally, in light of the complexity of the new technologies, participants generally expressed the view that it would be a mistake to try to establish a single process for the assessment of all hybrid and co-dependent technologies. They believed that it would not be a case of one size fits all, and that the assessment process should be appropriate for the technology.

Appendix I: Stakeholder Consultation – Focus Groups and Bilaterals

In addition to meetings of the Inter Departmental Committee and Medical Technology Stakeholder Reference Group, the Department held focus groups and bilateral meetings with key stakeholder groups to, firstly, explore issues surrounding Commonwealth HTA processes, and secondly to explore options to address the HTA Review terms of reference. Details of the bilateral meetings and focus groups are provided below.

Bilateral Meetings

First Round – ‘Issues Identification’

20 May 2009	Medical Technology Association of Australia
26 May 2009	Medicines Australia
27 May 2009	Royal College of Pathologists of Australasia
17 June 2009	Western Australia Health
26 June 2009	National Association of People Living with HIV/AIDS and the Australasian Society for HIV Medicine
26 June 2009	Australian Orthopaedic Association
2 July 2009	Royal Australasian College of Surgeons
10 July 2009	AusBiotech Limited
16 July 2009	Australian Private Hospitals Association
31 July 2009	Australian and New Zealand Association of Physicians in Nuclear Medicine
31 July 2009	Catholic Health Australia
5 August 2009	Spine Society
20 August 2009	Invitro Diagnostics Australia Limited
9 September 2009	Australasian Cochrane Centre

Second Round – ‘Options Development’

14 October 2009	Catholic Health Australia
16 October 2009	Australian Medical Association
16 October 2009	Australian Orthopaedic Association
20 October 2009	Consumers Health Forum of Australia
20 October 2009	Royal College of Pathologists of Australasia
20 October 2009	Medical Technology Association of Australia
20 October 2009	AusBiotech
28 October 2009	Australian Health Insurance Association

Focus Groups

'Issues Identification' Phase – 9 Focus Groups

18 June 2009	Canberra (1 focus group)
19 June 2009	Sydney (3 focus groups)
27 June 2009	Melbourne (3 focus groups)
23 July 2009	Sydney (1 focus group)
24 July 2009	Teleconference (including stakeholders from WA and SA)

'Options Development' Phase – 11 Focus Groups

29 September 2009	Sydney (2 focus groups)
20 September 2009	Sydney (2 focus groups)
2 October 2009	Canberra (1 focus group)
6 October 2009	Adelaide (2 focus groups)
7 October 2009	Teleconference (Stakeholder from WA)
8 October 2009	Melbourne (2 focus groups)
9 October 2009	Melbourne (1 focus group)

Participant Organisations

Abbott Diagnostics
 Abbott Vascular
 ACSS Health
 AHM Health Insurance
 Alcon Laboratories (Australia) Pty Ltd
 Allergan Australia
 Amgen Australia Pty Ltd
 Anatomics
 ASDM Limited
 Aus Biotech
 AusMedtech Victoria
 Australian Society for HIV Medicine
 Austofix
 Australasian College of Podiatric Surgeons
 Australasian Medical and Scientific Ltd
 Australasian Tissue and Biotherapeutic Forum
 Australian and New Zealand Hyperbaric Medicine Group
 Australian Association for Exercise and Sports Science
 Australian Biotechnologies
 Australian Diagnostic Imaging Association
 Australian Health Care and Hospitals Association
 Australian Health Insurance Association
 Australian Health Management
 Australian Health Service Alliance

Australian Medical Association
Australian National Musculoskeletal Research Institute
Australian Orthopaedic Association
Australian Physiotherapy Association
Australian Practice Nurses Association
Australian Society of Orthopaedic Surgeons
Australian Unity
Barwon Health
Barwon Health Bone Bank
Baxter Healthcare Ltd
Bermaci Pty Ltd
Bio 21, University of Melbourne
Biotronik Australia Pty Ltd
Boston Scientific Corporation
Bristol-Myers Squibb Australia Pty Ltd
Bupa Australia Group
Cancer Voices NSW
Cardiac Prostheses Clinical Advisory Group
Cardiac Society of Australia and New Zealand
Catholic Health Australia
Catholic Negotiating Alliance
Cell and Tissue Therapies WA
Cochlear Limited
Cochrane Consumer Network
Colorectal Surgical Society of Australia and New Zealand
Concept Vision Australia Pty Ltd
Consumers Health Forum of Australia
Cook Medical, Australia
Deakin University
Deloitte Actuaries and Consultants
Department of Health, South Australia
Department of Health, State Government of Victoria
Department of Human Services, State Government of Victoria
Device Technologies Australia
Donor Tissue Bank of Victoria
Edwards Lifescience
Eli Lilly and Company
Energy Orthopaedics
Garvan Institute of Medical Research
Genzyme Australasia Pty Ltd
GlaxoSmithKline Aus
Gytech Pty Ltd
HBF Western Australia
Health Economics and Funding Reforms



Healthscope Limited
Hologic (Australia) Pty Ltd
Hospira
HT Analysts
Human Genetics Society of Australasia
ICT Services
In Vitro Diagnostics Australia Ltd
Insight Surgical
Integra Neurosciences Pty Ltd
International Musculoskeletal Research Institute
IQ Medical
iSelect
Isoft Health
Johnson and Johnson Medical
Lifehealthcare
LMT Surgical
Medacta Australia
Medartis Australia and New Zealand
Medibank Private
Medical + Optical
Medical Device Evaluation Committee
Medical Intelligence
Medical Services Advisory Committee
Medical Technology Association of Australia
Medical Vision Australia
Medicines Australia
Medtronic Australasia
N Stenning and Co
National Centre for Sustainability
National Coalition of Public Pathology
Neupro
NHMRC University of Sydney
NSW Department of Health
Nutricia Australia
NuVasive Australia and New Zealand Pty Ltd
Omni Health Solutions
Open Sesame Consulting
Orthopaedic Solutions
Orthotech Holdings Pty Ltd
OSHC Worldcare
OT Australia
Parkinsons NSW
Pathology at Melbourne Health and National Coalition of Public Pathology
Peninsula Health

Penumbra Neuro Australia Pty Ltd
Perth Bone and Tissue Bank
Pharma in Focus
Pharmatel Fresenius Kabi Pty Ltd
Philips Health Care
Private Health Insurance Ombudsman
Prostheses and Devices Negotiating Group
Public Health and Clinical Coordination, SA Health
Quality Use of Medicines, National Prescribing Service
Queensland Health
Ramsay Health Care
REM Systems
Right Time Business Pty Ltd
Roche Diagnostics Australia Pty Ltd
Roche Pharmaceuticals
Roche Products Pty Limited
Royal Australian and New Zealand College of Ophthalmologists
Royal Australian College of General Practitioners
Royal College of Pathologists of Australasia
Saint Vincent's Hospital, Melbourne
Sanofi Aventis Australia and New Zealand
Sirtex Medical Limited
Smith and Nephew Surgical Pty Ltd
South Australian Tissue Bank
Spine Society of Australia
St Jude Medical Australia Pty Ltd
Surgical Synergies
Surgiplas Medical
Swinburne Uni of Technology
Synthes Australia Pty Ltd
Tag Medical
Teachers Federation Health
The Hospitals Contribution Fund of Australia Limited
Vital Diagnostics
Zimmer Pty Ltd



Appendix J: Discussion Papers Presented to 'Options' Focus Groups 14–28 October 2009

Review of Health Technology Assessment in Australia – Proposals for HTA Reform to Inform Discussion

Discussion Paper 1 – A Conceptual Framework for Commonwealth HTA Processes

Discussion Paper 2 – Streamlining Application Processes

Discussion Paper 3 – Approaches to Evidence and Methodologies

Discussion Paper 4 – Improved Administration of Commonwealth HTA Processes

Discussion Paper 5 – Enhanced Post-Market Surveillance

Review of Health Technology Assessment in Australia Proposals for HTA Reform to Inform Discussion

As part of its ongoing consultation with stakeholders during the Review of Health Technology Assessment in Australia (the HTA Review), the Department of Health and Ageing (DoHA) is conducting a second round of focus groups and bilateral meetings to explore draft proposals that aim to address concerns raised during initial consultations.

To stimulate discussion of possible reform proposals during this second round of consultation, following consideration of a range of concerns and proposals raised in initial feedback from stakeholders through 86 written submissions, 9 focus groups and 14 bilateral meetings with peak bodies, DoHA has prepared five Discussion Papers:

Discussion Paper 1 – A Conceptual Framework for Commonwealth HTA Processes

Discussion Paper 2 – Streamlining Application Processes

Discussion Paper 3 – Approaches to Evidence and Methodologies

Discussion Paper 4 – Improved Administration of Commonwealth HTA Processes

Discussion paper 5 – Enhanced Post Market Surveillance

The Discussion Papers are intended to stimulate focussed discussion and any proposals presented or omitted should not be taken to represent the policy position of the Australia Government. DoHA does not seek to suggest that all possible proposals for HTA reform have been identified in the Discussion Papers, nor that any particular proposal will be recommended to the Government in the final report of the HTA Review.

Most proposals outlined in the Discussion Papers require further considered consultation with stakeholders, including about how they may be appropriately resourced for effective implementation. Because the HTA Review is constrained to put forward recommendations that can be implemented within existing funding levels, some of the proposals may be considered to be medium to longer term strategies to reform Commonwealth HTA processes. They may also potentially impose additional regulatory requirements that would need to be carefully considered prior to recommendation or implementation.

Interested parties who are registered to attend the second round of focus groups and bilateral meetings will have an opportunity to provide feedback on the Discussion Papers at these meetings. This feedback will inform the development of the HTA Review Report which is to be presented to the Minister for Health and Ageing, the Hon Nicola Roxon MP, and Minister for Finance and Deregulation, the Hon Lindsay Tanner MP, in late 2009.

To assist stakeholders with providing feedback on the Discussion Papers, an overview of the Australian Government's current health technology assessment functions for market regulation and reimbursement is attached (**Attachment A** and **Attachment B**) to provide a consistent and fully informed basis for input during the second round of consultation.

A schema for the Discussion Papers is at **Attachment C**.

Overview of Australian Government Health Technology Assessment (HTA) Functions for Market Regulation and Reimbursement

HTA to Inform Market Regulation

Therapeutic Goods Administration (TGA)

The Therapeutic Goods Administration (TGA) was established in 1991, with the current medical devices regulatory scheme commencing in 2002. The market entry functions, roles and responsibilities of the TGA and its advisory committees (Medical Device Evaluation Committee (MDEC) and its supporting sub-committees) are prescribed in legislation. The TGA assesses the safety, quality and efficacy of therapeutic products for the purposes of regulation of market entry. The TGA operates under full cost recovery and utilises internal and external expertise (as required) to undertake its assessments. In making a decision to include a product in the Australian Register of Therapeutic Goods (ARTG), the Secretary of DoHA (or delegate) considers an assessment report and approves the therapeutic products if quality, safety and efficacy are demonstrated. The TGA assessment of safety requires that the product should be “free from unacceptable risk”.

HTA to Inform Reimbursement Decisions

Public Funding through the MBS

The Medical Services Advisory Committee (MSAC) was established in 1998 as a result of a 1997-98 Federal Government Budget decision to strengthen arrangements for assessing new technologies and procedures before they are considered for reimbursement under the Medicare Benefits Schedule (MBS). Its Terms of Reference require it to advise the Minister for Health & Ageing on the strength of the evidence relating to safety, clinical effectiveness and cost effectiveness for the purpose of advising the Minister for Health and Ageing on the circumstances under which medical services involving new technologies and procedures should be eligible for public subsidy. The MSAC assessments are undertaken by external HTA experts using a comparative approach in which the proposed service is compared with services currently receiving public reimbursement. All costs associated with supporting MSAC are met from Departmental resources.

Public Funding through the PBS

The Pharmaceutical Benefits Advisory Committee (PBAC) was established in 1954, with its functions, roles and responsibilities prescribed in legislation. It assesses comparative clinical and cost effectiveness for the purposes of advising the Minister for Health and Ageing on the eligibility of pharmaceuticals and vaccines for public subsidy under the Pharmaceutical Benefits Scheme (PBS). The PBAC assessment of clinical effectiveness involves an assessment of the harms versus the benefits of a pharmaceutical or vaccine against suitable comparators. Assessments of applications are mainly undertaken by Departmental staff (many with pharmaceutical, scientific or clinical expertise) or evaluation groups under contract. Funding for this function is provided through Administered Funds, although cost recovery will be implemented in the near future.

Private Health Insurance Reimbursement

The Minister for Health and Ageing established the Prostheses and Devices Committee (PDC) in 2004 to advise on what products should be included in the Prostheses List and the appropriate benefit for private health insurance reimbursement purposes. The Minister has also approved additional criteria (to those prescribed in legislation) for eligibility for listing on the Prostheses List. The PDC utilises guidance to define its processes and procedures, and assesses comparative clinical effectiveness and cost relative to clinical effectiveness for the purposes of determining an appropriate benefit. Management of the prostheses listing arrangements operates under full cost recovery. Assessment of clinical effectiveness is conducted by external experts (through the Clinical Advisory Groups and Panel of Clinical Experts).

Public and Private Reimbursement Arrangements

MBS Funding

Once the Minister for Health and Ageing notes the MSAC advice, the Department of Health and Ageing (DoHA) negotiates with the medical profession through consultative committees to determine the proposed MBS item descriptor and fee, and provides further advice (including costings, which must be agreed with the Department of Finance) to the Minister. The Minister makes a decision within the context of broader government priorities about whether the proposed medical service should be included in the Health Insurance Regulations which give rise to the MBS.

PBS Funding

Once PBAC has recommended a pharmaceutical for listing on the PBS, the Pharmaceutical Benefits Pricing Authority (PBPA) makes a recommendation on the proposed price for a new PBS item based on advice from PBAC, including consultation with the applicant and other sources. Where the projected net costings are less than \$10 million per annum, the Minister notes the advice, and a delegate (of the Minister) approves the inclusion of the product on the PBS. If the costings (which must be agreed with the Department of Finance) are greater than \$10 million per annum, then approval by the Minister for Health and Ageing and Cabinet is required. The Minister (or delegate) authorises the inclusion of pharmaceuticals in legislative instruments which gives rise to the PBS within the context of broader Australian Government priorities.

Prostheses List Benefit

The PDC makes a recommendation to the Minister for Health and Ageing (or delegate) on the appropriate benefit for a product to be included on the Prostheses List. PDC's recommendation is based on benefit negotiations conducted through the Prostheses and Devices Negotiating Group (PDNG). A delegate (of the Minister) approves the inclusion of products in the Prostheses List by signing Rules which gives rise to the List.

Post Market Surveillance

The TGA currently conducts surveillance of the manufacturer's compliance with post market obligations including vigilance programs.

A diagrammatic representation of Commonwealth HTA functions is at **Attachment B**.

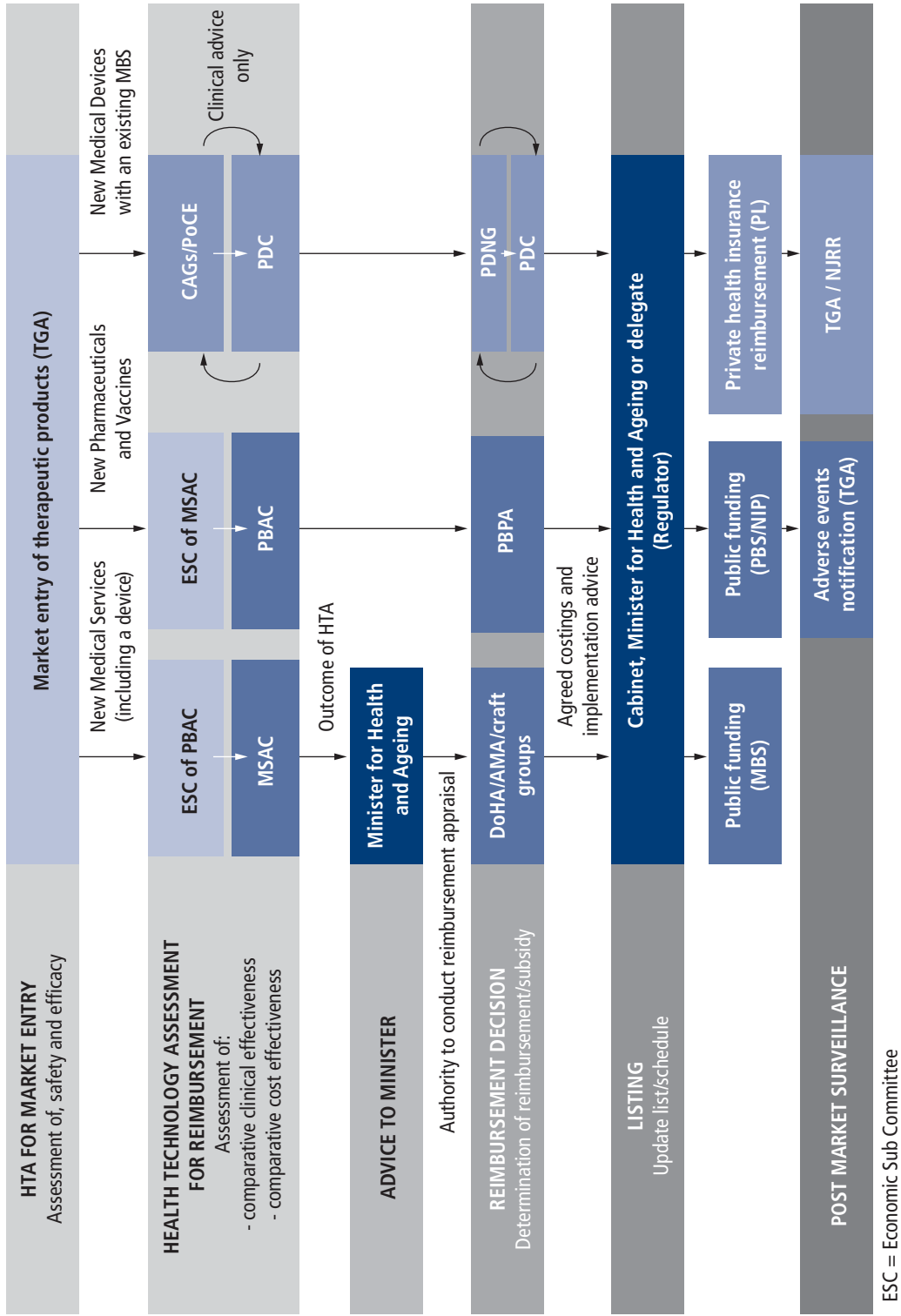
Australian Government Better Regulation Agenda

The Australian Government has an ambitious regulatory reform agenda reflecting its policy objective that well-designed and targeted regulation reduces costs and complexity for business and the not-for-profit sector, and that better regulation will enhance Australia's productivity and international competitiveness

The Minister for Finance and Deregulation has portfolio responsibility for this agenda, and is leading a number of better regulation initiatives at both the Commonwealth level and inter-jurisdictional level through the Council of Australian Governments process.

Better Regulation Ministerial Partnerships (Partnerships), between the Minister for Finance and Deregulation and Ministerial colleagues are a key part of the Better Regulation agenda to achieve substantive regulatory reform at the Commonwealth level. The HTA Review is being progressed as a Partnership between the Minister for Health and Ageing and the Minister for Finance and Deregulation.

Current Commonwealth HTA Functions



Schema for Discussion Papers

Paper 1 - A Conceptual Framework for Commonwealth HTA processes Proposed Vision, Goals & Objectives, Principles, Functions *(The future system)*

Paper 2 Streamlining Application Processes

- Single entry point
- Triaging of HTA applications
- Allowing submission based assessment for potential new Medicare benefit items

(Public interface between applicant and DoHA)

Paper 3 Approaches to Evidence and Methodologies

- Risk based approach to assessment
 - Evidentiary processes
 - Methodologies and methodological processes
- (Treatment of application - including for co-dependent/hybrid technologies)*

Paper 4 Improved Administration of Commonwealth HTA Processes

- Public information
 - HTA Process management
 - Specified communication points
 - Review mechanisms for processes and decisions
 - Better information on performance
- (Program Arrangements)*

Paper 5 Enhanced Post Market Surveillance

- PMS Scope
- CED framework
- Registers
- Data Linkage
- Disinvestment

(Post Implementation Management)

Discussion Paper 1 – A Conceptual Framework for Commonwealth HTA Processes

Disclaimer

The proposals for reform to Commonwealth Health Technology Assessment (HTA) processes as outlined in this Discussion Paper represent a range of responses to the issues raised in submissions to the HTA Review and during stakeholder consultation. The Discussion Papers are intended to stimulate discussion at the forthcoming consultations and any proposal presented or omitted should not be taken to represent the policy position of the Government. The HTA Review is required to put forward proposals that can be sustained within existing funding levels and that are consistent with Government policy objectives.

Introduction

Health technology assessment (HTA) is a key tool for the Australian Government to inform its reimbursement decisions in order to achieve its overall objective of delivering a safe, effective and efficient health care system that is fiscally sustainable in the longer term.

As in many countries, Australian Government policy regarding subsidised access to medical procedures, devices and medicines requires demonstrated comparative safety, effectiveness and cost effectiveness to inform decisions regarding health care funding.

This paper describes the current Commonwealth system for HTA for market regulation and HTA for reimbursement, and provides a proposed way forward to maintain and improve the elements of Australia's Commonwealth HTA system for the future. More specific details of how this might occur are explored in Discussion Papers 2 to 5.

Current Australian Government management of access to and funding of health technologies

The Department of Health and Ageing (DoHA) has a legislative, policy and program framework to support the following functions:

- assessment of the safety and efficacy of health technologies for market regulation – to ensure that therapeutic products are safe, perform as intended and are produced using appropriate quality controls before marketing approval is granted in Australia through the Australian Register of Therapeutic Goods (ARTG);
- assessment of the comparative safety, clinical and cost effectiveness of health technologies which informs decisions about:
 - public funding of medical services (with or without a device), procedures and diagnostic technologies, pharmaceuticals and vaccines through the Medicare Benefits Schedule (MBS), the Pharmaceutical Benefits Scheme (PBS) and the National Immunisation Program (NIP) respectively;
 - private health insurance reimbursement of prostheses through the Prostheses List (PL); and
- post market surveillance of these health care interventions to inform ongoing decisions about the marketing approval of therapeutic products or the reimbursement of health technologies that prove not to be safe or do not perform as intended.

Resources to support these functions are managed by different Divisions within DoHA, and by the Therapeutic Goods Administration (TGA).

Concerns Raised in HTA Review Consultations

Concerns raised by stakeholders in public consultations about the current overall Commonwealth approach to HTA in Australia included:

- the lack of a strategic, systematic and integrated framework for Commonwealth HTA functions including the absence of practical linkages between the HTA advisory committees assessing health technologies, and their assessment within a holistic model of care;
- insufficient recognition and adoption, where appropriate, of international developments in assessing health technologies; and
- insufficient coordination between Commonwealth HTA functions and those of State and Territory governments.

Proposal 1 Proposed Conceptual Framework for Commonwealth HTA Processes

In the light of concerns about the coordination and management of Commonwealth HTA processes, there may be benefit in explicitly defining the vision, goal, scope and principles for an overall HTA system. This might provide a benchmark against which to assess other more specific changes and also facilitate a common approach to the various elements of the system.

The following proposed vision, goal and underpinning principles for an overall Commonwealth HTA system have been formulated by drawing on views expressed by stakeholders during the HTA Review consultation process. These principles aim to reflect a system that is consistent with the Government's regulatory reform agenda and Better Regulation Ministerial Partnership between the Minister for Health and Ageing, the Hon Nicola Roxon MP, and the Minister for Finance and Deregulation, the Hon Lindsay Tanner MP.

Proposed vision for a Commonwealth HTA system

Commonwealth HTA in Australia should be recognised as an international leader in the field – providing a structure and capability to ensure the timely and equitable access to cost effective health care interventions for the Australian community, and which achieve optimal health outcomes within available resources.

Proposed goal and objective of a Commonwealth HTA System

The proposed explicit primary goal for the Commonwealth HTA system is to maximise beneficial health outcomes within the health budget.¹

¹ The proposed goal: could be more than the means by which this primary goal is achieved; encompasses the central concept of opportunity cost; focuses on provision of health care resources and health outcomes, not indirect outcomes of health via changes in production (i.e. emphasises the full health care system perspective over the societal perspective); could be open to how the availability of health care funds is determined, and could include other goals of the health care system, such as equity of access according to capacity to benefit, promoting innovation to achieve the primary goal, and being flexible to deal with rare conditions

Proposed underpinning principles of Commonwealth HTA in Australia

The Commonwealth HTA system in Australia should be:

Principle	Descriptor
1. Independent and consultative	<ul style="list-style-type: none"> HTA processes should independently verify evidence in the Australian health care context. HTA processes and advice should be informed by appropriate consultation.
2. Transparent and accountable	<ul style="list-style-type: none"> A clear distinction of roles should be evident between applicants, process administrators, affected health professionals, evaluators, advisory committees, payers and policy-makers in terms of their powers/functions in the HTA process. A clear explanation of HTA processes (including the assessment², appraisal and decision making steps, the expertise and criteria applied to perform each step, timelines and how each step is consistently applied) should be publicly available (where appropriate). HTA processes should be procedurally fair throughout the assessment leading up to the reimbursement decision by explaining clearly what information is needed and how a decision will be made, conducting an unbiased assessment and giving relevant stakeholders appropriate opportunities to contribute. HTA advisory committee appraisals, recommendations and advice should incorporate wide, multidisciplinary stakeholder input, while remaining consistent and credible, and adhering to pre-agreed timelines and key performance indicators. There should be public disclosure of HTA advisory committee appraisals, advice and recommendations (with facts and reasons leading to these recommendations) and of subsequent reimbursement decisions.
3. Efficient	<ul style="list-style-type: none"> HTA processes should be seamless and minimise duplication. HTA processes should be managed as a single system that anticipates and manages assessment issues. HTA processes should minimise regulatory cost remaining cognisant of the need to ensure scientific rigour and sustainability of the health care system. HTA processes should share information and expertise (including independent evaluator and clinical expertise).
4. Informed by best available evidence and aligned with contemporary clinical practice	<ul style="list-style-type: none"> HTA appraisals should be based upon research evidence as well as informed by contemporary clinical practice and societal values. HTA appraisals should have regard to all relevant comparators that are used inter-dependently within a clinical model of care. HTA appraisals should take into account globally harmonised evidence requirements and should apply internationally collaborative evidence in order to remain relevant to the Australian context.
5. Flexible and fit for purpose	<ul style="list-style-type: none"> HTA processes should be able to identify and accommodate emerging health care interventions (through horizon scanning) and changing clinical practices. Assessment methodologies should be continually reviewed and updated in the light of validated innovations and developments. HTA processes should 'triage' applications so that the appropriate type of assessment (e.g. full versus targeted assessment/brand versus generic assessment) is undertaken.
6. Capable and manages risk effectively	<ul style="list-style-type: none"> HTA appraisals should consistently apply rigorous analytical methods while reflecting patient and fiscal risks associated with adoption of a health care intervention. HTA appraisals should inform risk sharing arrangements between government and applicants where appropriate.
7. Sustainable	<ul style="list-style-type: none"> The HTA system should contribute to the sustainability of the broader health system through the identification of safe, clinically effective and cost effective health care interventions for consideration for reimbursement as well as the identification of health care interventions that are of questionable clinical and/or cost effectiveness that should be considered for disinvestment. The HTA system should provide suitable incentives to build and sustain a HTA workforce with up to date skills.

2 For the purpose of this discussion paper, the term "assessment" means "the evidence base to consider the health technology"; "appraisal" means "the consideration of the evidence and other relevant factors by the advisory committee"; and "decision making" means "the final funding decision"

Commonwealth HTA functions

Overview

A proposed approach to future HTA governance of functions and elements of a HTA system is outlined below. HTA processes should provide the necessary synergies to deliver access to safe, effective and cost effective health technologies to the Australian community.

A diagrammatic representation of the proposed Commonwealth HTA functions is at **Attachment A**.

Scope of HTA coverage

In the short term, the Commonwealth HTA system would continue to assess:

- medical services;
- surgical interventions;
- diagnostic technologies (including pathology);
- devices;
- vaccines;
- drugs;
- hybrid technologies; and
- co-dependent technologies.

In the longer term, and consistent with any future Australian Government policy decisions about the scope of health care intervention types it is prepared to consider funding, the Commonwealth HTA system could be expanded to also assess, for example:

- health care prevention;
- clinical models of care (including their integration with technology);
- medical aids and appliances;
- blood and blood products and services;
- cell therapies and other biologics;
- other emerging health care interventions; and
- health care system guidance.

The resource implications of expanding Commonwealth and HTA sector capacity and capability would also need to be addressed.

Horizon scanning

Commonwealth HTA processes should include a horizon scanning mechanism to be able to proactively identify and respond to new and emerging technologies and to adapt to changes in models of clinical care.

These horizon scanning activities would inform any impending health care intervention 'pipeline' and highlight where assessment of these health care interventions may be focussed to meet the needs of the health care system, whilst aligning with national health priorities.

HTA for market entry

The TGA's role of evaluating the intrinsic safety, clinical effectiveness and efficacy for the market regulation of therapeutic products is an important contributor to the Commonwealth HTA functions for reimbursement (noting that the ARTG includes some therapeutic products not seeking HTA for reimbursement).

Evidence received and assessments made by the TGA in its market regulation role can usefully inform the Commonwealth's HTA processes – particularly the safety and effectiveness of therapeutic products which may inform the comparative assessments made during the HTA for reimbursement phase.

HTA for reimbursement

HTA is the prime means by which the Australian Government makes informed decisions about public and private reimbursement of health care interventions. These health care interventions are required to satisfy demonstrated comparative effectiveness and cost effectiveness requirements.

Reimbursement decision

Decisions about reimbursement of health care interventions by payers (Australian Government and private health insurers) would be informed by recommendations and advice from HTA advisory committees. Decision makers would also consider the broader financial implications of funding each health care intervention to ensure longer-term sustainability of the health care system.

Listing

The creation and maintenance of schedules and listings of health care interventions through the MBS, PBS and the PL would be at the discretion of the Minister for Health and Ageing, Cabinet or a delegate of the Minister for Health and Ageing and implemented through legislative instruments. Listing is the mechanism that makes health care interventions available to the Australian community.

Post implementation management – post market surveillance (PMS)

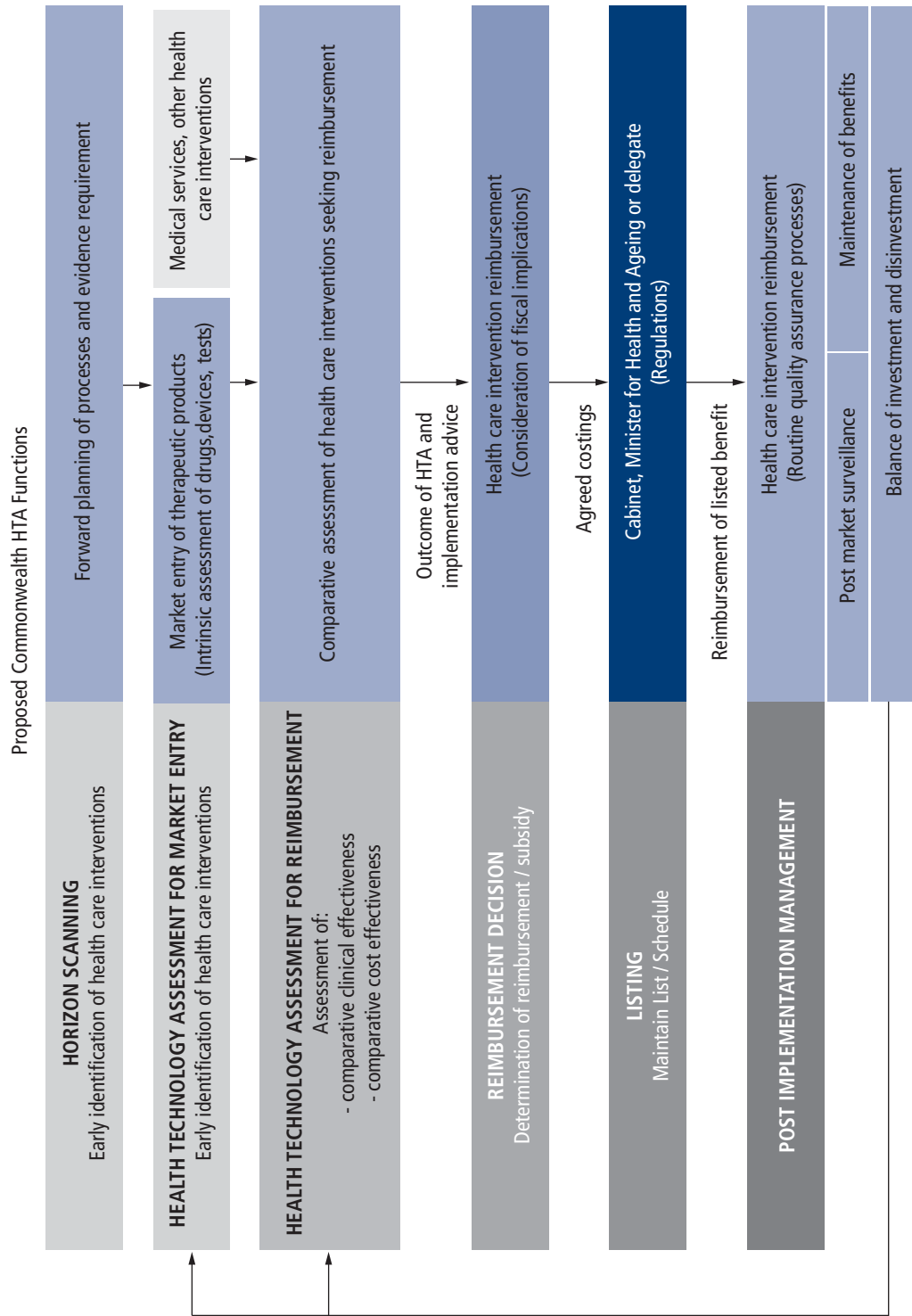
Post market (and post reimbursement) surveillance of health care interventions would provide routine quality assurance processes including:

- post market surveillance (PMS);
- maintenance of benefits; and
- the balance of investment with disinvestment.

PMS is important because:

- it can provide valuable new evidence on the performance of a health care intervention on an ongoing basis, especially where pre market and pre reimbursement evidence is limited; and
- the information collected will inform ongoing investment recommendations such as:
 - should a health care intervention continue to be publicly funded or privately funded?
 - should the eligible population be reviewed?
 - should price (benefit) paid for health care interventions increase, decrease or stay the same?
 - should a health care intervention be removed from the market (disinvestment)?

Discussion Papers 2 to 5 provide more detailed proposals.



Discussion Paper 2 – Streamlining Application Processes

Disclaimer

The proposals for reform to Commonwealth Health Technology Assessment (HTA) processes as outlined in this Discussion Paper represent a range of responses to the issues raised in submissions to the HTA Review and during stakeholder consultation. The Discussion Papers are intended to stimulate discussion at the forthcoming consultations and any proposal presented or omitted could not be taken to represent the policy position of the Government. The HTA Review is required to put forward proposals that can be sustained within existing funding levels and that are consistent with Government policy objectives.

Introduction

A range of policy, program and legislative arrangements underpin the multiple advisory committees and associated administrative processes which make up Commonwealth Health Technology Assessment (HTA) processes. These HTA processes inform decisions about market regulation and listing of medical services, pharmaceuticals, vaccines and devices on the Medicare Benefits Schedule (MBS), Pharmaceutical Benefits Schedule (PBS), National Immunisation Program (NIP) and the Prostheses List (PL) respectively.

Currently, applicants are required to traverse four different public interfaces within the Department of Health and Ageing (DoHA) to make applications for the Australian Register of Therapeutic Goods (ARTG), MBS, PBS/NIP and PL. These four interfaces have different processes and approaches to the management of applications.

This paper presents a number of proposals to facilitate streamlined, efficient and timely application processes – including how applications are managed through the different assessment processes and the factors taken into consideration in determining the assessment pathway.

Concerns Raised in HTA Review Consultations

Concerns raised by stakeholders during public consultations included:

- DoHA manages the HTA advisory committees (Medical Services Advisory Committee (MSAC), Pharmaceutical Benefits Advisory Committee (PBAC) and Prostheses and Devices Committee (PDC)) differently. As a consequence, DoHA's approach has been criticised as being siloed, overlapping, duplicated and lacking in coordination;
- there is limited formal and routine interaction between the different areas of DoHA about their functions despite the fact that HTA eligibility criteria includes successful completion of a previous step (e.g. ARTG listing and MBS Item);
- the sequential (rather than concurrent) nature of lodging applications for HTA for market entry and reimbursement causes delays and that processes should take place concurrently there is perceived duplication of HTA assessment activities between the market entry and the reimbursement processes. This delays use of the

technology and limits the already short life-cycle of health technologies;

- there was general criticism of the HTA processes undertaken by MSAC and the PDC, in particular their perceived inconsistent application requirements and assessment outcomes, the lack of transparency of processes, timelines and decisions, the lack of procedural fairness (including application costs) and the availability in the public hospital system of products which are not available on the MBS or the PL – creating perceived equity of access issues;
- however, stakeholders also expressed support for:
 - the HTA processes undertaken by the TGA and PBAC (which can be attributed to factors such as key processes being prescribed in legislation and depth of departmental experience in their execution resulting in greater transparency, predictability of requirements, and specified timeframes and outcomes);
 - a single entry point or “umbrella” function for Commonwealth HTA processes; and
 - the establishment of an “independent” HTA agency.

Proposal 2 Single Entry Point

Establishment of a single entry point within the health agency portfolio to manage applications for the Commonwealth HTA processes for market entry and reimbursement which could include the following features:

1. a public interface with stakeholders (through a website and guidance documents);
2. capacity to monitor the progress of applications;
3. single liaison point for applicants and the HTA processes;
4. responsibility for organising broad based pre-lodgement meetings – which could provide a “whole-of-HTA system” view to aid an applicant’s understanding of how its application could progress through the various Commonwealth HTA processes and advisory committees, and the likely evidence requirements;
5. a coordination function for those applications which would need to be assessed by multiple HTA processes and advisory committees such as hybrid¹ or co-dependent² technologies;
6. management of information requests between the HTA processes and advisory committees and the applicants; and
7. responsibility for coordination of evidence requirements and assessment processes to promote greater consistency across the HTA processes and advisory committees.

1 Where the characteristics of different health technologies (eg a medicine or a medical device or a biologic) are combined in one intervention (eg laser activated medicines such as photodynamic therapy, or drug eluting stents)

2 Where therapy involving the use of one health technology to directly improve health (eg 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.

Discussion

A single entry point could improve role clarity and provide better co-ordination of Commonwealth HTA processes by facilitating concurrent or integrated processes where assessments are built on those completed by other HTA processes (including international) rather than undertaken sequentially and from the ground up.

It could ensure that appropriate communication and collaboration takes place among the TGA and HTA advisory committees (MSAC, PBAC and PDC), as well as public and private payers and State and Territory Governments.

It could provide an opportunity to standardise application requirements (including guidance), where appropriate, to be consistent with the flexibility of the parallel proposal to introduce a risk-based assessment process.

Discussion Paper 3 – Proposal 5 “Implementation of a risk-based approach to evidence requirements and methodologies” explores options for triaging of HTA levels of assessment.

It might also lead to efficiency gains through the processing of applications in a consistent manner, and improved communication with applicants. Management of pre-requisites (ARTG number, MBS item) could be simplified, and the flow of applications across more than one HTA process could be better controlled.

Set out below are a number of ways a single entry point might be implemented.

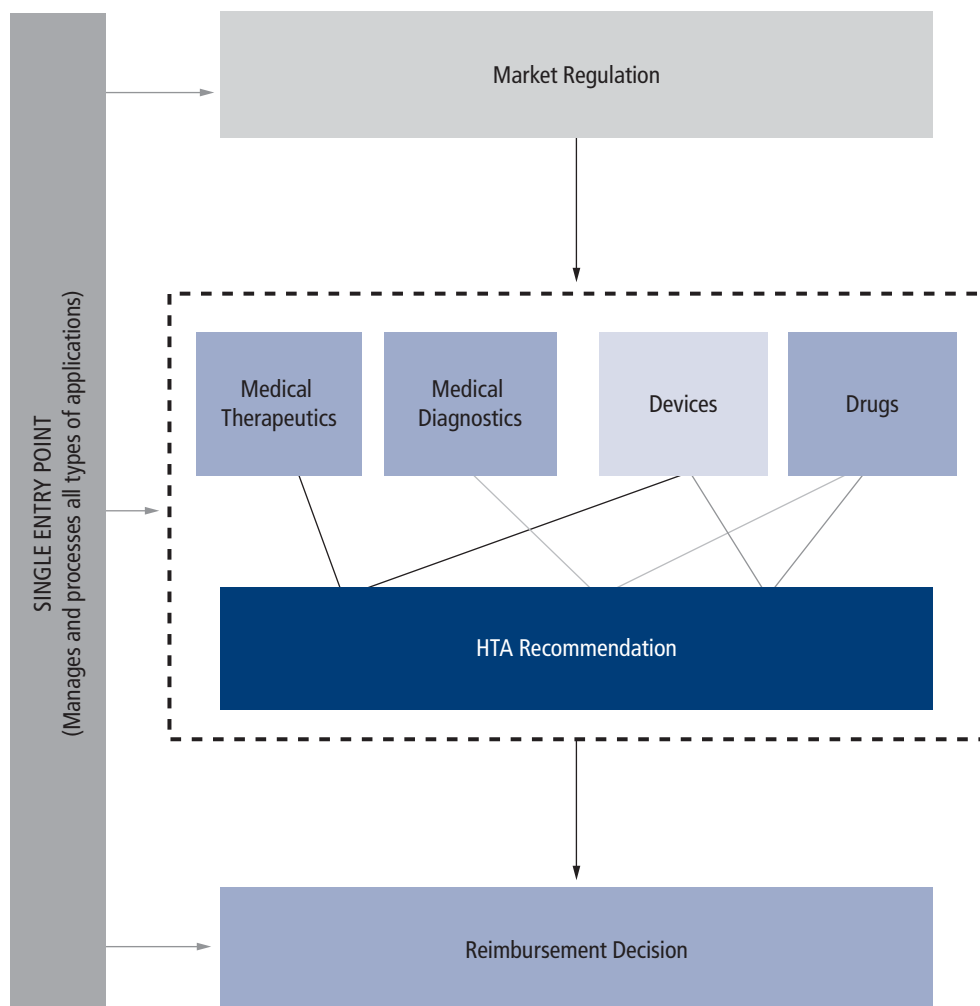
Option 2A – A new single entry point to process and manage all applications

A new single entry point could be established to process and manage all applications for HTA for market entry and reimbursement.

Discussion

This would provide an opportunity for consistent processes and guidelines to be developed. In addition, potential applicants would only be required to interact with one Commonwealth process to seek information about and apply for HTA for both market regulation and reimbursement.

Diagram 1 Option 2A



Option 2B – A single entry point manages applications for HTA for market regulation and a single entry point manages applications for HTA for reimbursement

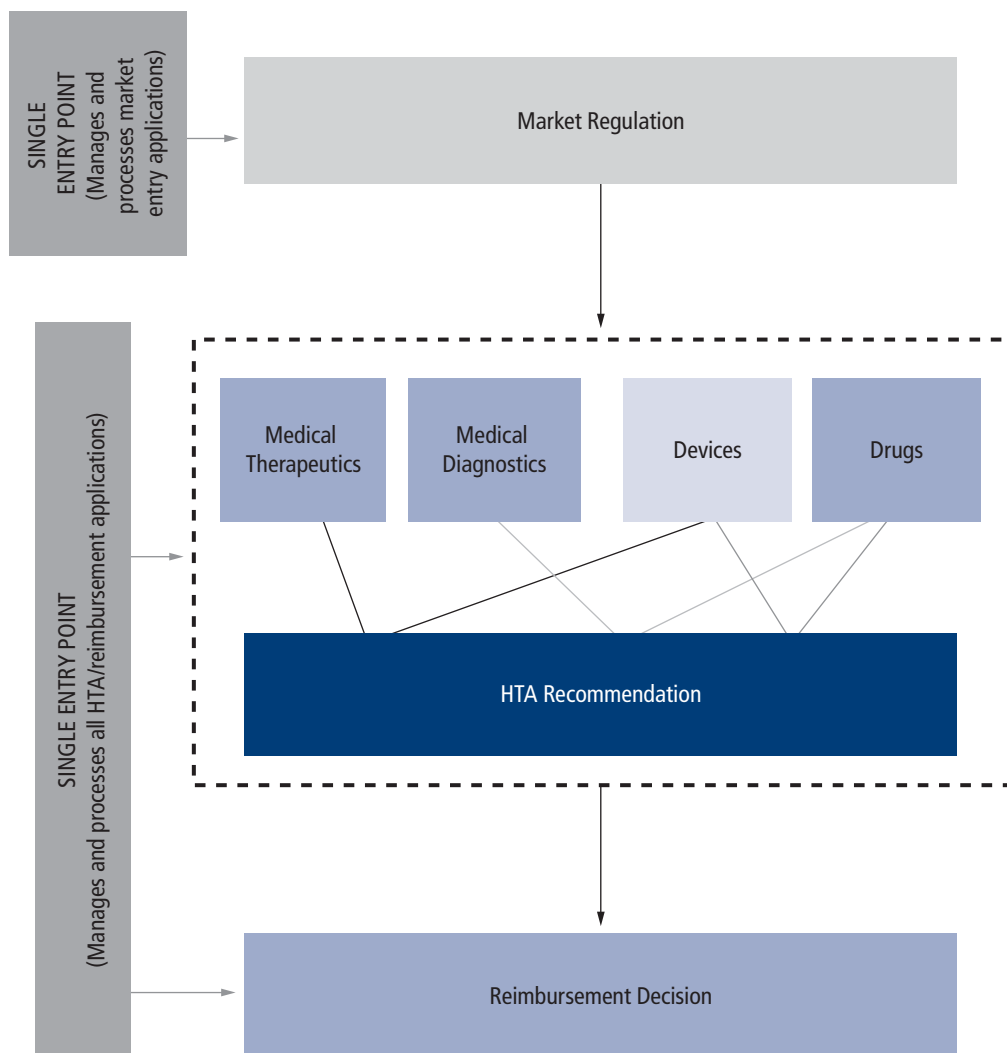
The TGA maintains its role as the market entry regulator and another area within the Health portfolio assumes responsibility for coordinating all applications for Commonwealth HTA processes for reimbursement.

Discussion

This option could maintain the current separation of HTA for market regulation and HTA for reimbursement activities which may reduce role confusion. However, it might also continue the perception that there is fragmentation between HTA for market entry and HTA for reimbursement, particularly whenever market authorisation is part of the eligibility criteria for HTA for reimbursement, noting that stakeholders have been critical of the coordination of timing of granting market authorisation and the commencement of HTA for reimbursement.

The DoHA area taking responsibility for overall coordination of the current HTA processes and advisory committees (MSAC/PDC/PBAC) would have an opportunity to develop more consistent processes and/or manage the different application requirements.

Diagram 2 Option 2B



Proposal 3 Triaging of HTA Applications

The overall triaging process could determine:

- the most appropriate HTA process(es) and HTA advisory committee(s) to undertake assessment of the product or service (including any combination of these); and
- the most appropriate assessment level for different types of applications within each HTA process (such as new products, “me-too” products, variations to existing products and co-dependent and hybrid products), the likely evidence and time implications.

This proposal seeks to implement a more consistent approach to triaging applications across DoHA, while allowing for the individual requirements of the different HTA processes.

Note: The proposal for triaging is not dependent on the proposal for a single entry point.

Discussion

Both the TGA and PBAC processes incorporate triage systems to inform the assessment pathway and assessment levels for applications using a risk based approach. The PDC process has an informal triaging process for its applications. Applications to MSAC are currently accepted without triaging.

The triage within an *assessment process* could determine whether the application requires a full HTA, targeted HTA, listing advice on the basis of the triage report or is unsuitable for further assessment (or listing) on the basis of the triage report.

Implementing an overall triaging process could aid applicant understanding of the HTA processes and create resource efficiencies by enabling planning for upcoming HTA assessments (including assignment of resources [HTA assessors and funding]).

Proposal 4 Allowing Submission Based Assessment for Potential New Medicare Benefit Items

MSAC applicants could be expected to gather all necessary evidence to support their application, rather than the evidence being generated during the assessment process. Applications would be made to the MSAC Secretariat and be independently evaluated (using appropriate expertise). The evaluation report would be provided to MSAC alongside the application which would determine whether to recommend the proposed health technology for listing on the MBS. If the application provided an insufficient basis to recommend MBS listing, the MSAC reasons would identify the deficiencies in the application.

Discussion

This proposal could be assisted through improvements to application forms, clearer eligibility criteria and evidence requirements and improved pre-lodgement consultation mechanisms. It could represent a shift from the current practice of MSAC commissioning a full HTA by external evaluators and might assist DoHA with triaging applications (refer to Proposal 2 above).

This proposal could reduce assessment timelines, enhance procedural fairness, build capability in Australia (including increased skills in conducting trials, health economic [cost effectiveness] analyses), increase the evidence base for potential new Medicare Benefit items and increase clinical trial capacity in Australia in relation to medical devices and medical procedures.

Should an applicant provide insufficient information to support an application, it could be directed (prior to reapplying to MSAC) to either:

- undertake its own research to generate the necessary evidence; or
- seek the assistance of a coordinating research body to apply for a funded trial of its procedure/device which could contribute to the evidence base.

Discussion Paper 3 – Approaches to Evidence and Methodologies

Disclaimer

The proposals for reform to Commonwealth Health Technology Assessment (HTA) processes as outlined in this Discussion Paper represent a range of responses to the issues raised in submissions to the HTA Review and during stakeholder consultation. The Discussion Papers are intended to stimulate discussion at the forthcoming consultations and any proposal presented or omitted could not be taken to represent the policy position of the Government. The HTA Review is required to put forward proposals that can be sustained within existing funding levels and that are consistent with Government policy objectives.

Introduction

Commonwealth HTA processes for reimbursement purposes are undertaken by three separate HTA advisory committees: the Medical Services Advisory Committee (MSAC), Pharmaceutical Benefits Advisory Committee (PBAC) and Prostheses and Devices Committee (PDC). These advisory committees assess health technologies, including devices, pharmaceuticals, diagnostics and pathology tests. The manner in which these different advisory committees approach HTA (approaches to evidence and methodologies) varies, as do the ways each single advisory committee approaches different technology types. It is recognised that there is a strong need for consistency across and within HTA advisory committees where possible, as well as the ability to undertake fit for purpose assessments where appropriate.

This paper summarises the key concerns expressed by stakeholders about the current approaches by the Department of Health and Ageing (DoHA) to evidence and methodologies and the way that they are applied to HTA in Australia. It also presents a number of proposals to address these concerns, within the scope of the HTA Review.

Concerns Raised in HTA Review Consultations

Concerns raised about approaches to evidence and methodologies for HTA processes during public consultations ranged across six themes:

Transparency of methods

- Stakeholders sought greater transparency of approaches that are used to assess technologies, including:
 - what methodologies will be used to assess technologies;
 - how those methodologies will be applied; and
 - how much evidence of what quality/level of evidence is expected.
- Stakeholders identified a need for better feedback about limitations in the evidence provided by sponsors (either prior to, during or following the assessment process).
- The consequences of the current lack of transparency were considered to be:
- inconsistent or unpredictable application requirements, assessments and decisions;

- duplication of work by sponsors and HTA advisory committees;
- inefficiencies for government due to the receipt of insufficiently substantiated applications; and
- poor public perception of the fairness of Commonwealth HTA processes.

Evidentiary requirements

- The levels of evidence required for assessments are regarded by some stakeholders as lacking clarity or consistency. Clarity of evidentiary requirements, consistent with a high likelihood of a positive HTA outcome, was important to stakeholders who have financial interests and desire some degree of certainty around HTA decisions.
- The perceived high number of HTA recommendations that did not support reimbursement for health technologies, was seen as being linked to unreasonably high evidentiary requirements, and was of concern for many stakeholders. Stakeholders stated that level 2 National Health and Medical Research Council evidence is difficult to obtain for many medical technologies.

Comparators

- Stakeholders identified a need for greater clarity regarding the determination of comparators in assessing new health technologies. Current levels of guidance, both formal and informal, were criticised with regard to the appropriate use of comparators, the scope of what can be considered a comparator, and what options are available if there is no obvious direct comparator.

Societal values

- The use of 'societal values' in economic evaluations was felt to be lacking in the current system. Failure to consider wider economic benefits (other than health benefits) was thought to result in the undue exclusion of some technologies from reimbursement.

Risk-based approach

- A risk-based approach to assessment methodologies was considered desirable in many submissions. The current system was criticised as being inflexible and unable to undertake 'fit for purpose' assessments in which the potential risks involved with a technology could determine the level of assessment (such as complex versus rapid assessments) and the level and quality of evidence required.

International harmonisation of methodologies

- The international harmonisation of HTA methodologies was supported by stakeholders, particularly for assessments of comparative safety and comparative clinical effectiveness. By ensuring economic evaluations are local, but HTA methods and some assessments are translatable internationally, harmonisation could add efficiencies to HTA and make better use of expertise and resources.

Proposal 5 – Implementation of a Risk-based Approach to Assessment

A more risk-based approach to assessment would mean ensuring that the intensity of assessment matched the risk of the technology. Such an approach would require the ability to vary the amount and level/quality of evidence for different technologies through the development and use of:

An HTA risk classification table

This would be a tool that, based on the characteristics and clinical performance of the technology, could produce an individualised risk rating (eg rating the fiscal risks and/or risks of harm to the patient). This could consist of a table or a series of tables comparing factors to come up with an individualised risk rating, akin to the Therapeutic Goods Administration's (TGA) risk classification system and the work of the Global Harmonisation Task Force (GHTF) on risk management principles. This table could enable applicants to easily identify the likely evidentiary requirements for an application (see next point below) and the likely level of assessment (eg full or streamlined). However, in order to ensure that a fit for purpose approach is taken, this table could only provide an indication of these expectations. The implementation of this approach could provide transparent and more consistent guidance on risk assessment and thus some certainty to applicants regarding the initial approach to assessment. It would provide no indication on the likely outcomes of the subsequent assessment.

Linking risks to evidentiary requirements

Once a technology had been risk-assessed, sponsors could then be formally advised of what type and quantity of evidence would be required for an individual application¹. The risk-assessment could also determine the clinical and economic evaluation tools to be used, related to relevant outcome measures.

Different methods for grading evidence could be considered in the development of the final evidentiary requirements and associated guidance. These should take international requirements into consideration (see next point below). The implementation of this proposal could facilitate upfront discussion of limitations in evidence with sponsors (see also Discussion Paper 4).

The implementation of a transparent risk-based approach, alongside improved transparency of evidentiary requirements and improved communication with stakeholders around decisions, might better enable applicants to meet these requirements, and more clearly highlight the relationship between the strength of evidence and assurance in recommendations for public and private funding.

Consideration of harmonisation with international evidentiary requirements

The harmonisation of risk-based evidentiary requirements and methodologies to align with those of other countries where possible could provide applicants with some degree of certainty about possible outcomes, reduce duplication of effort and more efficiently use HTA expertise. This would be particularly helpful to multinational sponsors dealing with HTA expectations across different countries for the same health technology. Assessments would continue to be undertaken at the Commonwealth level, incorporating the local context.

¹ The levels of evidence required could have been set out in advance, at the time of the pre-lodgement meeting (see Discussion Paper 2).

Discussion

The implementation of these approaches to evidence and methodologies could involve a review of risk classifications, evidentiary requirements and harmonisation across HTA advisory committees, with consolidation where possible, and allow publication of more transparent requirements. The intent of this proposal is to address the consistently raised concerns around the lack of transparency and consistency, not necessarily to increase evidentiary requirements. These approaches may also address the identified need for greater simplicity in the HTA processes and may promote timeliness of assessments.

With regard to risk, the work undertaken on this proposal could define the types of risk to which it refers (eg fiscal risk and risk of harm) and explain their importance in the assessment process.

With regard to harmonisation with international requirements, the TGA has already adopted similar principles developed for the European Union in relation to the market regulation of devices. Whilst higher levels of harmonisation have been called for by some stakeholders than are currently proposed, it is important that this proposal enables the benefits of harmonisation (such as efficiencies) without jeopardising the ability to make HTA decisions based on local contexts, values and resources, and that harmonisation does not hinder the ability to undertake fit for purpose assessments. In addition, it would need to be ascertained whether HTA evidentiary requirements in other countries are compatible with the proposal to develop risk-based evidentiary requirements.

Stakeholders may dispute the defined risk for a health technology and consequential evidentiary requirements. However, this should be mitigated by a clearer articulation of the reasoning behind these evidentiary requirements (eg comparative safety and financial implications for government). It is also possible that a more transparent approach to risk classification and evidentiary requirements will further reduce the perceived inflexibility of the system to accommodate other relevant factors.

Proposal 6 – Improved Guidance on Methodologies and Methodological Processes

Guidance for applicants that is consistent, transparent and publicly available. This could outline explicit HTA methodologies and methodological processes to address the following concerns including:

Perspectives considered in assessments

An assessment could be undertaken across the current HTA processes to provide a clear description of, and reasoning behind, the perspectives adopted for economic evaluations considered by these approaches (with consequences for the consideration of indirect costs). If any changes were agreed as a result of this assessment, further guidance could be developed about the way in which relevant issues are considered (including any caveats).

The use of comparators

Guidance for the selection of comparator technologies or services and their use in the assessment could include consideration of:

- the current clinical management option(s) that the proposed health technology would most likely replace or augment in practice;
- what is current best practice;
- what are similar technologies; and
- what are other comparators from other technology or service types.

The guidance documentation could also explain the way in which comparators are used in assessments.

Evaluation methodologies

An assessment could be undertaken across the current HTA evaluation methodologies, with a view to making them consistent wherever appropriate and explaining different evaluation methodologies as required. This could be conducted during the routine review of each of these methodologies, or as a single commissioned exercise. It could cover topics such as scope of the evaluation, development of research questions, and evaluation tools to be used. It could also include a clear explanation of how methodologies would differ for different types of assessments to ensure that they are fit for purpose, such as different HTA methodologies for treatments and for diagnostic tests. MSAC currently has different guidelines for these.

Specified points in time for obtaining further input leading up to a HTA recommendation

Guidance on the timing and number of opportunities for the applicant and other affected stakeholders to contribute information (eg evidence or feedback) during the HTA process. The reasoning around the number of evidence collection points could be explained clearly, for example the need to ensure adequate procedural fairness, as well as the tension around enhancing timeliness of assessments. This could link to the provision of timeframes identified in Discussion Paper 4.

Discussion

The use of economic evaluation as a method of allocating scarce health resources has wide acceptance, however the methodologies and perspective of such evaluations are often debated. An initial assessment of the perspectives adopted across MSAC and PBAC, for example, indicates a broad agreement, especially in relation to giving a lesser weight to indirect costs for policy, technical and equity reasons. These committees already include societal values about health consequences wherever health outcome changes relating to a new technology can be measured through Quality Adjusted Life Years (QALYs). However, many applications to MSAC have not been supported by evidence of health outcome changes, which makes societal values difficult to apply to such assessments.

A major focus of the HTA Review is improving the timeliness of assessments and decision-making. There is some tension between the desire for faster HTA processes and ensuring adequate procedural fairness. Shorter timeframes for the provision of information, or a restricted number of opportunities to provide further input, may be perceived as inadequate or unfair. However, shortening overall assessment time frames may ameliorate some of these concerns.

This proposal should also help address transparency, procedural fairness and improve communication with stakeholders around common areas of concern. It may also address the need to simplify the assessment of health technologies through enhancing the clarity around methodologies for applicants.

Some applicants might perceive a reduction in the flexibility of assessment processes if transparency of methodologies is increased, due to an enhanced understanding of processes even if no changes are made to the processes themselves. It is also likely that there will continue to be varying views on how societal values should be considered in assessments.

There may be some applications for which new evidence arises during the assessment process which could have an impact on the assessment of the health technology under consideration. Improved timeliness of HTA processes (and the submission of applications only when relevant evidence has become available) should decrease the likelihood or consequences of this occurring.

Discussion Paper 4 – Improved Administration of Commonwealth HTA Processes

Disclaimer

The proposals for reform to Commonwealth Health Technology Assessment (HTA) processes as outlined in this Discussion Paper represent a range of responses to the issues raised in submissions to the HTA Review and during stakeholder consultation. The Discussion Papers are intended to stimulate discussion at the forthcoming consultations and any proposal presented or omitted could not be taken to represent the policy position of the Government. The HTA Review is required to put forward proposals that can be sustained within existing funding levels and that are consistent with Government policy objectives.

Introduction

The Department of Health and Ageing (DoHA) has a legislative, policy and program framework to administer Commonwealth Health Technology Assessment (HTA) processes to inform:

- market entry regulation – to ensure that new therapeutic goods are safe, perform as intended and are produced using appropriate quality controls before granting marketing approval in Australia;
- reimbursement decisions – the assessment of comparative clinical and cost effectiveness of the use of health technologies, which informs decisions about:
 - public funding of medical services (with or without a device), pharmaceuticals and vaccines through the Medicare Benefits Schedule (MBS), the Pharmaceutical Benefits Scheme (PBS) and National Immunisation Program (NIP) respectively;
 - private health insurance reimbursement of prostheses through the Prostheses List (PL); and
- post market surveillance of marketed therapeutic goods and reimbursement of health technologies.

This paper summarises stakeholder concerns about DoHA's current approach to managing Commonwealth processes for market entry and reimbursement and presents a number of proposals to address these concerns.

Concerns Raised in HTA Review Consultations

Concerns raised during the consultation process about DoHA's administration of Commonwealth HTA processes included:

- public information about DoHA's administration of the HTA processes to inform market regulation and reimbursement decision on websites and in program guidelines is not presented in a systematic manner nor on a central site. The Therapeutic Goods Administration (TGA) and each HTA advisory committee have a website and program guidelines that describe their individual role and function within the Commonwealth system but not how it interrelates with other HTA processes;
- reflecting this lack of information, stakeholders have difficulty understanding the different HTA processes

performed by the various HTA advisory committees;

- Commonwealth HTA processes appear to be uncoordinated, with duplication and overlap between processes, especially in regard to safety assessment;
- the view that the Medical Services Advisory Committee (MSAC) and the Prostheses and Devices Committee (PDC) have unpredictable requirements and outcomes, lack transparency and procedural fairness and are inconsistent in decision-making, whereas the TGA and the Pharmaceutical Benefits Advisory Committee (PBAC) have predictable requirements and are viewed as transparent in their processes and decisions; and
- stakeholder desire for:
 - more extensive and clearer guidance on the HTA processes with greater consistency across all parts of the Commonwealth HTA system;
 - clearly defined roles and responsibilities for HTA advisory committees and evaluators;
 - process improvements that simplify and speed up the HTA assessment process;
 - more open, timely and mandated communication between the various HTA advisory committees;
 - an independent review mechanism for HTA advisory committee recommendations;
 - clearer explanation of the rationale(s) for HTA advisory committee recommendations and advice;
 - better handling of conflicts of interest especially in membership on HTA advisory committees and their supporting committees and panels;
 - better performance information, reporting and evaluation; and
 - standardised timelines for HTA processes and for each key step within each process.

Proposal 7 – Improved Public Information on HTA Processes

DoHA's website could provide an overall view of the Commonwealth HTA system, including an explanation of each of the different HTA processes, a description of how these processes are implemented by each HTA advisory committee and regular updates on performance against agreed performance indicators.

Discussion

DoHA currently does not have an overall "HTA" website. Prime information sources for each of the HTA processes and advisory committees are contained on discrete sites on DoHA's or TGA's website. The format and content of each website is different and none provides a coherent link to the other sites. Only the TGA's website includes a formal application tracking component which is updated in real time; only the TGA and PBS websites cater for different stakeholder groups.

A central website that provides a DoHA overview of HTA with links to the other HTA processes and advisory committee websites could improve the information publicly available to stakeholders, promote role clarity, transparency of processes and decrease stakeholder confusion about DoHA's HTA processes.

Proposal 8 – Standard Approach to HTA Process Management

DoHA could provide greater clarity about its current management framework for the Commonwealth HTA processes for market entry and reimbursement including:

- development of a guide to all Commonwealth HTA processes as a whole, as well as the purpose of each individual process and the interactions between the different DoHA and TGA HTA processes and advisory committees;
- development of a standard approach to structure and content (to the extent possible) for all HTA process guidelines, using consistent definitions and language and including descriptions of:
 - the appointment, roles and responsibilities of the HTA advisory committees
 - processes for handling conflict of interest;
 - decision making processes and criteria;
 - review mechanisms;
 - processes subsequent to HTA, but prior to a decision to provide reimbursement;
 - estimated timelines for HTA processes and decision making; and
 - the roles of particular stakeholders; and
- strengthened committee management by:
 - ensuring committee secretariats make better use of DoHA's Committee Support Unit's guidance (eg management of conflicts of interest);
 - more clearly articulating HTA advisory committee roles and responsibilities; and
 - enhancing expertise of DoHA staff to provide technical HTA support as well as secretariat support to the HTA advisory committees.

Discussion

This proposal could assist in:

- enhancing applicant understanding of requirements prior to making an application as well as improving understanding of how the various functions and processes fit into the overall Commonwealth HTA process;
- enhancing transparency of the Commonwealth HTA processes, through clear articulation of the HTA processes for market entry and reimbursement and increasing public confidence in DoHA's HTA processes;
- improving internal process consistency and minimising any duplication and burden on applicants; and
- providing a smoother transition towards the better alignment of HTA advisory committees (whether in parallel or in series for co-dependent or hybrid technologies) to reduce timeframes, and minimise any real or perceived duplication in HTA processes.

Proposal 9 – Specified Communication Points

External communication

Proposals 7 and 8 would assist with improving external communication. However, key communication points could be introduced across the HTA processes so that applicants could more easily monitor progress of their application through the Commonwealth HTA processes. The communication points could align with key decision points in the HTA processes and could be monitored internally and externally.

Key communication points could be at the time of:

- pre-lodgement meetings;
- application receipt;
- application acceptance, eligibility and triaging;
- stages within the assessment phase (eg to enable questions about the application, procedural fairness to the applicant with opportunities to review and comment on finalised documents prepared in response to its application, and input from stakeholders other than the applicant);
- finalisation of the HTA assessment documents prior to their consideration by the HTA advisory committees;
- meetings of HTA advisory committees at which they decide what recommendations and advice to provide, together with a rationale for each decision (whether the recommendation is positive or negative);
- subsequent reimbursement decision; and
- implementation of final listing.

DoHA (internal) communication

In the short-term, communication between all HTA functions and processes across DoHA could be more formalised. This could involve regular meetings of the chairs of HTA advisory committees and/or secretariats across the HTA processes.

Discussion

Key communication points would need to be agreed with stakeholders as increased points of communication will impact timeliness.

The proposal for internal communication through regular meetings of the HTA advisory committees secretariats could assist in addressing concerns about insufficient coordination.

In the long-term, the single entry point proposal in Discussion Paper 2 may also assist in addressing concerns raised about communication.

Proposal 10 – Establish Review Mechanisms for HTA Processes and Decisions

The two key HTA advisory committees within the scope of the HTA Review (MSAC and PDC) are non-statutory committees. By contrast, PBAC and its functions are determined by legislation. These facts influence the possible proposals that might be contemplated for reviews of recommendations and advice made by these HTA advisory committees to the Minister for Health and Ageing about public funding decisions.

There are a number of issues to be considered in developing any new review mechanisms, including the type of review, who conducts the review, and the particular matters to be reviewed.

Types of review

Merits review is the process by which a person or body other than the primary decision-maker reconsiders the facts, law and policy aspects of the original decision and determines the correct and preferable decision. The result of a merits review is the affirmation or variation of the original decision.

A process review considers whether the process was administered appropriately. The result of a process review does not necessarily change the original decision. If errors of process are found, then it would be recommended that the correct processes be instituted before the original decision is re-considered by the primary decision maker. In other words, a review of process might not necessarily alter the nature of the recommendation or advice of the HTA advisory committee.

Issues to be reviewed

Reviews could address the recommendation by a decision-maker.

Conduct of the review

A review could be conducted either by the original agency/decision-maker, or by an independent body.

Taking the current independent review mechanism arrangements related to PBAC decisions not to recommend PBS listing as an example, a review could be triggered by an applicant indicating its dispute with specific technical matters relied upon by the HTA advisory committee. An independent convenor could appoint a reviewer from a panel of identified experts. The appointed reviewer could then have access to all the information placed before the HTA advisory committee and might seek clarification from the applicant, the HTA advisory committee, DoHA or other relevant experts as needed. However, no new information would be provided to the reviewer. The reviewer would finally submit a report to the HTA advisory committee to reconsider the original application in light of the review findings.

DoHA could also implement a consistent internal review of process across the Commonwealth HTA processes (being more efficient than a system of process reviews of individual HTA advisory committee recommendations). This could be initiated by the relevant secretariats and considered by an appropriately qualified DoHA officer independent of these processes. Alternatively, an external complaints commissioner or probity adviser could be appointed in conjunction with the HTA advisory committees and DoHA to review these processes for a set period of time.

Discussion

The majority of stakeholders supported independent review of decisions by HTA advisory committees where the committee recommended that a health technology not be supported (noting that payers were not as supportive as applicants).

A review mechanism independent of the HTA advisory committee and DoHA should provide for greater accountability.

Proposal 11 – Better Information on Performance of the HTA System

Good performance information would help demonstrate the extent to which the Commonwealth HTA processes are effective and efficient.

The development of a set of Key Performance Indicators (KPIs) for Commonwealth HTA processes is proposed where DoHA and/or the relevant HTA advisory committee has control over the outcomes and the KPIs can be measured and reported against. If this proposal were accepted, the KPIs could be made publicly available (in the guidance documentation), with a view to aligning these KPIs across the HTA processes over time. Information reporting the results against these KPIs would also be made publicly available in performance reports and on HTA websites, to enable comparisons of these results over time and across HTA processes.

The KPIs could include:

- timeliness of assessment;
- HTA outcomes: supported, rejected, conditionally supported;
- other HTA advisory committee activity;
- alignment of HTA outcome with reimbursement decision; and
- improvements in health outcomes achieved (currently difficult to measure).

Discussion

The inclusion of KPIs would provide for greater accountability and while it would be desirable to align KPIs, the KPIs should also be fit for the purpose for each Commonwealth HTA process. The HTA processes would endeavour to reach defined levels of performance where appropriate, for example where it is clear that the KPI measures an outcome over which the HTA process has sole control.

Discussion Paper 5 – Enhanced Post Market Surveillance

Disclaimer

The proposals for reform to Commonwealth Health Technology Assessment (HTA) processes as outlined in this Discussion Paper represent a range of responses to the issues raised in submissions to the HTA Review and during stakeholder consultation. The Discussion Papers are intended to stimulate discussion at the forthcoming consultations and any proposal presented or omitted could not be taken to represent the policy position of the Government. The HTA Review is required to put forward proposals that can be sustained within existing funding levels and that are consistent with Government policy objectives.

Introduction

Because of the uncertainties in the evidence base around particular health technologies at the time of regulatory and reimbursement decisions, it is necessary to ensure the ongoing monitoring of health technology safety and performance. Post market (and post reimbursement) surveillance of health technology safety and performance is important because:

- it can provide valuable new evidence on the performance of a health technology on an ongoing basis especially where pre market and pre reimbursement evidence is limited; and
- the information collected helps to inform potential decisions such as:
 - should a technology be removed from the market?
 - should a technology continue to be publicly funded?
 - should the eligible population be reviewed?
 - should price (benefit) paid for technologies increase, decrease or stay the same?

This paper puts forward a number of proposals to address different elements of post market surveillance. They require further considered consultation with stakeholders including on how they may be appropriately resourced for effective implementation. Because the Review of Health Technology Assessment in Australia (the HTA Review) is constrained to put forward recommendations that can be implemented within existing funding levels, some of the proposals may be considered to be medium to longer term strategies to improve post market surveillance. They may also potentially impose additional regulatory requirements that would need to be carefully considered prior to recommendation or implementation.

Concerns Raised In HTA Review Consultations

The following concerns were raised about Australia's post market surveillance system:

- it is too passive;
- it is heavily weighted in favour of safety concerns, with minimal comparative effectiveness focus. It needs to be more wide reaching and systematic across the health system by being proactive in seeking information about the comparative safety and effectiveness of particular technologies;

- it is over reliant on notification of concerns from suppliers and manufacturers which gives rise to potential conflict of interest;
- There is no nationally consistent process for alerting different jurisdictions in the event of a serious fault in a health technology;
- it needs to move beyond signal generation and into the realm of quantifying risks and benefits¹; and
- an expanded but targeted use of registers is needed to generate data that are more representative of health technology performance.

There were concerns also expressed around the post reimbursement evidence gathering arrangements ('interim funding') of the Medical Services Advisory Committee (MSAC):

- sponsors (and practitioners rendering the service) are not compelled to collect evidence to support a review (data collection is an expectation rather than requirement);
- it is not always clear who should pay for the collection of evidence, and the design and execution of the data collection is often methodologically weak;
- where data are collected, the quality of the data is such that definitive conclusions cannot be made; and
- there is currently no clear mechanism for the Government to have specific trials performed for new technologies and procedures for Medicare funding whether or not Medicare Benefits Schedule (MBS) listing is approved on an 'interim funding' basis².

Proposal 12 – Widening the Scope of Post Market Surveillance

Instead of primarily evaluating and acting on *intrinsic* safety, efficacy and short-term effectiveness data, Australia's post market surveillance system could expand its scope and consider *comparative* safety, clinical effectiveness and cost effectiveness. This could include an analysis of information about longer term risks, benefits, and costs in real life settings (in the hands of typical clinicians as applied to the broad range of patients encountered outside the usual investigational context).

Discussion

Traditionally, post market surveillance systems collect data of interest primarily to regulators. This proposal is about to what extent post market surveillance systems should collect comparative data which is of interest primarily to funders, but which may also be of interest to regulators.

There are many definitions of surveillance, but a widely used definition describes surveillance as the 'ongoing, systematic collection, analysis, interpretation, and dissemination of data about a health related event for use in public health action to reduce morbidity and mortality and to improve health'³. This definition could be interpreted as inclusive of any data, including comparative, that inform a decision to reduce harm and maximise benefit (regardless of whether it is a regulatory or reimbursement decision). However it may be more feasible

1 Submission 85. Medical Services Advisory Committee (MSAC). 1st July 2009

2 It is important to note that MSAC is not the principal funder of clinical trials. Rather, it may recommend temporary MBS listing "to support data collection to address specific areas of uncertainty with respect to MBS listing decisions."

3 Centre for Disease Control and Prevention. Morbidity and Mortality Weekly Report; 50:1-35. 2001

to have separate but closely related evidence generating systems that support the distinct needs of each these decision makers rather than mushrooming the size of the current post market surveillance system. A situation would need to be avoided where loosely connected 'silos' of evidence gathering are created.

Proposal 13 – Establish a More Rigorous Coverage with Evidence Development Framework

Coverage with Evidence Development (CED) is defined as *any health policy initiative that links use of health care technology to a requirement for data collection, with the intent of informing future decision making*⁴. CED is one of several policy options that have been postulated to overcome the problems of remaining uncertainty associated with making decisions to cover (i.e. reimburse the use of) a health technology. Conditionality allows a promising technology to be made available under specific conditions, usually for a defined period, after which the benefits of the technology are reviewed. Within this proposal, there are at least two possible options.

Option 13A – More stringent data collection requirements following MSAC recommendation of 'interim funding'

This option would simply tighten the rules around existing interim funding arrangements including the enforcement of data collection. The disadvantage of this option is that it remains confined to services that have been considered by MSAC.

Option 13B – An independent CED research program

This could be coordinated by a separate research agency that conducts post HTA assessments on behalf of the HTA advisory committees such as MSAC, the Pharmaceutical Benefits Advisory Committee (PBAC) and the Prostheses and Devices Committee (PDC) with its own guidelines, protocols and earmarked funding.

Discussion

There are several methods of evidence development that could be adopted under a CED type program depending on the type of uncertainty in the evidence base that needs addressing. If the uncertainty is over the *cost-effectiveness* of a technology, then CED offers a way of generating further evidence on these variables without delaying access to treatments with clinical benefits adequately demonstrated in prior evidence⁵. It may be possible to identify the range within which the values of the uncertain variables must fall to give reasonable confidence that an appropriate level of clinical benefit and/or cost-effectiveness will be achieved⁵. The new data collection could be designed to show more robustly whether the variables fall within the required ranges.

When the uncertainty is around the *clinical effectiveness* of a technology, there are multiple choices in study design depending on the research question for example:

- randomised pragmatic clinical trials (where feasible); or
- observational studies (for example through the use of registers).

4 HTAi Special Interest Group on Conditional Coverage and Evidence Development for Promising Technologies. Found at: <http://www.cmpnet.org/cmp-research/applied-policy-and-methods/coverage-with-evidence-development/htai-special-interest-group>.

5 Hutton J, Trueman P, Henshall C. Coverage with Evidence Development: an examination of conceptual and policy issues. *International Journal of Technology Assessment in Health Care* 23: 4; 425-435. 2007

Whatever study design is chosen, care must be taken to ensure that, in the pursuit of seeking evidence of more practical value to clinicians and patients in the real life local health care environment, this is not at the expense of robust study design or else this may inadvertently increase the uncertainty in the evidence base.

Given potential ethical issues⁶ associated with CED, a robust consent framework would be required that makes it clear to all participants (patients and medical professionals) that further evidence about the new procedure or technology is being collected about identifiable patients and that informed consent and data collection are required for participation and funding. CED has several consequences for stakeholders⁵:

For manufacturers and sponsors:

- it might allow promising technologies to be made available sooner that might otherwise be rejected, but might also introduce additional regulatory burden through more stringent data collection requirements;
- there might be little interest in conducting research if it carries the risk of proving that a product is not what it was hoped to be; and
- it might allow sponsors to reconsider the pricing of the technology, although this might not always be feasible.

For decision makers:

- it might allow a health technology to be made available in a controlled manner while also allowing the decision maker to define what evidence is required to support further reimbursed use of the technology;
- it would potentially place extra demands of approving the study design and monitoring and reviewing the data collected; and
- it might introduce the challenge of withdrawing coverage if this is the conclusion reached.

For health care providers:

- it might allow for earlier access to promising health technologies, thus increasing treatment options available for their patients but health care providers might also remain reluctant to use a technology that remains under evaluation.

For patients:

- it might allow access to health technologies that have apparent benefits, but patients might also fail to recognize or appreciate that there are distinctive risks, burdens, or greater uncertainties relating to benefit associated with CED participation. They might also incorrectly presume that coverage might imply that the risks of the intervention are well-known and considered reasonably low for all patients; and
- Alternatively, patients (and, in some instances, providers) might develop an inflated perception of the intervention's benefit because it already attracts reimbursement and thus infers that sound evidence has already justified the use of the intervention.

If a CED type program were formally adopted, care would need to be taken to safeguard against creating unrealistic expectations about CED assessment outcomes for the various stakeholders. It is critical that the potential implications of embarking on a CED process (in terms of future decisions) are well defined at the outset. Timeframes set for the completion of CED research would need to take into account the time it takes to put a research team together, recruit sufficient number of participants and allow for collection and analysis of data.

6 Miller FG, Pearson SD. Coverage with Evidence Development. Ethical issues and Policy implications. *Medical Care*; 46 (7): 746-751. 2008

Proposal 14 – Expanded Use of Registers for Post Market and Post Reimbursement Data Collection

Many of the submissions advocate the setting up of additional registers as a data collection tool to reduce the uncertainty in the technology evidence base after both regulatory and reimbursement approval. This tool for post market surveillance could be used in conjunction with CED, or independent of it.

The primary criterion for implementing any register is that there is widespread confidence that it would be capable of generating convincing data on safety and relative effectiveness to support any subsequent decision about ARTG listing and reimbursement. By definition, registers are databases that systematically collect health-related information on individuals who are⁷:

- treated with a particular surgical procedure, device or drug (e.g. joint replacement);
- diagnosed with a particular illness (e.g. stroke); or
- managed via a specific healthcare resource (e.g. treated in an intensive care unit).

The system or organisation governing the register is known as the *registry*. The purpose of the register would dictate what type of data collection is needed. Within this proposal there are at least three possible options in terms of type of registers that could be adopted.⁸

Option 14A – Device or Procedure Specific Registers

These types of registers are established to assess the specifics of a single device. They are often required by regulators to address questions about the real life characteristics of a procedure or device. The downside of this option is that if a register was set up for every single device or procedure, then the number of registers may become unmanageable. This option is likely to be reserved for certain circumstances (for example if considerable concerns have been raised about the safety and efficacy of a particular device or procedure, then this type of register could be set up to specifically investigate these concerns).

Option 14B – Class Registers

Class Registers collect data on all devices and procedures used in a specific class of intervention. The National Joint Replacement Register (NJRR) is an example of a class register. Several submissions supported the wider use of registers based on the NJRR model and this type of register may be well suited to support the PDC which is currently sorting prostheses on the Prostheses List into groups for the purpose of benefit negotiation.

Option 14C – Comparative Registers

Comparative Registers look at a range of different types of treatment options for a specific type of disease. They collect information on the different treatment pathways that might apply, including the use of surgical procedures, pharmaceuticals, and devices. This type of register is more suited to answering questions of interest primarily to reimbursement decision makers but may also be of interest to regulators. They can be very complex and expensive to operate and hence careful consideration would need to be given before their adoption.

7 The NHMRC Centre of Research Excellence in Patient Safety. Guidelines for the establishment and management of clinical registries. A report prepared for The Australian Commission on Safety and Quality in Health Care

8 Submission 39. Medical Technology Association of Australia. 22 May 2009

Discussion

Because of the potential expense involved in setting up and maintaining a register, careful consideration would need to be given to defining criteria of high risk for selection and inclusion of a health technology into any future registers. For example, in relation to devices (or class of devices) these criteria could be informed by the risk classification of medical devices set down by the TGA⁹, and also by the risk classification model proposed for HTA processes, which might also capture the longevity of each device.

If clinical registers were set up as a conduit to collect data as part of any enhanced active post market surveillance (or post reimbursement evidence collection system), there are several important requirements of a clinical registers that need careful consideration⁸.

There must be good clinical buy in (clinicians are more likely to want to participate if the method of contributing information is relatively straight forward in terms of time and effort). Care would need to be taken to avoid duplication of data collection across registers, so that clinicians do not have to repeatedly supply the same information to a number of registers for the same procedure. The potential users of the register data must feel that the information is not tainted by bias and that interpretation is not made out of context. Financial incentives to encourage register participation would also need to be carefully constructed.

If poorly designed and resourced, registers have several limitations including:

- a lack of timely reporting, with some registers taking significant periods of time to provide reports;
- lack of clarity around ownership and privacy of data and compliance by users of the health technology being assessed;
- lack of comparability with other data sources in the absence of standardised definitions and practice;
- variable approaches to data audit, especially with regard to the capacity to recruit an eligible population and the completeness of the assessments;
- validity and comprehensiveness of data reporting; and
- potential for conflicts of interest in registry management, regardless of the manager.

It is therefore essential that the purpose and design of a register be carefully considered before embarking on establishing it. Draft operating principles and technical standards for registers developed by the Australian Commission for Safety and Quality in Health Care could be drawn upon in the first instance.

9 Therapeutic Goods Administration. 'Australian Medical Devices Guidance Document Number 25. Classification of Medical Devices'. January 2005

Proposal 15– Enhanced Data Linkage to Support Post Market Surveillance

There are at least two possible options in terms of improving linking of data for post market surveillance.

Option 15A – ‘Piggy back’ on existing national data linkage and e-health initiatives that would then feed information into post market surveillance system

The issue of data linkage is one the broader Australian health care system continues to grapple with and is being addressed elsewhere by various national data linkage and e-health initiatives coordinated by the Australian Health Ministers’ Advisory Council (AHMAC). Given that there are already some highly sophisticated infrastructure projects being put in place nationally aiming for cross-jurisdictional data linkage on a de-identified unit record level, any recommendation for improved post market surveillance data collection could be incorporated into these existing data linkage initiatives.

Option 15B – ‘Pilot’ a specific data linkage project for post market surveillance purposes

This project could initially link appropriate datasets at a Commonwealth level followed by datasets at a State and Territory level to specifically extract information relevant for post market surveillance purposes. Care would need to be taken that this option does not duplicate existing efforts to improve data linkage nationally. A clearer idea about what information is being sought for post market surveillance would need to be resolved before considering what data linkage systems are needed to best extract this information.

Discussion

The current inability to link datasets within and across jurisdictional boundaries was stated amongst the submissions to the HTA Review as an impediment to post market surveillance. Building a capability for post market surveillance using data linkage will require investment in structures and frameworks for governance, privacy, ethics and community involvement; information technology and information management; methods and tools for data linkage and analysis of linked datasets; and human capacity¹⁰. The potential benefits of data linkage include¹¹:

- increased cost-efficiency of research compared with performing de novo longitudinal studies and other more traditional approaches to epidemiologic and health services research;
- adding value to existing information assets and generating a research return on the substantial existing investment in routine administrative and clinical data sets within health;
- fostering collaborative research involving population health researchers, clinical researchers and biomedical scientists, with direct benefits for clinical outcomes; and
- community development through enhancing interactions among researchers, clinicians, administrators, consumer groups and the mass media.

10 Australian Government. Department of Innovation, Industry, Science and Research. National Collaborative Research infrastructure Strategy (2005-2011) Scoping Paper – Population Health and Data Linkage. 2005.

11 Data Linkage Australia. Scoping paper: a model for a data linkage facility in New South Wales. Sydney: the Sax Institute, 2005.

Proposal 16 – A Review Process with Capacity to Recommend Disinvestment

The discipline of HTA could play a larger role in making recommendations around the disinvestment of health technologies including the:

- identification of ineffective technologies;
- provision of advice recommending reducing or refining the use of technologies; and
- provision of advice recommending the removal of technologies from government and insurance funding schedules altogether¹².

This would allow reallocation (or reinvestment) of funding to interventions and programs that offer overall health gains more efficiently and could encourage more robust and efficient processes around all health care decision making, not just disinvestment.

Discussion

In the discipline of HTA, criteria have already been developed for determining priorities for assessing new and emerging health interventions. Preliminary work has begun at an academic level to build upon these criteria to develop a framework to facilitate systematic and transparent identification of existing, potentially cost-ineffective health interventions for formal review¹². The preliminary criteria are as follows:

- new evidence on safety, clinical effectiveness and/or cost effectiveness may come to light that changes previously held conclusions;
- provider and geographical variations in care where choice of intervention significantly varies for a particular condition;
- when an intervention has evolved to the point that it differs markedly from the initial or prototype intervention that was originally assessed or funded;
- temporal variation in volume of use i.e. a trend in MBS item volume between time points (eg 2, 3, 5 years) of a substantial percentage (say 30%, 50% or 80%). This may be a decrease or increase;
- public interest or controversy;
- nominated by expert clinical groups for formal review: This could be through a consultation process via an overseeing 'disinvestment committee' with broad stakeholder representation;
- when a new intervention is presented to the relevant HTA advisory committee and is considered a potential replacement for (an) established comparator(s) for that indication, then that comparator could also be considered for formal review;
- technology use (with reimbursement) is outside the evidence based indications or conflicts with clinical practice which is accepted as cost-effective. This has also been 'leakage' or 'indication creep'; and
- 'legacy' items – long established interventions (or class of interventions) that have never had their cost-effectiveness assessed.

12 Elshaug AG, Moss JR, Littlejohns P, Karnon J, Merlin TL, Hiller JE. Identifying existing health care services that do not provide value for money. *Medical Journal of Australia*; 190: 269-273. 2009

Criteria would also need to be developed to inform prioritization of candidates for formal review after identification such as¹²:

- high cost per item of intervention or high overall due to high volume;
- the potential health, cost and equity impacts of disinvestment versus maintaining the status quo;
- a cost-effective alternative;
- a high level of disease burden; and/or
- a pre-designated time for follow up review has arrived.

Given the potential negative connotations around the term disinvestment (i.e. stakeholders may perceive this term as implied criticism of clinical practice or an intrusion on clinical autonomy), it is important that any implementation also includes a transparent and consultative process that actively engages all affected parties. In the short to medium term, a disinvestment review framework that traverses across all Commonwealth HTA processes (the Medicare Benefit Schedule, the Pharmaceutical Benefit Scheme and the Prostheses List) could be established. This could be in the form of a specialist subcommittee, with broad stakeholder representation, supporting each of the HTA advisory committees (MSAC, PDC and PBAC).

In the 2009-10 Budget, the Government provided \$9.3 million over two years under the *Medicare Benefits Schedule — a quality framework for reviewing services* measure to put in place a new evidence-based framework for reviewing services listed on the MBS. The new framework will take effect from 1 January 2010. Under the new arrangements, services will be evaluated and aligned with contemporary evidence to ensure clinical relevance and appropriate pricing. New services will be evaluated three years after being listed. The aim of this budget measure is to improve health outcomes for patients and help maintain the financial sustainability of the MBS. The Department of Health and Ageing has commenced work on implementing this budget measure.

Appendix K: Report of Stakeholder Focus Groups – Options Development and Reality Testing Phase Final Report on Stakeholder Options Development Focus Groups 29 September–9 October 2009

Options Development and Reality Testing Phases

1. Background to the HTA Review

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, jointly announced the Review of Health Technology Assessment in Australia (HTA Review). The HTA Review is one of the first Better Regulation Ministerial Partnerships to be undertaken by the Australian Government. It is due to report in late 2009.

The HTA Review will make recommendations about options for improving process efficiency and reducing regulatory costs that can act as impediments to medical innovation, without compromising timely and affordable patient access to medical services and devices that: are demonstrated to be safe, effective and cost effective; and deliver improved outcomes and value for money.

The HTA Review, co-ordinated by the Commonwealth Department of Health and Ageing (the Department) will canvass opportunities for deregulation reform that are consistent with the government's policy objectives, against the following (abridged) terms of reference:

1. Simplification and better coordination between the Commonwealth HTA processes (as identified in the Review scope), which includes:
 - consideration of a single entry point and tracking system for applications for market registration and funding;
 - making time to affordable access as short as possible for new technologies while maintaining or improving the rigour of evaluation processes; and
 - 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 and hybrid technologies.

The scope of the HTA Review includes the processes of the Medical Services Advisory Committee (MSAC) and the Prostheses and Devices Committee (PDC), and the Therapeutic Goods Administration's (TGA) regulation of therapeutic goods for market entry in Australia. The Pharmaceutical Benefits Advisory Committee (PBAC) processes will also be considered where there is an interface between medical services and devices and pharmaceuticals. The HTA Review will have regard to the outcomes of earlier reviews of HTA in Australia.

2. Background to the Focus Groups and this Report

Effective public consultation is an essential component of the HTA Review. Interested parties have had the opportunity to participate in the HTA Review to date through the following processes:

- **public submissions** against the HTA Review Terms of Reference;
- **a stakeholder reference group** involving key stakeholders meeting during the Review process;
- **bilateral discussions** between the Department and some key stakeholder groups;
- **a dedicated consultation process with health consumers** conducted by the Consumers' Health Forum; and
- **two series of Focus Groups with a broad range of stakeholders in major capital cities and by teleconference** to provide an opportunity for
 - discussion and clarification of issues and priorities to be considered by the HTA Review; and
 - consideration of draft proposals for reform of HTA processes.

The first round of focus groups was undertaken between 18 June 2009 and 24 July 2009, with 102 participants representing 90 different organisations participating in a total of nine Focus Groups held in Canberra, Melbourne and Sydney and by teleconference from Perth, Melbourne and Sydney. A Report prepared on the outcomes of those discussions is publicly available on the HTA Review website at (http://www.health.gov.au/internet/main/publishing.nsf/Content/htareview_focus_group_report.htm).

The second round of Focus Groups was undertaken between 29 September and 9 October 2009, with 113 participants representing 105 different organisations participating in a total of 11 Focus Groups held in Sydney, Canberra, Adelaide and Melbourne and by teleconference from Perth. The discussions in the second round are the subject of this Report.

Both rounds of Focus Groups were facilitated by Origin Consulting and the reports prepared by the facilitators.

Participation in the Focus Groups was by open invitation and an attempt was made to accommodate participants from the various sectors with an interest in HTA: industry, health professionals, health insurers, State and Territory Health Departments and health consumers. It should be noted however that the separate process for gaining consumer input convened by the Consumers' Health Forum resulted in a reduced participation level in the Focus Groups by representatives of that sector. Nonetheless, consumer representatives did make an important contribution to the sessions in small numbers and the interests and perspectives of consumers of health technology were often raised by participants representing the other sectors in both rounds of Focus Groups.

Discussion in the second round of Focus Groups was structured around five Discussion Papers which had been made publicly available on the Review website in advance of the Focus Group sessions. The five papers were:

- Discussion Paper 1: A Conceptual Framework for Commonwealth HTA Processes;
- Discussion Paper 2: Streamlining Application Processes;
- Discussion Paper 3: Approaches to Evidence and Methodologies;
- Discussion Paper 4: Improved Administration of Commonwealth HTA Processes;
- Discussion Paper 5: Enhanced Post Market Surveillance.

The Discussion Papers contained a series of 16 proposals, with some proposals containing options within them. Focus Group discussions centred on these proposals. The proposals were developed to take account of and address concerns raised by stakeholders during the consultation process, issues arising from other research and analysis undertaken by the Review team and matters raised in previous reviews and reports on HTA in Australia.

It should be noted that proposals presented in or omitted from the Discussion Papers should not be taken to represent the policy position of the Australia Government. The Department of Health and Ageing is not suggesting that all possible proposals for HTA reform were identified in the Discussion Papers, nor that any particular proposal will necessarily be recommended to the Government in the final report of the HTA Review.

In addition, the Department indicated in its presentation of the proposals in the Discussion Papers that they would require further close consideration, including in regard to resourcing for effective implementation. Given that the HTA Review is constrained to put forward recommendations that can be implemented within existing funding levels, some of the proposals may be considered to be medium to longer term strategies to reform Commonwealth HTA processes. They may also potentially impose additional regulatory requirements that would need to be carefully considered prior to recommendation or implementation.

Participants were asked for their response to the proposals, with the following prompts:

- Were all concerns identified?
- Are the proposals right?
 - Are they consistent with the desired principles underpinning HTA?
 - Do they deal with the main concerns?
 - Which are the most important, or priority, proposals?
 - Are they offering the best return on investment?
 - Are there risks or possible unintended consequences with any of the proposals?
- Where a proposal contains options, which is best?
- Should any other proposals be considered?

The following Report attempts to synthesise, summarise and draw out the main responses, themes and issues emerging from the Focus Group sessions, highlighting priority concerns and recurring themes and noting areas of consensus or tension and contested views where they arose. While viewpoints or ideas are not ascribed to individual participants or their organisations in this Report, the basis of participation in the sessions was an acknowledgement that participant input was not confidential.

3. Introduction to the Findings from the Focus Groups

There are some important caveats to the findings outlined in the Report below.

Firstly, Commonwealth Public Servants from the following Departments also attended the sessions strictly as observers and provided the rare point of clarification on request from participants:

- Department of Health and Ageing; and
- Department of Innovation, Industry, Science and Research.

Given their observer status, the presence of Government representatives in the sessions does not imply Government agreement with the views or perspectives outlined in this Report. The aim of the sessions was to capture responses to and views about the proposals from the perspective of the key stakeholder groups without discussions influenced by input from Departmental officers.

Secondly, it should be noted that as participation in the Focus Group sessions was by self-selection, the views expressed cannot be assumed to be 'representative' of all stakeholder groups. Some participants may have been motivated to attend by holding particularly strong views on some aspect of HTA or in response to a particular proposal under consideration. Some may have chosen to come because they had not made a written submission while others may not have attended because they had already submitted their views in writing.

4. General reaction to the Discussion Papers

Overall participant feedback on the Discussion Papers and the proposals was very positive. A number of participants across the Focus Groups from various categories of stakeholders stated that the papers were comprehensive, capturing all the key issues and broadly addressing and representing the views of stakeholders as expressed through the submission process, the 1st Round of Focus Groups and other consultations. One participant stated that it was "good to see that the stakeholder voice is being heard".

The key concern expressed about the papers was that they were quite high level and there is a need for greater detail on the proposals under consideration; "the devil is in the detail" was an often repeated phrase. Many participants commented that they were unable to commit to a firm view on the proposals until the detail was more developed.

Other general reactions to the papers raised on more than one occasion across the groups were as follows.

Participants particularly saw the value of the proposals as a package. For example, concern about a particular proposal was often allayed when it was read in concert with another proposal.

Participants wanted to know what the structural and organisational implications of the suite of proposals were for existing agencies. A number felt that the logic of the proposals was pushing towards a single agency, the possibility of which received mixed support.

A number of stakeholders pressed for a national approach to HTA. They considered that this is a gap in the current discussion papers and proposals. They are looking for it to be addressed in the Review findings and reflected in communication between the Commonwealth and the State and Territory jurisdictions regarding implementation of Review outcomes. For example, participants questioned how a reformed application process would interact with State and Territory agencies where the item will largely be used in the public hospital system and does not need a reimbursement decision in MSAC or PDC.

A health consumer and patient perspective was felt by a number of participants to be lacking in the papers and the proposals.

A range of stakeholders were concerned about the scope of the system in regard to particular types of health technologies. Stakeholders with an interest in technologies not currently easily dealt with in the HTA system (for example, tissue technologies, genetic testing, non-implantable devices, preventative health technologies and custom made devices) could not see their concerns with current arrangements addressed in the proposals for change.

In addition, some participants considered that the assessment and reimbursement arrangements for devices used in the community or the home outside of the hospitals and clinics were not adequately addressed by current HTA processes and not addressed in the proposals for change.

A small number of participants were concerned to know more about resourcing issues and in particular what role cost recovery will play in a reformed system. A number of industry stakeholders indicated an openness to cost recovery or cost sharing, but only in the context of greater consultation and involvement in decision-making. Similarly, a small number of participants raised the desire to see more about transparent reimbursement decision-making and price setting in the papers and proposals.

The turnover of staff in Commonwealth HTA agencies (particularly in the administrative stream) came up in a number of contexts within the Focus Group discussions. Participants were concerned with this in regard to both maintenance of relationships and knowledge, skill retention and capacity in the system.

A number of participants expressed the view that whatever proposals for change come out of the Review, implementation is critical, and that a number of the proposals have been floated or recommended before in previous reviews but not been implemented.

5. Response to: A Conceptual Framework for Commonwealth HTA Processes

Discussion Paper 1 outlined a possible Vision, Goal and Objective, Principles and Functions for reformed Commonwealth HTA processes.

Proposal 1: Conceptual Framework for Commonwealth HTA Processes

Vision

The Vision presented to stakeholders for consideration was:

Commonwealth HTA in Australia should be recognised as an international leader in the field – providing a structure and capability to ensure the timely and equitable access to cost effective health care interventions for the Australian community, and which achieve optimal health outcomes within available resources.

The main responses in discussion were as follows.

A consistent theme in almost all Focus Group sessions was that aiming to be an international leader was inappropriate, even at the level of the Vision. The general consensus was that the Commonwealth ought to be focussing on excellence and best practice (part of which includes greater consistency and predictability) as the drivers in our HTA processes and if that results in Australia being seen as an international leader, well and good. There was also a view that world leadership aspirations could lead to unnecessary, additional processes, layers of evidence gathering (or “reinventing the wheel”), requirements for new infrastructure, delays and inefficiencies.

It was acknowledged that in some aspects of HTA Australia is already seen to be leading the way. However, given the size of our health technology market (which was variously quoted as 1 or 2% of the world market) and the fact that we mostly take up technologies from elsewhere and have a small manufacturing sector in this field, most participants felt it would be inappropriate to be specifically aiming to be seen as HTA world leaders.

The view that Commonwealth HTA should be a “National” leader, with an emphasis on national consistency and a national approach, was expressed a number of times as appropriate for inclusion at the level of the Vision or Goal for the system.

The reference in the proposed wording to “optimising health outcomes within available resources” was contentious. There was the occasional voice supporting the “realistic”, explicit recognition that HTA operates within resource limits. However, the overwhelming response from participants on the inclusion of this concept in the Vision was negative. The view from participants largely seemed to be concern that the overall affordability of health technology was a responsibility for Ministers and Cabinet to resolve, rather than resting with those assessing individual technologies.

The inclusion of the term “cost effective” was debated in most sessions. Most participants considered that the system currently gave too great an emphasis to cost effectiveness and not enough to the inherent effectiveness to improve health outcomes. For example, the view was expressed that if the therapy was effective it should be available irrespective of the cost implications. On the other hand, some participants noted that without sufficient regard to cost effectiveness available health resources could be spent on technologies that might offer less benefit overall.

A large number of participants argued for the inclusion of concepts of quality and safety along with timely and equitable access as key components of a Vision for HTA in Australia. However, there was a minority viewpoint that equitable access is not an appropriate component for an HTA Vision, in that is the domain of funding agreements between the Commonwealth, States and Territories and consumers, not a function of HTA. Some participants also queried the definition of equitable and suggested that it should also address equity between public and private health systems.

Goal

The Goal presented to stakeholders for consideration was:

The proposed explicit primary goal for the Commonwealth HTA system is to maximise beneficial health outcomes within the health budget.¹

1. The footnote to the Goal:

- could be more than the means by which this primary goal is achieved;
- encompasses the central concept of opportunity cost;
- focuses on provision of health care resources and health outcomes, not indirect outcomes of health via changes in production (i.e. emphasises the full health care system perspective over the societal perspective);
- could be open to how the availability of health care funds is determined, and
- could include other goals of the health care system, such as equity of access according to capacity to benefit, promoting innovation to achieve the primary goal, and being flexible to deal with rare conditions.

The main responses were as follows.

In general, participants felt that the current wording was too general, and generic to the overall health care system rather than specific to, and measurable in, the context of HTA.

Any reference to “health budget” or “resources” generally elicited a challenge from participants to define whose budget and resources; for example, Commonwealth, State or Territory governments, private health insurers, industry or consumers were all seen to contribute resources to HTA in one way or another. In general, participants considered the broader concept of “sustainability” would be more useful in this context.

A number of participants felt that optimising “health outcomes” was too narrow a goal, given the important impact the take-up of health technology is perceived to have on broader social and economic indicators. The explicit rejection of this broader societal perspective in the footnote to the Goal was viewed as a weakness by many participants. While acknowledging that it is difficult to measure, some participants argued that at least one European country currently attempts it, and taking account of a societal perspective should not be rejected out of hand.

In regard to the footnote, participants often wanted it to be clarified and its assumptions drawn out more. In a minority of cases this was because the participant agreed with at least an aspect of it, but more often because the participant disagreed with what was “buried” in it.

A minority of participants expressed the view that HTA is a tool to address reimbursement, funding and pricing decision making and that the provision of good advice should be the main goal of the system (for example, “should deliver streamlined, evidence-based advice to support good decisions”). These participants held the view that HTA is a facilitator of health outcomes, not a driver and therefore that the current wording was far too broad.

As in the Vision discussion, a number of participants wanted to see the concepts of safety and clinical effectiveness in the specific Goal of the system. Related to this, some participants considered the explicit Goal should also be to maximise protection of the individual patient.

Within a couple of groups there was discussion of the promotion of innovation as an important concept to include in the Vision or Goal (noting that it is currently included as part of the footnote).

Principles

A proposed set of underpinning principles for Commonwealth HTA processes were presented to stakeholders in the form of a table with high level principles accompanied by more detailed descriptors of the principle in practice within the system. For ease of consideration, that table is reproduced here along with participant key comments.

There was a general acknowledgment that an explicit, agreed set of principles is crucial to guide the strategic direction and operation of the system, even though there may at times be a need for “trade-offs” between principles. Participants were generally very positive about the inclusion of each of the principles and the description of their application in practice in the HTA system outlined in the Discussion Paper.

In addition, a number of participants argued for the expansion of the set of principles and recommended the following for inclusion.

Suggested Principle	Descriptor
Patient Focused	<ul style="list-style-type: none"> • Input from patient or consumer representatives in the HTA process (noting that it is a technical process and training to participate would be necessary in order to avoid slowing the process) • Actively seeking patient input in Post Market Surveillance in regard to both the experience of its take-up by the individual (eg were patients informed of risks or alternatives) and the performance of the technology. • Greater communication between patients and doctors about the risks and benefits of health technologies • Evaluation of a suite of treatments for a particular condition to meet the individual patient’s needs
Opportunity to appeal	<ul style="list-style-type: none"> • Both merit and process review sought • Considered essential if there is more public disclosure of appraisals, advice and recommendations • Desire expressed for a quick and responsive review process that avoids a litigious approach.

Note that these suggested principles were raised in most sessions and had strong support across stakeholder groups.

Participant responses to the set of Principles and Descriptors proposed in *Discussion Paper 1: A Conceptual Framework for Commonwealth HTA Processes*, were as follows.

The Commonwealth HTA system in Australia should be:

Principle	Descriptor	Focus Group Comments
1. Independent and consultative	<ul style="list-style-type: none"> HTA processes should independently verify evidence in the Australian health care context. HTA processes and advice should be informed by appropriate consultation. 	<ul style="list-style-type: none"> A recurring theme was that the most important aspect of independence in the HTA system is that sponsorship, assessment and funding/ reimbursement decision-making should be independent of each other in order to avoid conflicts of interest. Participants did, however, acknowledge that, given the size of the Australian Health Technology industry, involving the right people with the right skills and knowledge in HTA may create potential conflicts of interest or perceptions of bias. They considered that there were however ways to manage this issue. Some participants also argued that, just as they are independent of industry, HTA agencies should be independent of funders and payers, and not be organs of government. There was a view that current Departmental oversight is not independent. PBAC was considered by some to be a valuable model in this regard. In regard to the current descriptor of “independent”, which takes a national sovereignty approach, a strong, consistent theme emerged from all sessions (particularly from industry stakeholders). They argued that Australian HTA should not unnecessarily repeat assessments or seek new evidence where overseas evidence exists and has already been accepted in other international jurisdictions by HTA systems comparable to Australia’s. The generally agreed view was that Australian HTA should be verifying or validating the applicability of international evidence, on a risk basis, in the Australian context, rather than “reinventing the wheel” or having to produce evidence generated in Australia. Some participants would be concerned if applying this principle resulted in adding another layer of regulation or more hurdles to Australian HTA. Some participants felt that combining “independent” and “consultative” in the one principle was not useful, particularly given there may need to be trade-offs between them occasionally, and that each has its own intrinsic importance. There was strong support for “Consultative” as a principle, and some participants argued that it should be a separate principle to highlight its importance. Most sessions rejected the adjective “appropriate” to describe consultative, and argued for a broad-based approach which specifies stakeholder groups (including the community at large and health consumers and patients). In addition, many argued that the purpose, role, quality, nature and specific points of consultation and communication with stakeholders were critical to spell out in detail. Sponsors, in particular, want to see much improved consultation practices built into HTA processes as an application moves through the system, and argued for two-way dialogue as the appropriate style of communication. State and Territory Government participants also raised the need for better consultation between the Commonwealth and the other jurisdictions.

Principle	Descriptor	Focus Group Comments
2. Transparent and accountable	<ul style="list-style-type: none"> A clear distinction of roles should be evident between applicants, process administrators, affected health professionals, evaluators, advisory committees, payers and policy-makers in terms of their powers/functions in the HTA process. A clear explanation of HTA processes (including the assessment², appraisal and decision making steps, the expertise and criteria applied to perform each step, timelines and how each step is consistently applied) should be publicly available (where appropriate). HTA processes should be procedurally fair throughout the assessment leading up to the reimbursement decision by explaining clearly what information is needed and how a decision will be made, conducting an unbiased assessment and giving relevant stakeholders appropriate opportunities to contribute. HTA advisory committee appraisals, recommendations and advice should incorporate wide, multidisciplinary stakeholder input, while remaining consistent and credible, and adhering to pre-agreed timelines and key performance indicators. There should be public disclosure of HTA advisory committee appraisals, advice and recommendations (with facts and reasons leading to these recommendations) and of subsequent reimbursement decisions. 	<ul style="list-style-type: none"> Participants strongly supported the principle of "Transparent and Accountable". They often saw this principle as closely connected to consultation and some participants argued that consumers and their advocates should be specifically included in the descriptor of role distinction. The connection to consultation was made most acutely in response to the suggestion in the descriptors that there should be public disclosure of HTA advisory committee appraisals, advice and recommendations. Sponsor and industry participants in particular were open to the idea of more public disclosure of decisions if there was more opportunity for communication and consultation – and especially the capacity to respond to any concerns – before submission (to ensure quality of the application), during and at the conclusion of the assessment. Industry noted that a rejection of a technology in Australia could have implications for its acceptance in other countries. They were generally, but not universally, comfortable with the reasons for rejections to be disclosed as long as they had an opportunity to comment on the material that would be released and commercial-in-confidence material was protected. It was also noted by some participants given the high volume of decisions made by some agencies, such as the PDC, there would be significant resource implications arising from public disclosure of the detail associated with all decisions. Most sessions raised the desire to see the opportunity to appeal as a principle underpinning the system (see discussion above about additional principles). They generally supported the capacity for both merit and process reviews, and saw this as a key component of both accountability and transparency. It was also viewed as essential if more public disclosure of appraisals, advice and recommendations is to occur. However, participants wanted a quick and responsive review process that avoids a litigious approach. Some participants also believed that greater transparency could encourage greater consistency and quality in assessments and recommendations. There were discussions in a number of sessions about the role of the Clinical Advisory Groups (CAGs) in the context of this principle. A majority of participants considered that there would be benefits from greater disclosure of identities of the individual members of the CAGs. These participants considered that given the small pool from which to draw for CAG membership, the likely identities were usually known and that it would be better to deal with any possible conflict of interest more directly and openly, while developing protocols to govern contact between CAG members and other stakeholders. Nevertheless it was generally agreed that the discussions and individual positions taken within the CAG needed to remain confidential to encourage continued participation by the small pool of experts available. Some participants argued that there should also be more transparency in reimbursement decisions.

Principle	Descriptor	Focus Group Comments
3. Efficient	<ul style="list-style-type: none"> HTA processes should be seamless and minimise duplication. HTA processes should be managed as a single system that anticipates and manages assessment issues. HTA processes should minimise regulatory cost remaining cognisant of the need to ensure scientific rigour and sustainability of the health care system. HTA processes should share information and expertise (including independent evaluator and clinical expertise). 	<ul style="list-style-type: none"> Although related, participants differentiated between HTA administrative efficiency and efficiency of getting a new technology into patient treatment and suggested that this principle most appropriately should address the former. Benchmarking against other appropriate jurisdictions was suggested as potentially valuable. Some participants argued that the concept of efficiency should mean minimising cost to both taxpayers and sponsors, not just be concerned with administrative costs to government, and that the HTA system should be seen to be providing value for money regulation. The descriptor of “seamless and minimise duplication” was viewed as the most important aspect of administrative efficiency by a number of participants. The removal, rather than minimisation, of duplication was considered the goal by some. At the same time, a number of participants felt strongly that HTA processes needed to be differentiated, eg, what was appropriate for assessing a pharmaceutical may not be appropriate for a device etc. Participants were wary of taking a one-size-fits-all approach in the name of efficiency. Some participants argued for greater efficiency from international harmonisation of evidence requirements. Better communication and feedback within the system were agreed by a number of stakeholders to be essential to efficiency. In particular, participants identified the need for a better flow of information from TGA to MSAC and PDC. One specific suggestion was to have a representative of TGA on both these committees to improve co-ordination and communication. A number of participants felt that timeliness is a key efficiency concept in the HTA context and should be drawn out and highlighted more. Clarification of roles within the system was identified as a key action from an efficiency standpoint. One participant made the argument that efficiency in the HTA system ought to take account of broader concepts of environmental sustainability. Participants want greater clarity about the reference to “a single system”. Session facilitators clarified that “single system” did not necessarily imply any particular form for the agency/agencies, but rather a more integrated, less fragmented approach. Some participants preferred to see a new single agency, while others did not. However, whatever form of agency/agencies is put in place, participants supported a single interface with it and a seamless approach from the perspective of stakeholders. In regard to measuring efficiency in the HTA system, a minority of participants argued that it is no good being efficient in processes if wrong decisions are emerging from them. They cited, for example, an apparent increase in the number of adverse events with health technologies, and argued that while TGA’s process is considered efficient, it may not be fully effective and that this should be taken into account in performance measurement.
4. Informed by best available evidence and aligned with contemporary clinical practice	<ul style="list-style-type: none"> HTA appraisals should be based upon research evidence as well as informed by contemporary clinical practice and societal values. HTA appraisals should have regard to all relevant comparators that are used inter-dependently within a clinical model of care. HTA appraisals should take into account globally harmonised evidence requirements and should apply internationally collaborative evidence in order to remain relevant to the Australian context. 	<ul style="list-style-type: none"> Participants generally strongly supported the suggestion that drawing on current clinical practice should be a crucial component HTA, particularly in cases where evidence may not be forthcoming for a number of years. Some participants considered that the principle should emphasise “best” clinical practice rather than “contemporary” clinical practice. A number of participants questioned whether there was any current globally harmonised approach to evidence. They noted that there were a number of different approaches taken to the categorisation and assessment of evidence and that the main focus should be on consistent approach to evidence within Commonwealth HTA. They also felt that internationally collaborative evidence should be taken into account, rather than “applied”. There remained concern from some that the reference to the use of comparators needs to be better defined and communicated and some were also uncertain what the term “interdependently” meant in the descriptor. While generally supportive overall of the idea of including consideration of societal values in the appraisals, participants asked questions such as “whose values?”, “who decides?” and “what are the boundaries of these values?”. Another issue raised by some participants was that the current wording of the principle and descriptor appears to exclude expert opinion and patient preference as legitimate inputs to the assessment.

Principle	Descriptor	Focus Group Comments
5. Flexible and fit for purpose	<ul style="list-style-type: none"> HTA processes should be able to identify and accommodate emerging health care interventions (through horizon scanning) and changing clinical practices. Assessment methodologies should be continually reviewed and updated in the light of validated innovations and developments. HTA processes should 'triage' applications so that the appropriate type of assessment (e.g. full versus targeted assessment/brand versus generic assessment) is undertaken. 	<ul style="list-style-type: none"> In the interests of clarity, some participants suggested splitting the first dot point in the descriptor to one point on horizon scanning and a separate point on continual review of methodologies. Concern was voiced in several sessions with the choice of the word "triage", although not the intention behind it. Its technical meaning of allocation of scarce resources in a crisis or emergency situation, or sorting on the basis of need, was thought by some to give the wrong message. Some preferred simply referring to "classification" of applicant technologies according to pre-specified criteria including risk levels. A more useful concept was considered to be one of navigation of applications through pathways in the system appropriate to the particular technology. A number of participants argued for a fast track route through the system as a component of triage. The issue of horizon scanning was discussed in detail in regard to both this principle and the later discussion of functions of the system. See the discussion below on functions for more detail about participant views. Flexibility and innovation in the HTA system itself was also strongly supported, although some noted that this might come at the cost of efficiency. Participants supported the principle, but were uncertain how the initial classification of an application would be done, particularly in the case of hybrid or multi-component technologies. They expressed concern that flexibility requires the exercise of discretion by the system and therefore that the principles and guiding criteria need to be explicit and agreed. A number of participants argued that a more flexible HTA system ought also to allow for consideration of broader health policy and priorities in the system as a whole and in individual assessments. On the other hand, some participants raised the risk that this approach may lead to the HTA system being caught up in debates such as whether to focus on, for example, cancer technologies above those addressing coronary heart disease.

Principle	Descriptor	Focus Group Comments
6. Capable and manages risk effectively	<ul style="list-style-type: none"> HTA appraisals should consistently apply rigorous analytical methods while reflecting patient and fiscal risks associated with adoption of a health care intervention. HTA appraisals should inform risk sharing arrangements between government and applicants where appropriate. 	<ul style="list-style-type: none"> Participants were largely unclear about what was meant by “capable” and how it relates to risk management and suggested its removal. There was overwhelming support by participants for a risk based approach to HTA in order to give practical meaning to the other principle of “Flexible and Fit for Purpose”. However there was a desire to see the details of how a risk approach would operate, and concern that it should neither duplicate TGA risk management nor operate an entirely different, incompatible risk management approach. A number of participants questioned the meaning of the risk sharing descriptor in this principle. They were unclear about what risk was being referred to here and how it would operate in practice. For example, some participants questioned how it is possible to share clinical risk and what role Private Health Insurers and hospitals could play in this. If the intention in the drafting was to refer only to financial risk, a number of participants considered this too narrow. In regard to financial risk sharing, participants stressed that these arrangements should be negotiated in advance and communicated to sponsors. Related to this, some participants argued that there needs to be an explicit, agreed approach to dealing with cost sharing in regard to subsequent sponsors, or ‘2nd to market’ situations. There was a degree of uncertainty amongst participants in regard to the inclusion of fiscal risk in the descriptor. Participants often asked, “Whose fiscal risk?”, and assumed that it was referring to risks for the Commonwealth budget. A number of participants questioned whether it was appropriate to include this as part of the principles for HTA as it was a function of government funding decisions not HTA. Some participants suggested that a key risk that will need to be examined is the potential for a missed opportunity for positive health outcomes when a particular technology is rejected. There was a strong view expressed in some of the sessions that the approach to, rules governing, criteria applied and operation of the risk assessment should be fully transparent to both the sponsors and the public more generally. The interaction between the principles (particularly 4, 5 and 6) was felt by some to throw up real challenges at a practical level. A number of participants in a number of sessions proposed that the principle ignores the benefit side of the equation, and should give greater prominence to this. This might include benefit sharing if the technology is even more cost effective than expected, for example, the sponsor might receive a higher price if the technology was more effective than expected. There was some disquiet about the reference in the descriptor to applying “rigorous analytical methods”. Some felt this was at odds with the principle as it implied rigidity in approach and that “methods appropriate to the level of risk” was a more useful formulation. If one of the ways to manage risk in HTA is to incorporate more rigorous Coverage with Evidence Development and Post Market Surveillance, with a reduced reliance on pre-market assessment, some participants argued that consumers should be made aware through informed consent arrangements for the item. A key concern for a number of participants was that safety should never be compromised.

Principle	Descriptor	Focus Group Comments
7. Sustainable	<ul style="list-style-type: none"> The HTA system should contribute to the sustainability of the broader health system through the identification of safe, clinically effective and cost effective health care interventions for consideration for reimbursement as well as the identification of health care interventions that are of questionable clinical and/or cost effectiveness that should be considered for disinvestment. The HTA system should provide suitable incentives to build and sustain a HTA workforce with up to date skills. 	<ul style="list-style-type: none"> There was agreement across the Focus Groups that sustainability is an important HTA principle, but a view that a lot more consideration needs to be given to what this means in practice. In principle, most participants agreed that disinvestment was an important part of a sustainable system, although a significant minority (particularly among industry and clinical stakeholders) felt that it was a massive, high resource undertaking that is not necessary. They generally argued that the market naturally drives disinvestment already, with clinicians moving away from using technologies that prove not to be efficacious or moving to newer, more efficacious technologies that come on the market. They gave the example of the Joint Register playing this role. In addition, companies themselves remove items from the list that are no longer in favour. In the case of prostheses, companies have to pay to keep an item on the list, and therefore, it was argued, there is no incentive to do so if the item is no longer used. On the other hand, some participants noted a number of technologies and procedures that were currently being used were manifestly undesirable or poor practice, yet there was no existing way to deter their use. Some participants also argued that patient and clinician choice was an important variable and did not want to see a situation where a technology was still in use and preferred by particular doctors and patients but the HTA agency was "dictating" that it be removed from listing. The argument was made that some patients may be happy with a particular device or procedure that works for them, even though the HTA agency may view a newer one, in comparison, as better. They also gave the example of when a technology was found to be valuable and in use for a different purpose than originally intended. Delisting may not take this into account. In several of the sessions, participants also added the caveat that "disinvestment" is not a stark, black and white decision. It may be a case of re-investment with changed indications or applications. A few participants argued that the same level of evidence should be applied to disinvestment decisions as invest decisions. There was general agreement with the descriptor addressing workforce sustainability. Participants pointed out that there is no formal program of learning in Australia for HTA, unlike the US, UK and Canada, and argued that a sustainable HTA workforce would begin with developing educational capacity. In one session, the broader issue of environmental sustainability was considered. An advocate for environmental responsibility in the group argued that all the consequences of adoption of health technologies should be considered in the assessment, including factors such as resource intensity in production, pollution generated in all phases of development and use of a technology and the carbon footprint of a technology. A counter argument was provided that at this point such an examination was not part of the legislated mandate of the TGA and was therefore outside of its coverage.

Functions

Stakeholders were presented with a proposed approach to future HTA functions and elements of an HTA system for consideration. The proposed functions were presented independently of any presumption of agency arrangements, for example single agency, current agency structure or restructured agencies.

The main comments from participants were as follows.

Many participants had difficulty discerning what changes were proposed to current arrangements, and required more detail. On the surface, most participants could not see any particular innovations in the proposed functions and were not sure it was adding anything new. The linkages *between* functions were the key concern for participants and the proposal did not elucidate these adequately. One participant made the suggestion that a few case studies of hypothetical applications could be tracked through the system in order to map the functions and their relationships and processes. Many participants considered the main processes in the system through which devices and medical services move to be the key issue, along with clarity of roles within the system. A recurring example was in regard to tissue based technologies. Sponsors could not see how these technologies would be handled any more efficiently or effectively.

Whether intrinsic safety assessment (currently undertaken by the TGA) should be considered as a part of a broader HTA system as proposed in the diagram or not, was a contested issue among participants. On balance, there appeared to be more support for incorporating all components, including intrinsic safety assessment, into a streamlined HTA system. However, there was one caveat to this.

A number of participants were uncomfortable with what they perceived as the implication that this could lead to a mega-agency, or at least a “one-size-fits-all” approach to the currently distinctive components of market entry assessment, HTA and reimbursement decision-making. A concern here was there is currently perceived to be great variability in the efficiency and effectiveness of the various agencies and components of the system, and participants were concerned that the higher functioning parts of the system may be dragged down to the less well functioning level in any amalgamation.

The scope of technologies considered by the system was raised on numerous occasions. In a number of sessions the importance of preventative and public health, such as screening programs and genetic testing, was raised. Several participants believed that HTA processes should be consistent with broader government health policy which has a strong emphasis on prevention of illness. To that end, they felt that the scope of the HTA system ought to explicitly address this issue.

The inclusion of horizon scanning in the function diagram and a descriptor in the principles generated a great deal of interest. A few participants questioned whether horizon scanning was an appropriate role for an HTA system, but others supported the development, arguing that a more pro-active approach from the HTA agencies would position the system to cope more effectively with new classes of technologies that would eventually come before it for assessment. While a number of participants thought it would assist in the development of openness to change in the system, it was acknowledged that significant resources would be needed for a horizon scanning function. Participants wanted greater clarity about what HTA agencies would do with information from horizon scanning, and it is fair to say that there was widespread doubt about whether such a function would ever eventuate in the system.

Those who strongly supported horizon scanning argued that diagrammatically it needed to feed into most other functions and connect up with Post Market Surveillance. One participant made the point that enhanced horizon scanning played an important role in ensuring that Australia would not be a dumping ground for redundant technology from overseas.

A related view was that the system needed to be also able to identify where particular emerging technologies might be actively encouraged. One example was the suggestion that MSAC itself could effectively act as the sponsor for a technology that was seen as worthwhile, but for which there was no other proponent. This would operate similarly to its current handling of references from other parts of the health system.

In addition, participants suggested that a horizon scanning effort needs to take into account, or build relationships with, other similar activities already being undertaken by industry or other health research agencies.

In regard to the presentation in the diagram, participants often did not understand the diagram containing a separate box for medical services and other interventions and they suggested that the diagram needs exit arrows, for example where a technology might leave the system where it does not require a subsidy.

In regard to Post Implementation Management, a recurring question from participants was whether the reference to “Balance of investment and disinvestment” meant a “one on, one off” approach. If so, they certainly did not support this.

6. Response to: Streamlining the application process

Proposal 2: Single Entry Point

There was overwhelmingly strong support for the proposal to streamline applications through a single entry point, as seen from the point of view of the applicant. The single entry point was especially supported when considered together with other proposals on triaging applications, a risk approach to assessment and improvement of administrative processes, consultation and communication.

For some, the main benefit of a single entry approach with triaging would be realised with applications for hybrid or multi component technologies, which are considered to be served poorly under current arrangements.

A minority voice, however, questioned whether a single entry point really is a priority among the other pressing issues to be addressed.

A small section of participants felt they could not comment on the proposal until they had a better understanding of the current throughput of applications (both in terms of volume and type) and more detail of the processes proposed behind the single entry point; for example what would be its implications for the current committee structure and use of expert input?

In addition, a number of participants, including supporters of a single entry point, argued that there would be little benefit in it if it became just another layer of administration delaying consideration of applications, or if the subsequent processes did not improve application tracking, timeliness of assessment, communication, consistency, predictability and other concerns voiced by stakeholders.

Most participants supported Option 2A, “a single entry point to process and manage all applications” over Option 2B, “a single entry manages applications for market regulation and a single entry point manages applications for HTA reimbursement”.

Some supporters of Option 2A were, understandably, most interested in the potential for the single entry point to obviate the need for them to navigate unclear processes and multiple agencies for themselves, and had less interest in the detail of specific administrative arrangements for the entry point. Although, it is probably fair to say that most supporters of Option 2A expected to see a specific entity managing the process, rather than just a web portal. This was considered essential to ensure that no technologies fall through the cracks as currently happens. One example given was where a technology requires a new test to accompany it and therefore both the technology and the test need a coordinated assessment and decision-making process.

The implications of a single entry point for the structure and form of HTA agencies was of strong interest to participants. For some, the single entry point indicated that the system was moving towards a single agency approach, and there were mixed responses to this possibility. Some were concerned a single agency or a single system would result in a one-size-fits-all approach to the processes which they considered would be inappropriate and counterproductive.

Those participants who supported Option 2B tended to do so because of either the view that TGA’s role as the regulator assessing pre-market safety should remain separate from the HTA process and/or they had a lot of confidence in current TGA processes. The key concern held by this group was that a single entry point may become a bottleneck and slow down what is currently generally viewed as a good process for consideration of applications for market entry. As one participant said, they did not want to see “the single door turn into the black hole”. Participants wanted to see at least current best practice administration in the system become the benchmark in any new arrangements.

A related view held by some was that those technologies for which reimbursement would not be sought would be better served by Option 2B. One other possible benefit identified in regard to Option 2B was that accountabilities in regard to performance and decisions may be clearer.

Should a single entry point be implemented, some participants (particularly those from smaller companies) also wanted the flexibility to be able to choose to submit the regulatory component of the application ahead of the reimbursement component, in order to manage the workload of gathering and presenting information. On a related point, there was a strong view that the potential pathways for assessment of an application through the system would need to be explicit and understood by sponsors in advance of submission to enable them to prepare applications appropriately.

A common view expressed in the sessions was that, irrespective of the nature of the entry point, a reformed system ought to allow for the assessment of a technology for both market entry and reimbursement concurrently. In other words, the assessment for reimbursement could begin before final regulatory approval was given, with the understanding that should regulatory approval be refused, all further processes would cease.

Proposal 3: Triageing of HTA Applications

There was strong support in the Focus Groups for the concept of triaging applications to identify the type and intensity of assessment required. However, a number of participants made the point that the basis for streaming applications through different pathways should be explicit and governed by public guidelines, with a minimal role for discretion by the triaging agents.

Participants considered that establishing the triage framework would involve some complex and difficult decisions around need, risk, evidence requirements, clinical effectiveness, transparency and a number of other matters, and that this would be a large task. In addition, they saw the exercise of the triage role to require a degree of skill and knowledge and were concerned by turnover of staff in Commonwealth HTA agencies and the implications for management of the triage function.

Participants also insisted that strict timelines for completion of triage decisions would need to be put in place and adhered to.

Some participants pointed out that there will need to be the capacity for review the outcome of the triage where the pathway to which an application is assigned for assessment turns out to be incorrect.

As noted in the discussion of principles in Chapter 5 above, concern was voiced in several sessions with the choice of the word “triage”, although not the intention behind it. Its technical meaning of allocation of scarce resources in a crisis or emergency situation, or sorting on the basis of need, was thought by some to give the wrong message. Some preferred simply referring to “classification” of applicant technologies according to pre-specified criteria. A more useful concept was considered to be one of navigation of applications through pathways in the system appropriate to the particular technology.

Good pre-lodgement communication between the sponsor and the Department leading to quality applications was viewed by a number of participants as a critical prior step to efficient triaging.

Proposal 4: Allowing Submission Based Assessment for Potential New Medicare Benefit Items

The response from participants in the Focus Groups to this proposal was very positive. A number of sponsor participants argued that many applications currently coming before MSAC already are full evidence-based submissions, but that MSAC rules require the evidence to be entirely generated again by the independent evaluators.

Most participants agreed that it should be *optional* for a sponsor to provide a submission. Support for this proposal was based on the hope that it will expedite assessment timelines for those sponsors who are able to prepare applications that meet the evidence requirements. It was also seen to have the additional benefit of freeing up external evaluator capacity to undertake the traditional MSAC approach of researching the evidence for those sponsors who are unable to undertake the task themselves.

The key to participant response on this proposal was that it has to be optional and have detailed guidance on what is expected in preparation of a submission. They argued that the nature of the industry for devices and medical services is different to pharmaceuticals where the submission approach is used for listing on the Pharmaceutical Benefit Schedule. For example, some items will come before MSAC for consideration as references from clinician groups who do not have the resources to prepare a PBAC-style submission, but nonetheless may be proposing an item of importance.

Participants (particularly sponsors) indicated there would be an expectation that the return for investment in preparing evidence-based submissions would have to be guaranteed faster, specified timelines for assessment and decision on listing.

However, other participants argued that equity between the two classes (commercial and non-commercial) of application would have to be guaranteed, and that capacity to pay should not be the prioritising criterion.

Participants were interested to know how the process would work under the proposal; for example, what role would the advisory panels play? Some participants wanted to know how the submission-based applications would be validated and verified. Would the independent evaluators be engaged in this task? High quality guidance was also considered to be a prerequisite to the proposal succeeding as was improved capacity within the panels in regard to matters such as statistics and economic advice.

In addition, some participants questioned how cost recovery might operate under this proposal if it is introduced.

7. Response to: Approaches to evidence and methodologies

As indicated above in the discussion on principles, a strong, consistent theme emerged from all sessions (particularly from industry stakeholders) that Australian HTA should not unnecessarily repeat assessments or seek new evidence where overseas evidence exists and has already been accepted in other international jurisdictions by HTA systems comparable to Australia's. The generally agreed view was that Australian HTA should be *verifying or validating the applicability of* international evidence, on a risk basis, in the Australian context, rather than "reinventing the wheel" or having to produce evidence generated in Australia.

A major issue identified by participants was ensuring that the extent of evidence required was realistic (given the difficulties in conducting randomised control trials for devices and medical procedures) and consistent with the likely use and risk of the technology. Although the proposals implicitly recognise this issue, participants wanted to see how it would be dealt with in practice.

Proposal 5: Implementation of a Risk-Based Approach to Assessment

There was overall, solid agreement by participants with a risk-based approach to assessment, while suggesting that defining and identifying risk in the HTA environment is often a difficult task.

As indicated above in the discussion of principles, a number of participants strongly supported a broader risk/benefit approach, believing that, for example, with some technologies the benefit may outweigh significant risks for particular groups of patients or consumers.

Participants often clarified that they did not want to see a risk-based approach compromise intrinsic safety assessment in any way. They were also concerned that whatever risk model was adopted be used as common basis across all agencies in the system so that the TGA, MSAC and PDC were using the same language and concepts.

Participants supported an internationally harmonised approach to risk management of HTA, where this was possible. There was some debate about the extent to which an internationally harmonised approach existed.

Participants want more detail on matters such as:

- the scope and definition of risks to be considered, in particular for clinical and fiscal risk, and how to negotiate an agreed approach between the key stakeholders;
- how such an arrangement would deal with new evidence emerging (from Post Market Surveillance and other sources) once a device or medical service is in the market;
- who will be responsible for conducting the assessment;
- how this process would relate to the triage process;
- what input sponsors and stakeholders would have to the design of the risk approach;
- how a risk matrix would accommodate a wide variety of technologies and procedures; and
- whether a risk approach would increase the amount of information required of sponsors, for example, sponsors were keen not to be required to provide information that was not directly available to them such as community costs.

Proposal 6: Improved Guidance on Methodologies and Methodological Processes

Participants strongly supported the proposal for improved guidance on methodologies and methodological processes. They agreed that Guidelines would be valuable, but also argued that written guidance needs to be complemented with good person-to-person communication, especially in the pre-submission period. They cited the PBAC situation where an extensive Guideline exists but there are still differences between sponsors' and evaluators' interpretation of requirements.

Participants generally agreed that the issues identified in this proposal – perspectives in assessment, use of comparators, evaluation methodologies and specified input times – were the correct ones requiring clarification.

In regard to perspectives considered in assessment, participants raised the following main concerns:

- the difficulty and cost in collecting data for a full cost effectiveness analysis (industry participants considered that they were being asked to provide costing data that was not easily accessible to them and would be better sought by HTA agencies from, for example, State and Territory hospital systems);
- the need for clarity at the outset in regard to the level of evidence required; and
- the particular uncertainty around the role of indirect, or non-health system, costs and benefits in the assessment.

In regard to use of comparators, participants generally accepted the suggested approach in the proposal and raised the following main concerns:

- as was raised in the first round of Focus Groups, there was still confusion about the selection of comparators for radically new technologies;
- it can be difficult deciding if a comparator is truly identical when a change to an incidental component such as a battery might significantly affect performance; and
- how a comparator that is listed on the MBS but is not actually being used should be considered.

In regard to evaluation methodologies, most the issues raised by participants have been dealt with above in relation to perspectives considered in assessment.

Participants gave significant support to the proposal for specified communication points during assessment and appraisal, and made the following points. They argued that this approach would assist in managing the significant resource implications that could arise from increased communication. However, they acknowledged that the pre-meetings would need to be conducted very carefully so as to avoid raised expectation and misunderstandings on the status of the advice given by the agencies to individual sponsors. They supported a consistent approach to guidance and communication across the HTA streams to avoid current confusion and frustration.

In addition to responses to the proposal, some participants made the additional comments about guidance on methodologies:

- there is a fundamental difference between procedures and pharmaceuticals in that it is easier to conduct randomised control trials on the latter and that this needs to be recognised in the evidence requirements and suggested methodologies for HTA of devices and procedures;
- the up and down-stream environmental impacts should be considered in the assessment;
- assessors and committee members may need additional skills to effectively implement any new requirements under reformed arrangements;
- guidance needs to also recognise and support any new triage process; and
- guidance needs to be sufficiently flexible so as not to stifle innovation or create new difficulties in the assessment of hybrid or interdependent technologies.

8. Response to: Improved administration of Commonwealth HTA processes

In general, participants in the Focus Groups were less engaged with most matters taken up under this proposal (with the exception of a few important issues such as conflict of interest and review mechanisms) than some other proposals. They were in strong agreement that the administration of processes needs an overhaul, but were more concerned with indicating priorities and preferred general directions than the detail of implementation of most administrative processes under consideration here. In addition, the proposals in this Discussion Paper lack much detail, so were more difficult for participants to engage with.

Proposal 7: Improved Public Information on HTA Processes

This proposal received support from participants. A repeated response was about broadening access to information about the HTA system for the general public. A number of participants considered that unlike the FDA in the USA, HTA for market regulation and reimbursement had minimal profile with the Australian general public and health consumers. This proposal was considered important to implement the suggested principle of including a greater patient and consumer focus in Commonwealth HTA.

Participants recommended that more work be done on identifying what types of information would be of value to specific groups of stakeholders in the system.

In a number of sessions the suggestion was made that the key to an HTA system website would be to keep it up-to-date and useful to the intended audience.

Some participants proposed that a client focus should see staff from HTA agencies out in the field more, keeping industry and other stakeholders up-to-date with events and developments in face-to-face communications.

Proposal 8: Standard Approach to HTA Process Management

The proposal to develop a Guide to Commonwealth HTA was welcomed and some participants cited the better performance of the NICE system in the UK in this regard. The need for transparency and predictability in processes was a recurring theme from participants.

There was general agreement with the need to increase consistency within and between processes within Commonwealth HTA. Nonetheless, participants once again voiced the view that while greater consistency in terminology and general approaches would be valuable, generic processes would not necessarily be appropriate and that the principle of fit-for-purpose should be applied.

The concept of “standardisation” of processes sat less comfortably with most. Some participants pointed out that in areas such as terminology, not only was there inconsistency within HTA agencies, but that clinicians and sponsors often also used different language to describe the same thing. This would need to be addressed in any attempt to standardise terminology in the agencies.

Participants in all sessions were particularly interested in reform of management of conflict of interest or perceived bias in the CAGs. They generally did not understand current rules or mechanisms for identifying, addressing, managing and minimising these issues in the operation of the CAGs and had little confidence in management of this issue. It was a sore point for a number of participants, particularly from industry, and was an area that they believed could be greatly improved upon. They were interested to hear more detail about what was proposed in this regard.

Proposal 9: Specified Communication Points

The general point was made on a few occasions that the most important aspects of communication were the quality of the engagement and the impact it has in terms of implementation. The style and approach to communication were considered by some to be as important as identifying set communication points in the processes.

A number of participants argued that the current “siloed” effect of Commonwealth HTA agencies is a critical issue to address and supported the proposal for formalised, regular meetings of the advisory group chairs and secretariats of HTA agencies. The suggestion was also made that the various agencies should have representatives on each other’s committees to enhance communication and information sharing.

Another suggestion was for “an account manager” to escort an application through the system which could result in early warnings of any administrative hitches and identify points where there would be benefit in speaking to sponsors to clarify any matters that were holding up the progress of the application.

Some participants suggested that internal and external communication could be enhanced with online tracking of applications. In addition, a number of participants identified the important area of communication with State and Territory Governments as needing to be specified and developed within HTA processes.

Proposal 10: Establish Review Mechanisms for HTA Processes and Decisions

Access to review mechanisms was overwhelmingly supported by participants as an essential component of procedural fairness (see the discussion of this issue above in regard to principles for the system). In general they preferred the terminology of “appeal” to be used rather than “review” which they considered to be a more ambiguous term.

Most participants supported the capacity to appeal on both merit and process grounds (although a number of participants considered process appeal of limited value) and viewed the possibility of appeal as even more essential if there is to be greater public disclosure of appraisals, advice and recommendations. It was noted that if public disclosure is increased, it should not take place until after any review process is complete.

Some participants asked for clarification as to whether broader stakeholders (such as clinician or patient groups) would be able to appeal in their own right under any reformed review arrangements.

While the initial reaction in most sessions was to argue for independent review, a number of discussions went on to acknowledge the potential costliness of and time needed for such a process, as well as the difficulty of finding independent arbiters with adequate knowledge of the technology. Some argued that going to the agency responsible for the process or recommendation may be more viable. There was a common desire expressed for a well-informed, quick and responsive review process that avoids an adversarial and litigious approach.

A pre-condition for making informed decisions about whether or not to appeal, according to some participants, is much better information about the assessment and recommendations than sponsors currently receive. Indeed, if an appeals mechanism becomes available across the system, it will be in the agencies’ interests to provide good feedback throughout the process as a way of avoiding some appeals that are based on lack of understanding of why a technology has been rejected.

Some participants considered improved feedback and communication as a higher priority than an appeals mechanism and were concerned about merit reviews in particular drawing resources away from timely HTA. Related to this view, other participants argued for the linkage to be explicitly made between any appeals mechanism and the system’s quality assurance arrangements.

Proposal 11: Better Information on Performance of the HTA System

Participants agreed that better, more freely available performance information on the HTA system was crucial, suggesting that it is an important driver of performance and essential for accountability. However, they argued for it to be collected and communicated in the most cost effective way. A number of participants expressed the view that most of the proposed Key Performance Indicators (KPIs) were in fact types of activity data rather than KPIs – albeit interesting and useful data – and suggested more careful thought goes into constructing the indicators. They also noted that there were no quality indicators in the proposed list and argued strongly for the importance of these. International benchmarking of administration of Australian HTA processes was suggested in a number of sessions.

Examples of KPIs or activity data participants indicated they would be interested in included:

- HTA client/user, health consumer/patient and other stakeholder satisfaction (the most commonly requested KPI);
- % of applications not recommended for market entry or reimbursement;
- % of reimbursement decisions that are aligned with reimbursement recommendations/advice;
- % of appeals that are upheld;
- Cost per application to sponsor and government;
- Staff turnover rates in HTA agencies; and
- Participation turnover rates in expert committees.

9 Response to: Post Market Surveillance

In general, participants agreed on the need for an enhanced Post Market Surveillance (PMS) capacity within HTA.

Most participants saw the involvement and cooperation of the clinicians as the essential component in any effective PMS. The State and Territory jurisdictions were generally viewed as best placed to encourage and engage clinicians in reporting on the efficacy of devices and procedures. Therefore a number of participants are looking for proposals for more cooperative arrangements between the Commonwealth and the jurisdictions to give effect to enhanced PMS.

Some participants went even further, with a minority arguing that the overall emphasis in HTA should shift from pre-market to post-market evidence, based on the degree of risk associated with the device or procedure. This met resistance from some, who insisted that certainly in regard to intrinsic safety, pre-market assessment should remain paramount.

A general concern from participants was that there was not much detail in the proposals for PMS. More than some of the other proposals they were especially keen to see more detail in regard to PMS in order to provide an informed viewpoint and input was often given with that caveat in mind.

Proposal 12: Widening the Scope of Post Market Surveillance

There was strong support for widening the scope of PMS, with the view that TGA's current efforts in the field represent the bare minimum. Participants identified a number of issues in TGA's management of the current system, including that:

- reporting by industry is seen as optional;
- warnings to TGA are not automatically disseminated more broadly; and
- the process of replacing devices occurs at the cost of the health system rather than suppliers.

Some participants argued that while enhancing PMS to collect data to inform comparative cost effectiveness is important, PMS of intrinsic safety should be expanded as the priority. In fact, some participants positively noted the recent establishment of mandatory reporting for some devices. However, a number of participants acknowledged that it will be difficult and expensive to expand any PMS effort and therefore it should be carefully targeted to achieve the best return and opportunities for cost recovery, sharing and shifting should be carefully considered.

The major challenge to a broader and more effective PMS system identified by participants is the difficulty collecting data, with key concern being with gaining the cooperation of surgeons and hospitals. It was suggested that any initiatives should make use of existing college quality assurance arrangements and also have regard to the suggested framework Quality and Safety Commission.

On the other hand, participants saw potential for more work "mining" existing data sets to inform decisions.

In regard to partnerships, the potential role of NHMRC in PMS was raised by several participants (recognising that additional, earmarked resources would need to be made available), and the possibility of involving private health insurers in some kind of data collection and risk sharing arrangements was also canvassed.

The connection between PMS and horizon scanning was often raised in discussions; for example, Australian horizon scanning could draw on international PMS to avoid approving devices and procedures here that have already been discredited elsewhere.

Proposal 13: Establish a More Rigorous Coverage with Evidence Development Framework

While there is significant support for Coverage with Evidence Development (CED) (particularly from industry stakeholders), participants generally agreed that current arrangements for it are poorly defined, managed and evaluated. Most agreed with the proposal, in that if CED is to play a more prominent role in HTA it will need to need to operate within a much more rigorous framework. A key issue raised was that agencies needed to define the minimum, or floor level, of evidence that is required for acceptance into a CED arrangement and put a PMS plan in place as part of any agreement.

However, it is crucial to note that most participants assumed that CED would only be used when the safety and efficacy of the technology or procedure is assured and the only uncertainty is around cost effectiveness. In other words, there should be no conditional market entry permissible and there should be no question of devices or procedures being "tested" in the market.

In addition, as noted above in the discussion on principles, participants felt that if one of the ways to manage risk in HTA is to incorporate more rigorous CED and PMS, with reduced reliance on pre-market evidence, consumers should be made aware in informed consent arrangements for the item.

The main benefit of CED in the view of a number of participants is that it would reduce the risk of potentially useful technology being excluded due to not quite enough pre-market evidence.

Participants felt that the major risk inherent in CED is that pre-agreed data collection requirements may not provide the right sort of information to support a final decision. It was noted that strong clinician input and support is often required to collect this information and one option suggested was that sponsors be able to explicitly ask for CED on the basis of an already negotiated arrangement for the collection of data.

Proposal 14: Expanded Use of Registers for Post-Market and Post-Reimbursement Data Collection

There were fairly evenly mixed views from participants regarding the expansion of registers for PMS data collection.

In support, participants noted that registers can:

- provide very detailed device specific information;
- demonstrate how a device operates in “real life”; and
- contribute to rapid change in the use of particular technologies, if used well.

On the other hand, participants noted that:

- registers are very expensive to run;
- they are difficult to implement requiring strong cooperation from clinicians
- it is vital that they be designed to inform particular decisions; and
- they do not always provide high quality evidence.

In regard to the options presented in the proposal about the type of registers, participants generally supported the concept of “class” registers as the approach that would give the most value and have the most impact on decision-making.

Proposal 15: Enhanced Data Linkage to Support Post Market Surveillance

Participants generally saw great value in improving data linkage to support PMS. However, most were doubtful about the systems’ ability to implement this in the face of the current legal and administrative barriers associated with protection of citizen privacy. The other major barrier was considered to be the absence of unique patient and provider identifiers.

In regard to the options presented, most participants considered that “piggy-back” option is unlikely to succeed given that there is little to piggy-back on. They felt that the option of piloting a specific data linkage project was more feasible and made the suggestion that the creation of a “meta-register” that enables temporary linkage rather than ongoing real-time linkage should be trialled.

Proposal 16: A Review Process with the Capacity to Recommend Disinvestment

In considering the final proposal, overall, participants agreed that disinvestment in comparatively ineffective technologies was essential. However, they were sharply divided on whether there is a role for government in this process. A substantial number of participants (particular industry and clinician stakeholders) considered that the market worked effectively to discourage the use of outdated or ineffective technologies. They also doubted whether it would be practical or cost effective for any agency to proactively review and identify specific technologies for disinvestment.

On the other hand, some participants noted that there are a number of procedures and technologies that continue to be used and subsidised despite common knowledge that they are at best ineffective or at worst harmful.

Some participants suggested that if it emerged that a technology was more cost-effective than the pre-market evidence suggested there ought to be scope for reimbursement levels to be increased.

Appendix L: Consumer Participation in the Review of Health Technology Assessment – Progress Report 2

Consumer Participation in the Review of
Health Technology Assessment
Progress Report 2

24 November 2009

Consumer Participation in the Review of Health Technology Assessment

Progress Report 2

The Consumers Health Forum of Australia (CHF) is pleased to provide the Department of Health and Ageing (DoHA) with Progress Report 2 on the *Consumer Participation in the Review of Health Technology Assessment* (HTA Review) project. This report contains:

- a. Overview of CHF's involvement in the HTA Review;
- b. Key discussion points and outcomes from consumer consultations; and
- c. Conclusion and recommendations.

The report is written from a consumer perspective, and specifically outlines consumer opinions, concerns and suggestions raised with CHF in its consultations.

A. Overview of CHF's involvement in the HTA Review

CHF's involvement in the HTA Review has included:

- A submission to DoHA on the HTA Review, which included 18 recommendations identified from initial consultations with consumers (May 2009).
- DoHA and CHF entered into a contract for services to undertake additional consultation with consumers to further inform the Department's HTA Review about key consumer concerns (June 2009). A range of consultation methods were used:
 - An information paper based on initial consultations was distributed to all CHF's consumer networks together with DoHA's Discussion Paper, which identified five key terms of reference for the review (August 2009). The information paper contained further key questions and was distributed with a questionnaire that provided consumers an opportunity to raise additional issues that they thought should be addressed in the HTA Review.
 - Two focused teleconferences with 17 key senior consumer representatives were held on Friday, 14 August 2009. The teleconferences focused on questions outlined in the information paper. The information from this consultation, together with written responses to the questionnaire, was integral to developing the agenda for the national workshop.
 - A full day national workshop with 28 key consumer representatives was held in Melbourne on Tuesday, 8 September 2009. The aim of the workshop was to explore views on what a future HTA model would look like, building on the key findings from consultations held prior to the workshop which were outlined in Progress Report 1. The following objectives were set:
 - Hear the views of consumers on the HTA Review, building on feedback received from consumers to date;

- Explore consumer viewpoints on what would be a better future HTA model; and
- Consolidate consumer views on what is required post-approval.

The results from the workshop, together with all consumer consultations undertaken by CHF, form the basis for this Report, which aims to provide DoHA with a health consumer perspective on the key issues in current HTA processes in Australia. Through our extensive consumer consultation processes, CHF has been able to identify the key issues and to provide DoHA with policy recommendations for moving forward.

B. Key discussion points and outcomes of consumer consultations

National Forum

CHF's national forum, *HTA Review Workshop*, was held on 8 September 2009. An overview of presentations to the forum is provided below.

Guest Speakers

The workshop was opened by CHF Chairperson, Mr Antonio Russo. In the first session of the workshop, Dr Brian Richards, Principal Medical Adviser (DoHA) and Executive Manager, Health Technology and Medical Services Group, provided a background to the Review and informed workshop participants about the progress of the Review. Dr Richards outlined some of the findings of the consultations held to date.

Ms Karen Carey, Health Consumers Council (WA) and Consumer Representative on the Prostheses and Devices Committee (PDC), provided an informed address to the workshop which looked at the HTA Review from the perspective of consumers and their requirements. Ms Carey began her talk by acknowledging current media articles¹ which raised concerns about incentives provided by industry to doctors such as dinners and travel which could bias their clinical decision making. Ms Carey identified that there is a much more worrying trend in relation to devices which included sponsors providing research grants to doctors to encourage them to use their products.

Ms Carey stated, *"recently I have heard about manufacturers giving large sums of cash to doctors to use their product under the guise of conducting research, when really this is simply an inducement to get doctors to implant one brand of product instead of another."*

The health technology market involves huge sums of money. In Australia more than 65,000² joint replacements are conducted every year with most joints costing around the same as a small car (\$11,000–\$15,000)³ – so we are talking about suppliers with very large pockets who are able to pay large sums to influence doctors. The risk to patients is that the doctor implants a device based on financial gain rather than clinical effectiveness with the potential to cause injury and death. The problem is far greater than just free dinners and helicopter trips."

1 See: <http://www.theage.com.au/national/alfred-official-suggested-payment-for-polo-jaunt-20090907-fedg.html>

2 See: <http://www.dmac.adelaide.edu.au/aoanjrr/index.jsp>

3 National Joint Replacement Registry (NJRR), <http://www.dmac.adelaide.edu.au/aoanjrr/index.jsp>.

Ms Carey considered the HTA Review timely, recognising the significance of reviewing the three main parties involved in assessing health technology from a consumer perspective; Therapeutic Goods Administration (TGA), Medical Services Advisory Committee (MSAC) and PDC.

Ms Carey addressed the importance of consumers reporting adverse events, which is not common practice at present. It is through the reporting of adverse events that critical information and knowledge is obtained about devices and technologies directly from the consumers. This will allow for a more rounded and informed analysis from reviewing and governing bodies. Having actual consumer feedback incorporated into current review processes would ideally lead to safer technologies.

Ms Carey's address then moved on to identify some of the key aspects consumers require to improve the current HTA system. These included:

- Improved transparency from the TGA and DoHA about assessment and safety of medical devices;
- Development of registers that record outcome data for all high-risk devices and procedures;
- Improving informed consent processes to ensure that consumers receive accurate information prior to giving consent; and
- Timely reviews of relative safety of devices and technologies once listed on the Australian Register of Therapeutic Goods (ARTG).

Mr Russell McGowan, CHF Governing Committee member and Consumer Representative on the Medical Technology Stakeholder Reference Group (MTSRG), outlined models for consumer participation that might be applicable in an improved HTA system. Mr McGowan tabled the concept of 'Citizens' Councils' and the role they could play in a new model, arguing that they could play a part in assessing community views, but should not be used in isolation from other consumer input mechanisms.

Mr McGowan identified how the Australian Commission on Safety and Quality in Health Care (ACSQHC) could be utilised in addressing equity and access for all public patients, with particular emphasis on current disadvantaged groups:

- Aboriginal and Torres Strait Islander people;
- Culturally and Linguistically Diverse (CALD) people; and
- Rural and remote communities.

Mr McGowan argued that consumer input needs to be viewed as concrete evidence in assessment processes for individual devices and technologies. He discussed the importance of "*grey literature*" including consumer case studies. Mr McGowan did not explore in his presentation how this evidence could be captured, but this is discussed later in this paper.

Key Findings

The key findings from all consultations with health consumers are outlined below.

Elements of a HTA model that works for consumers

Consumers want to see a HTA system which is cost effective, efficient, transparent and accountable, and provides a single entry point into the system. Consumers described essential elements that the system would need to incorporate to meet the needs of consumers:

- Transparent mechanisms for genuine involvement of consumers at all stages, and for the consideration of consumer experiences in assessment processes;
- Clear criteria and approaches for assessing new applications that consider consumer experiences and needs, not just scientific and cost effectiveness data;
- The capacity for the granting of interim approval for some devices, to ensure that they are available to consumers more quickly, pending full assessment;
- Rigorous post market surveillance mechanisms which enable the capture and use of information on adverse events;
- Mechanisms for reviewing technologies on the ARTG, and removing them from the ARTG, when they have been shown to be dangerous, when they are superseded by superior products, or when they are no longer being used; and
- Consumer education programs to ensure that consumers understand both medical devices and technologies, and the HTA system designed to regulate their use in Australia.

Each of these elements is discussed below and incorporates consumer perspectives from all CHF consultations undertaken in this project.

Consumer involvement in the new system

It was clearly noted in consumer consultations that the HTA Review is part of a broader agenda of reform which aims to put consumers at the centre of the health system. Consumers emphasised that a key aim of the new HTA system should be to ensure consumer involvement at all stages of the HTA process.

A range of options is explored below. Consumers considered that all forms of consumer involvement were important, as they allow for the input of the people who will actually be using the devices and technologies. The consumer voice provides an important balance to the views of health care professionals, service providers and industry. As major stakeholders in HTA, it is essential that consumer views are captured.

Consumer Representatives – Consumer representation in all assessment and review processes was viewed as a particularly important form of engagement. Consumers argued for consumer representation at a consistent and high level on all assessment and review processes for the new HTA system. It was noted that confidentiality provisions are a barrier to consumer input, reducing capacity, ‘representativeness’ and involvement by preventing representatives from discussing issues (in general terms) with other consumers and consumer organisations. It was argued that this should be addressed in the new model. Consumer organisations need to be engaged in discussions to set new and less restrictive confidentiality parameters.

Consideration could be given to having a 'pool' of endorsed consumer representatives across, for example, the whole of MSAC rather than having endorsed consumer representatives on committees addressing individual technologies. This would provide an opportunity to empower consumer representatives to contribute to the whole HTA process, and would enable consumer representatives to liaise with consumer peers to discuss confidential information.

Consumers also wanted to see more than one consumer representative on each committee, arguing that this would be seen as a beneficial advance in including the consumer perspective in the assessment process and would reduce tokenism.

Input of consumer voices and experiences – Consumers argued that the new system must also hear the views of consumers more broadly, in addition to the extremely valuable role to be played by experienced consumer representatives. There should also be a positive weighting on more disadvantaged groups and those who are heavy users of health care, such as Aboriginal and Torres Strait Islander peoples, people from culturally and linguistically diverse (CALD) backgrounds, those with disabilities and those in regional and remote areas. Various mechanisms for gaining the views of consumers were suggested for further exploration:

- Citizens' Councils⁴, such as those used in the United Kingdom, could provide a mechanism to garner the views of a wide cross section of consumers. These councils have the advantage of being based on solid principles which acknowledge and respect the voice and diversity of consumers; however, they do not remove the right for individuals to provide their own views, especially when passionate about a particular technology. Consumers considered that Citizens' Councils would be a valuable addition to HTA processes, but should not replace other mechanisms for consumer engagement, including consumer representation on committees.
- Interest Sub-Groups (ISG) were introduced by Health Technology Assessment International (HTAi) to incorporate consumer and citizen involvement to inform HTA "decision making processes regarding the introduction and diffusion of health technologies"⁵.
- Documenting consumer stories about their experiences with health technologies, such as those published by the Australian Commission on Safety and Quality in Health Care (ACSQHC) *One Hundred Patient Stories* project,⁶ can provide a powerful source of information and ideas.

Consultations did not allow for detailed discussion of these options, or any prioritisation of different methods of engagement. However, consumers emphasised that a range of engagement methods must be used.

Basis for original decisions

In assessing the suitability of products for inclusion in the ARTG, consumers argued that the system currently fails to consider the lived experience and needs of consumers, the social value of a new technology and how inclusion on the ARTG may impact on equitable access to health care of both public and private patients. This point was strongly put forward by consumers in all consultations. Consumers, as users and beneficiaries of health technologies, are well placed to contribute to the assessment of social value of technologies. Social value could be assessed through existing committees, perhaps supplemented by mechanisms such as Citizens' Councils.

4 See: <http://www.nice.org.uk/newsroom/factsheets/citizenscouncil.jsp>

5 See: <http://www.htai.org/index.php?id=85>

6 See: http://www.safetyandquality.gov.au/internet/safety/publishing.nsf/Content/PriorityProgram-02_OD-Initiatives

Consumers strongly endorsed the view that the assessment of any device or procedure should include the 'journey' of the consumer as he or she uses the device, considering the risks and benefits for consumers of having the new technology on the market. Consumer stories were considered to put 'flesh on the bones' of the solely technological value and cost effectiveness of a device. It is important that the 'human side' of health technology is considered in the review process. The impact of these devices on consumers' quality of life must be considered for a comprehensive picture of their value and safety to be determined.

It was suggested that one way to collect relevant consumer data to contribute to the assessment process, categorically endorsed by consumers, would be the development and use of Health Technology Consumer Impact Statements⁷ (CIS), similar to Environmental Impact Statements⁸ or Pharmaceutical Benefits Advisory Council (PBAC) CIs⁹. Such statements could be used across all committees to inform their decisions. The views of a wide cross-section of consumers would ideally be considered in completing CISs, but particularly those of the consumers most likely to be affected by the device or technology.

Decisions should also be informed by information about adverse outcomes for consumers resulting from the use of similar devices. There was a view that the new system must have a mechanism or mechanisms for consumers to make complaints, and for these complaints to be aggregated and reported (See further discussion below).

Interim approvals

Consumers identified that many devices have already been approved for use internationally, so there is less reason to 'reinvent the wheel' in the assessment process. There was agreement that there should be a process for interim approval while a full evaluation process takes place. This would ensure consumers have faster access to new technologies, but would still protect them if new information should come to light via the regular approval process. It is important to note that, for high risk devices, interim approval may never be appropriate.

There are several elements that consumers considered should be included in an interim approval system:

Regulated data – It is important that the regulator, rather than the manufacturer, collects the data on international approvals. This would require the new HTA system to be up to date with current international trends, for example, through liaison and best practice international bodies, such as:

- European Network for Health Technology Assessment (EUnetHTA)¹⁰, which coordinates the HTA efforts of 25 of the 27 European Union countries as well as Norway, Iceland, Switzerland, USA, Canada, Australia and Israel;
- Health Technology Assessment International (HTAi), which "Collaborate[s] with both the International Network of Agencies for Health Technology Assessment (INAHTA), and regionally based HTA societies to improve the science and increase the application of HTA in health policy decision making around the world";¹¹
- National Institute for Health and Clinical Excellence (NICE)¹², which provides guidance on public health, health technologies and clinical practice under three centres of excellence:

7 CHF has been involved in developing CISs for some time and has published a position statement on medical technologies and devices. See: <http://www.chf.org.au/Docs/Downloads/hvo-2008-3-position-statement.pdf>

8 See: <http://dataserver.planning.sa.gov.au/publications/1017p.pdf>

9 CHF has developed three CIs for PBAC, on social anxiety disorder, spasticity following stroke and restless legs syndrome.

10 See: <http://www.eunetha.net>

11 See: <http://www.htai.org/index.php?id=24>

12 See: <http://www.htai.org/index.php?id=24>

- The Centre for Public Health Excellence, which develops public health guidance on the promotion of good health and the prevention of ill health;
- The Centre for Health Technology Evaluation, which develops technology appraisals and interventional procedures guidance; and
- The Centre for Clinical Practice, which develops clinical guidelines.
- International Network of Agencies for Health Technology Assessment (INAHTA), which provides a “forum for the identification and pursuit of interests common to HTA agencies”. The network aims to:
 - Accelerate exchange and collaboration among agencies;
 - Promote information sharing and comparison; and
 - Prevent unnecessary duplication of activities.¹³
- **Special informed consent** – Consumers should be made aware of devices that carry interim approval only, and that the interim approval is based on existing international rather than local knowledge, when their informed consent is being sought by their clinicians. This should be part of the regular informed consent process. Information that should be provided when seeking informed consent from the consumer includes why the device has been provided with interim approval and what is involved in the interim approval process.

Special price – Devices or procedures carrying interim approval should be priced lower in recognition that the consumer and/or the health system will need to pay if any problems with use are experienced. While the device may provide health benefits, the risk of side-effects and other negative consequences may be higher, which could result in significant additional costs due to the need for follow-up treatment or rehospitalisation. Again, this should be explained as part of the informed consent process.

No coercion – There should be sanctions in place for companies that try to pressure consumers to use products with interim approval to increase demand during the interim period.

Pre-market assessment

The consultations considered pre-market assessment processes. While the role of bodies such as MSAC and PDC were raised, most of the discussions addressed the role of the TGA in the HTA process.

The TGA generally divides its role into pre-market assessment and post-market surveillance. In pre-market assessment, the TGA uses a risk stratification method that organises devices into groups based on their level of risk. There are five levels:

Class I;

IIA;

IIB;

III; and

Active Implantable Medical Devices (AIMD).

13 See: <http://www.inahta.org/>

It was noted that the TGA assesses only the Class III and AIMD. Class I medical devices receive automatic entry to the ARTG after undergoing electronic review of specific information. Ninety percent¹⁴ of all devices fall within the first three classes, and this means that ninety percent of medical devices used in Australia do not undergo assessment by the TGA, although the TGA reviews evidence about the device to show that the device has been subject to a level of regulatory scrutiny on a level with that which would be applied if the device was presented to the TGA for assessment. Around two percent of devices undergo a full assessment.

Many of the devices that gain automatic entry on to the ARTG have a significant risk of causing harm. It is only now that the TGA is preparing to raise the risk level of joint replacements to Class III. Up until now, they have been judged to be a low risk despite the fact that many fail, requiring re-operation, and that for some groups the mortality rate resulting from these failures can be as high as 18 percent¹⁵.

In her presentation to the national workshop, Ms Carey commented that the PDC has made several referrals to the TGA in relation to concerns raised by Clinical Advisory Groups (CAG) about devices that clinicians have considered too unsafe for use in Australia, and in each case the TGA has failed to act and the devices remain on the ARTG. However, the TGA reported that only one report has been received by its Incident Report and Investigation System originating from the PDC. Ms Carey also reported that the PDC has received applications for which there have been no human studies, but the devices have still been listed on the ARTG. She argued that these examples highlight the flaws in the TGA pre-market assessment process and illustrate that current practices are failing to ensure safety and quality of health technology for health consumers.

Consumers supported Ms Carey's comments, and argued that the TGA should apply risk categories and assess evidence for applications with consumers' safety as their priority consideration. It was noted that consumers are the ones who suffer if assessment processes fail to take into account the level of risk or the inadequacy of evidence deeming products to be safe.

Post-market surveillance and review

There was consumer consensus that the TGA, which approves devices and procedures for use, fails to offer adequate post-market surveillance to identify problems and trigger reviews. Consumers suggested there should be careful consideration of a new post-market surveillance process to decide who will be responsible for collecting data about the use of products once they are on the market and ensuring strong governance and accountability for the process. The views of consumers about what the post-market system should include are discussed below.

The review agency

Consumers argued that current post-market surveillance conducted by the TGA is a failure. Although there is an adverse events reporting scheme, it is generally not known about or used and the TGA admits high levels of under-reporting.

14 TGA submission to HTA Review

15 NJRR, <http://www.dmac.adelaide.edu.au/aoanjrr/index.jsp>.

Many consumers reported that they are unaware of the adverse events reporting scheme. Although the Therapeutic Goods Act requires sponsors to report adverse events, there is no requirement for doctors to do so and it is, in fact, limited. Consumers are unaware of the system and would often report an adverse event to their doctor rather than the manufacturer or sponsor of a device. Often the sponsor is not aware of adverse incidents. In instances requiring that they act, the only requirement is that they report 'significant incidents'. The sponsor decides what should be reported, although there are regulations that describe what is required to be reported and the timeframes in which such reports must be made. Consumers wanted to see strengthening of regulations so that sponsor choice is not a factor in determining what is to be reported. They also wanted to see initiatives in place to develop and support increased awareness of the TGA's Incident Report and Investigation Scheme (IRIS) among consumers and health professionals, and also wanted to see increased awareness of the TGA's other post-market surveillance processes.

Ms Carey, in her address to workshop participants, argued that the TGA also has no process for cross-checking of sponsors' reports and relies entirely on the sponsor to report the facts. She drew attention to her own experience with a failed heart valve in identifying that consumers cannot rely on the sponsor, who has the greatest vested interest, to report truthfully about adverse events in spite of likely negative financial impacts.

There was a strong view that the post-marketing surveillance function should be the responsibility of an agency separate from the one that conducts the original assessment of health technologies. The ACSQHC and the Australian Consumer and Competition Commission (ACCC) were suggested as agencies which could possibly be given responsibility for post market surveillance, as these bodies already have related functions. Whether the recommendation to separate the processes is accepted, or the TGA remains responsible for post-market surveillance as well as assessment, consumers argued that surveillance and review processes need to be appropriately governed, funded and evaluated. If the TGA is to remain responsible for post-marketing surveillance, consumers argued that a separate section of the TGA should be created to conduct reviews, to ensure separation of assessment and review functions.

The review process

Consumers called for a number of types of review:

Routine reviews – Every device of a certain risk category should routinely be reviewed at specified time intervals after the product is approved for market in Australia.

Incident-triggered reviews – The mechanism for collection of information about incidents should trigger a review after a certain number of incidents, after faults have been reported, or after a single incident of significant severity.

Equivalent product reviews – Many new technologies claim equivalence with old technologies but do not undergo the same procedures as 'new' technologies. The evaluation of equivalence should be more rigorous, with specific review procedures required.

Reviewing obsolescence – There is a need for procedures to remove technologies from the ARTG when they become obsolete or are superseded by other products.

Sources of information

Post market surveillance relies on the capture of information from consumers, health professionals and manufacturers about the use of products once they are on the market. Consumers emphasised repeatedly the importance of the new system ensuring many avenues are available for the capture of such information, and then for its aggregation, public reporting and feedback into the review process. It was noted by national workshop participants that privacy constraints often meant that data already being collected on adverse events is not publicly available. There was a suggestion that consumer representatives need to have a wider discussion about privacy in order to find a way of protecting individual interests, while at the same time being able to access the rich sources of information collected by databases around the country.

Consumers suggested several sources of information to be used in post-marketing surveillance:

- **Manufacturers**, who should be compelled to report on adverse events of all levels of severity using a routine approach (current regulations do describe what events are required to be reported, with penalties for non-compliance).
- **Doctors and other health professionals**, who should be encouraged to report adverse events, for example via an 'adverse event reporting' item on the MBS schedule.
- **Consumers**, who should have a mechanism for adverse event reporting allowing them to report any problems they have and be confident that these will be addressed.
- **State/Territory Health Ombudsmen**, in the role of collection of incident and adverse event information, who should have an avenue for reporting this information to the review agency.

Many consumers were in favour of more registries being established to collect data, for example, by following the model of the National Joint Replacement Registry (NJRR), which collects data after each joint replacement procedure. These registries should be set up for those technologies for which post-marketing surveillance is most needed. Consumers emphasised that increased awareness of post-marketing surveillance mechanisms would be required, via public education, to enable and equip consumers and doctors to use the system.

Limiting the technologies on the ARTG

Consumers in the consultations agreed that the ARTG is there for consumers and they can best be served when the register is properly maintained. There should be elimination procedures available for lapsed, obsolescent devices so that they do not continue to 'clutter' the ARTG. It was suggested that there may need to be a National Register of technological devices that provides a cumulative record of comparative devices and integrates adverse events into the record.

Consumers agreed that there should be:

- Clarity about which agency or group is responsible for reviewing obsolescence of devices/technologies.
- Defined criteria by which obsolescence is determined (for example, when a certain number of equivalent or superior devices are on the market or when uptake of the product is very low).
- A phase-out program for superseded technological devices/procedures that allows individual consumer needs to be met, for example, if someone prefers or needs to continue using their current device, rather than changing to a new product. In some situations problems with a device currently in use can be remedied through a partial

revision, and removing devices from the ARTG when they are still being used by consumers could result in the need to fully replace the existing implant or device. Consumers should not be exposed to this increased risk by the premature removal of items from the ARTG.

Procedures for ensuring that a product cannot be taken off the ARTG until all State and Territory governments have agreed to make the newer products available for public patients.¹⁶

Consumer education

Consumers strongly endorsed widespread consumer education on health technologies and the HTA process, so that consumers:

- Know about the elements of the HTA system, including compliance requirements, complaints mechanisms, and where to report adverse events – enabling consumers to feed into the HTA system and ensuring learnings from current patient experiences (about what works and what does not) and the patient's journey are taken into account in the assessment and review processes.
- Understand the benefits and risks of using (or not using) various devices – ensuring that their consent to a procedure or device is fully informed and they are able to take more responsibility for their own health.

Consumers suggested that consumer education should be an integral function of the new HTA system involving, in the short term, a strategy to collect information on patient experiences with devices and distribute it to other consumers. This could include a 1300-number to receive and provide information to consumers about health technologies and the HTA system.

In addition to the technology itself, it was noted that consumers also had considerable concerns about how well a technology works and the potential problems that may arise in daily life as a result of using the device. Incorporating social values in the HTA process was considered to be of high importance to consumers.

Consumers in all consultations recommended that an educational tool, such as a Consumer Medicines Information (CMI) equivalent for health technologies, should be provided to consumers. This should contain information about the technology, how it should be used, possible risks and side-effects. It would also be important for this document to include information about what consumers should do if they experience difficulties or adverse events; for example, contacting their doctor or a helpline, or possibly the supplier, for which contact details should be provided.

Long-term education should begin in schools, and emphasise the rights of all health consumers. This could address what people can do about taking care of their own health and how the system can help them to do that. This could continue through university and any further education, particularly in the fields of social or government studies.

Consumers clearly identified that consumer education should never be used as a 'weapon' against consumers. It is not acceptable for health professionals to blame people for not knowing about a device or procedure on the basis that the information is publicly available. Consumers should be responsible for their actions only after being educated by the provider, and there are no reciprocal responsibilities.

¹⁶ It was suggested that relevant provisions under the Trade Practices Act (TPA) may provide a model. The rigorous TPA processes for ensuring manufacturers continue to maintain obsolete products at a reasonable cost to consumers for an agreed period of time may be particularly relevant.

It was also clearly identified that consumer education is insufficient, and that there should also be education of health professionals. Health literacy programs could enable them to communicate better with health consumers about health technologies. This would improve consumers' ability to provide informed consent when their health professionals are proposing the use of a technology in their treatment.

Other issues

A number of other important issues were highlighted through consumer consultations. These are briefly described below.

Who pays for the HTA system?

The burning question is always who will have to pay for any enhancements to the system since, in this case, the outcomes of the review must be cost-neutral. Consumers emphasised that the level of funding currently allocated to HTA processes and systems is significant and could be redistributed to develop effective and transparent new HTA systems and processes. Without details of the current distribution of funding for HTA processes, consumers were not able to explore in detail how funding could be redistributed, but emphasised that the objective of funding redistribution should be increased transparency and efficiency.

Participants at the workshop were asked whether suppliers or the public should pay for the HTA system. A range of important views were expressed and need to be taken into consideration in the design of any new systems.

Government funding – There was support for aspects of the system to continue to be funded by government, as the results are clearly in the public interest. Government funding of HTA processes demonstrates that government supports consumer access to the latest and safest technologies, while also demonstrating the integrity of the processes by ensuring that it is not entirely industry funded.

Danger of industry funding – While there was strong support for industry shouldering more of the cost of the HTA, there was concern that industry would simply pass costs on to consumers, inflating the price of already expensive health technologies.

Industry funding must be shared – There was also concern that reliance on industry application fees may have a disproportionately negative impact on some manufacturers. This occurs when one manufacturer pays the application fees, allowing others claiming equivalency of products to slip into the system without paying a fee. It was suggested that a better system to equalise the impost on industry would be through an income contingent loan scheme to support manufacturers to pay application fees to be repaid after profits are made from the device.

Transparency of funding – Consumers found it difficult to recommend how funding could be improved without having access to better information about how funding is currently derived and expended. They want information about how changes to the system are funded to be available for scrutiny.

A more efficient system costs less – There was a strong sense that reducing unnecessary wastage and bureaucracy in the current system would go a considerable way towards funding improvements in a new system.

A more cost effective system ensures more appropriate expenditure – Consumers emphasised that it costs under \$2 million per annum to maintain the NJRR¹⁷, which serves as a point for consumers to share their experiences of a whole category of health technologies, but \$250,000 for the TGA to make an assessment of a single device. However, it is often claimed that the establishment of registries is too expensive. The effectiveness of money spent in achieving the goals of the HTA must be carefully considered in shaping the new system.

Industry Wide Code of Conduct

Many consumers felt that the myriad of current codes of conduct that apply to health technologies and therapeutic goods, including the Medical Technology Association of Australia Code of Conduct, the Medicines Australia Code of Conduct and the Australian Self Medication Industry Code of Practice, are ineffectual, lack transparency, accountability and rigour. They suggested that to bring more rigour to the process, recognition of consumer experiences and requirements for action in relation to adverse outcomes is essential. A single enforceable code for all therapeutic goods would generate greater confidence in the system and dispel concerns that doctors and manufacturers are not acting in the best interest of health consumers.

Mechanisms for providing more rigour could include:

- Necessity for compliance at listing or registration on the ARTG;
- An independent complaints mechanism;
- Strict criteria for membership of Code of Conduct committees;
- Requirement for a large contingent of non-industry members on Code of Conduct committees; and
- Open and transparent reporting on compliance with Codes of Conduct.

Consumers argued for a single high-level, principles-based code that could be developed to cover the whole industry. Separate industry issues could be addressed under the auspices of this overarching ethical code. Consumers wanted to see a code of conduct that included:

- A single code covering both therapeutic complaints and advertising;
- A single and independent complaints mechanism;
- A single monitoring system; and
- Sanctions for non-compliance which go beyond retraction to substantial fines.

HTA must make allowances for equity considerations

Consumers stressed the need for the HTA system to take account of equitable access to health care devices. Of concern is that public patients do not always get access to approved technologies because state/territory health departments determine which approved technologies will be made available to public patients. There was an emphasis on the need to involve states and territories in the system to ensure that newly approved products are available to public patients. Currently, certain technologies and devices are not available through state public hospitals, despite the possibility that the device or technology might provide a better longer term outcome for the

17 Australian Orthopaedic Association 2008 Australian Orthopaedic Association Financial Report for the year ended 30 June 2008, Sydney.

consumer. Drug-eluting stents was an example given of a device available in some jurisdictions but not others. Also, there is concern about equitable access to technologies that are only available in certain major cities; for example, PET scanners. The ACSQHC also has a role to play in advocating for equitable access to devices and procedures for both public and private patients.

Priorities for action

In ranking priorities for action for the HTA system, a consistent set of issues was put forward:

More **effective mechanisms for post market surveillance and review**. Consumers indicated the need for:

- The review process to be separated from the assessment process;
- A mechanism for consumers to report adverse events;
- A mechanism to enable/mandate/provide incentives to doctors reporting adverse events; and
- A national register of devices, regularly reviewed and updated.

Education of consumers. Consumers indicated the need for education about adverse incident reporting to support shared decision making on the use of health technologies. The importance of educating doctors about HTA processes (ensuring health literacy) was also seen as a priority.

A single point of entry into the system and/or a reduction in red tape, bureaucracy and inefficiencies in order to speed up the approval process.

Inclusion of consumer views and experiences as a fundamental part of the assessment process.

Mechanisms to ensure that **consumers are placed at the centre of the system** – for example:

- Continuation of consumer representatives on committees, and increasing the number of consumer representatives;
- Use of consumer impact statements;
- Public reporting of consumer experiences with devices and technologies;
- International models as appropriate – for example, Citizens' Councils or Interest Sub-Groups could be considered for their applicability in an Australian context; and
- A single rigorous code of conduct for all therapeutic goods with appropriate sanctions for non-compliance with the code.

A number of other priorities were identified throughout the consultation process, including:

- Interoperability of the Australian HTA system with that of other countries;
- Requiring more of industry in funding and maintaining the system, particularly a complaints register;
- Giving regulators greater powers to identify issues and enforce sanctions;
- Increasing access to technological devices for all consumers; and
- Fully informed consent by patients prior to agreeing to the use of a procedure, device or medication.

C. Conclusion and Recommendations

This Report details the findings from all CHF consumer consultations undertaken as part of the **Consumer Participation in the Review of Health Technology Assessment** project. It clearly identifies that consumers see an urgent need for change within the current systems and processes for HTA in Australia. The overarching message is that consumers want to see a more robust HTA system which is cost effective, efficient, transparent and accountable, and provides a single entry point into the system.

Based on the evidence provided by CHF's consumer consultations, CHF makes the following recommendations:

Recommendation 1

Robust mechanisms should be developed to **take into account consumer experiences and needs** in all HTA stages through mechanisms such as:

- Consumer representatives on committees;
- Use of consumer impact statements;
- Public reporting of consumer experiences with devices and technologies; and
- International models as appropriate (e.g. Citizens' Councils, Interest Sub-Groups).

Recommendation 2

Rigorous **post market surveillance** mechanisms should be established, ideally governed by a separate body, to the body conducting assessments, to enable the capture, analysis and reporting of information on adverse events and for this information to feed back into assessment processes.

Recommendation 3

The HTA system should have the capacity to reduce red tape, bureaucracy and inefficiencies in the system, including through **a single entry point into the system** and **a process for interim approval for some devices**, to ensure that they are available to consumers more quickly, pending full assessment.

Recommendation 4

HTA pre-market assessment processes must apply clear risk criteria in the assessment of evidence for applications with **consumer safety allocated the highest priority**.

Recommendation 5

There should be mechanisms for regularly **reviewing the technologies on the ARTG**, and **removing them from the ARTG** when they have been shown to be dangerous, when they are superseded by superior products, or when they are no longer being used.

Recommendation 6

Consumer education programs should be developed to ensure that consumers have a strong understanding of both medical devices and technologies and the HTA system designed to regulate their use in Australia.

Recommendation 7

- A single rigorous code of conduct for all pharmaceutical and therapeutic goods industries with appropriate sanctions for non-compliance with the code should be established.

Consumers are the users and beneficiaries of health technologies. When health technology fails, consumers experience negative consequences. CHF considers that it is fundamentally important that consumer input be a core component of the HTA system in Australia to ensure that the system meets consumer needs and recognises the impact of health technologies on their lives. The recommendations outlined in this report recognise that a HTA system with genuine consumer input will ultimately contribute to improved health outcomes for all Australians.

Appendix M: Acronyms

AAT	Administrative Appeals Tribunal
ACSQHC	Australian Commission for Safety and Quality in Healthcare
ADJR	Administrative Decisions (Judicial Review)
AHIA	Australian Health Insurance Association
AHMAC	Australian Health Ministers' Advisory Council
AHMC	Australian Health Ministers' Conference
AHTA	Adelaide Health Technology Assessment
AIMD	Active Implantable Medical Devices
AMA	Australian Medical Association
ANZHSN	Australia and New Zealand Horizon Scanning Network
AOA	Australian Orthopaedic Association
APHA	Australian Private Hospitals Association
ARTG	Australian Register of Therapeutic Goods
ASERNIP-S	Australian Safety and Efficacy Register of New Interventional Procedures – Surgical
CAG	Clinical Advisory Group
COAG	Council of Australian Governments
CHA	Catholic Health Australia
CHF	Consumers' Health Forum of Australia
CRE-PS	Centre for Research Excellence in Patient Safety
CTEPC	Clinical, Technical and Ethical Principal Committee
DoFD	Department of Finance and Deregulation
DoHA	Department of Health and Ageing
DIISR	Department of Innovation, Industry, Science and Research
DVA	Department of Veterans' Affairs
EU	European Union
FDA	Food and Drug Administration (USA)
GHTF	Global Harmonisation Taskforce

HealthPACT	Health Policy Advisory Committee on Technology
HTA	Health technology assessment
HTAi	Health Technology Assessment International
HTA Review	Review of Health Technology Assessment in Australia
IDC	Inter Departmental Committee
ISH	in situ hybridisation
JBC	Jurisdictional Blood Committee
KPI	key performance indicator
MBCC	Medical Benefits Consultative Committee
MBS	Medicare Benefits Schedule
MDEC	Medical Devices Evaluation Committee
MSAC	Medical Services Advisory Committee
MTAA	Medical Technology Association of Australia
MTSRG	Medical Technology Stakeholder Reference Group
NEHTA	National E-Health Transitory Authority
NHHRC	National Health and Hospitals Reform Commission
NHMRC	National Health and Medical Research Council
NHS	National Health Service (UK)
NICE	National Institute for Health and Clinical Excellence (UK)
NIP	National Immunisation Program
NJRR	National Joint Replacement Registry
NPHS	National Preventative Health Strategy
NZ	New Zealand
PAG	Policy Advisory Group
PBAC	Pharmaceutical Benefits Advisory Committee
PBPA	Pharmaceutical Benefits Pricing Authority
PBS	Pharmaceutical Benefits Scheme
PDC	Prostheses and Devices Committee

PDNG	Prostheses and Devices Negotiating Group
PHI	private health insurance
PHIAC	Private Health Insurance Administration Council
PM&C	Department of the Prime Minister and Cabinet
PMS	post-market surveillance
PoCE	Panel of Clinical Experts
QALY	quality adjusted life years
SEP	single entry point
TGA	Therapeutic Goods Administration
ToRs	terms of reference
TPCA	Third Party Conformity Assessment
UK	United Kingdom
WHO	World Health Organization

Appendix N: Glossary of Terms

Appraisal	The consideration of the evidence and other relevant factors by the advisory committee
Assessment	The evidence base to consider the health technology by a HTA evaluator
Biologics	Commercial products derived from biotechnology
Clinical effectiveness	A consideration of the quality and strength of evidence in relation to a medical service, device, pharmaceutical or vaccine, as well as the magnitude of the effect and relevance of the evidence to Australian practice compared with currently funded items or current clinical practice
Co-dependent	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 (e.g. a pathology or imaging diagnostic technology) which might more accurately identify patient subsets most likely to gain from the therapy or monitor therapy response
Cost effective	Economic evaluation which entails a set of formal quantitative methods used to compare alternative strategies (or treatments) with respect to their resource use and their expected outcomes
Diagnosis	Identification of the cause and nature or extent of disease in a person with clinical signs or symptoms (for example, electrocardiogram, x-ray for possible fracture)
Device	<p>From s 41BD of the Therapeutic Goods Act 1989</p> <p>1. A medical device is:</p> <ul style="list-style-type: none"> a. any instrument, apparatus, appliance, material or other article (whether used alone or in combination, and including the software necessary for its proper application) intended, by the person under whose name it is or is to be supplied, to be used for human beings for the purpose of one or more of the following: <ul style="list-style-type: none"> i. diagnosis, prevention, monitoring, treatment or alleviation of disease; ii. diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap; iii. investigation, replacement or modification of the anatomy or of a physiological process; iv. control of conception; <p>and that does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but that may be assisted in its function by such means; or</p>

	b. an accessory to such an instrument, apparatus, appliance, material or other article
Effectiveness	How well a health intervention works in practice
Efficacy	Efficacy is not explicitly defined in the regulatory framework, but by complying with the essential principles outlined in Schedule 1 to the Therapeutic Goods (Medical Devices) Regulations 2002, a judgement is made that the product is efficacious.
Established	Considered by healthcare providers to be a standard approach to a particular condition or indication and diffused into general use
Experimental	Undergoing laboratory testing using animals or other models
Externalities	An incidental condition that may affect a course of action
Genome	A full set of chromosomes; all the inheritable traits of an organism
Genomics	The study of genomes
Global harmonisation	The process of making disparate international approaches to regulation etc similar
Health technology	Includes medicines; diagnostics, devices, equipment and supplies; medical and surgical procedures; support systems; and organisational and managerial systems used in prevention, screening, diagnosis, treatment and rehabilitation
Health technology assessment	Encapsulates a range of processes and mechanisms that use scientific evidence to assess the quality, safety, efficacy, effectiveness and cost effectiveness of health service delivery. The process is commonly applied to pharmaceuticals (including vaccines), medical devices, medical procedures, and public health approaches.
Horizon scanning	Was established to provide advance notice of significant new and emerging technologies to health departments in Australia and New Zealand, and to exchange information and evaluate the potential impact of emerging technologies on their respective health systems.
Hybrid technology	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)
Information asymmetry	Decisions in transactions where one party has more or better information than the other
Innovation	The introduction of new ideas, goods, services and practices which are intended to be useful. Innovation is a novel, beneficial change in art or practice

Medicare	A Commonwealth Government benefit scheme covering professional medical services. For each service included as an item on the Medicare Benefits Schedule (MBS), a proportion of the patient's cost is met through government reimbursement
Medicare Benefits Schedule (MBS)	List of professional medical services (items) approved for reimbursement under Australia's national health care budget
Medicines	Any substance or substances used in treating disease or illness; medicament; remedy
Obsolete/outmoded/abandoned	Superseded by other technologies or demonstrated to be ineffective or harmful
Off-label	(Unlabelled or unapproved) prescribing refers to prescribing a registered medicine for a use that is not included or is disclaimed in the product information. Examples include use for a different indication, patient age range, dose or route to that which is approved by regulatory authorities ¹
Post-market surveillance	The activity of monitoring the performance of a product post-approval
Prevention	Protect against disease by preventing it from occurring, reducing the risk of its occurrence, or limiting its extent e.g. immunisation, hospital infection control program.
Quality	Manufacturing quality is assessed in the context of the Quality Management System implemented by the device manufacturer, and those systems are assessed against Australian/International Standard AS ISO 13485 – Medical devices – Quality management systems – requirements for regulatory purposes
Quality adjusted life year	(QALY) A unit of health outcomes that adjusts gains (or losses) in years of life after a service, by the quality of life during those years. They provide a common unit for comparing cost utility across different interventions and health problems.
Regulation conduct	A law, rule, or other order prescribed by authority, especially to regulate
Rehabilitation	Restoration, maintenance or improvement of a physically or mentally disabled person's function and well-being (e.g. exercise program for post-stroke patients)

1 Turner S. Unregistered and off-label drug use in paediatric inpatients. Aust J Hosp Pharm 1999; 29: 265-268

Safety	<p>TGA – taken from Australian/International Standard AS ISO 14971 – Medical Devices – Application of risk management to medical devices – a standard endorsed in the regulatory framework, and defined as ‘freedom from unacceptable risk’. Safety is not explicitly defined in the regulatory framework, but by complying with the essential principles outlined in Schedule 1 to the Therapeutic Goods (Medical Devices) Regulations 2002, a judgement is made that the product is safe.</p> <p>MSAC and PBAC – a judgment of the acceptability of risk (a measure of the probability of an adverse outcome and its severity) associated with using a particular service in a particular situation – freedom from unacceptable risk.</p>
Screening	Detection of a disease, abnormality, or associated risk factors in asymptomatic people (for example, Pap smear, mammography)
Technology	The application of scientific or other organised knowledge including any tool, technique, product, process, method, organisation or system to practical tasks.
Treatment	Improvement or maintenance of health status, avoid further deterioration, or provide palliation (for example, antiviral therapy, coronary artery bypass graft surgery, chemotherapy)
Vigilance	Pro-active monitoring of the marketplace in which technology is supplied to detect problems



