



Australian Government

Department of Health and Ageing

Review of Health Technology Assessment in Australia

A Discussion Paper

Review of Health Technology Assessment in Australia - A Discussion Paper

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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.

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.

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

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.

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), 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)

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.

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

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

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 \$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).

⁶ Whereas TGA assesses a medical device to determine safety and efficacy, MSAC assess the safety, effectiveness and cost effectiveness of the medical service when using the device.

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.

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 all issues or 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) ensuring 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 those they are intended to impact.

The HTA Review will need to balance the competing demands of the different stakeholders (government, industry, health professionals and consumers) who have an 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 facing 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 in the ARTG. Once included in the ARTG the device can be supplied to the market. Access to devices not included in 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 hybrid or co-dependent 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, can advise on 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. a 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. the 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 Prosthesis List, a MSAC assessment will need to be conducted before the application for the Prosthesis 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.

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.

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 most likely to gain from the therapy or monitors therapy response.

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 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?

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 Health Technology 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.

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 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)

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.

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

