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.
### 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)*