Health Technology Assessment Access Point (HTAAP)

Information Pack

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<tr>
<th>Email</th>
<th><a href="mailto:hta@health.gov.au">hta@health.gov.au</a></th>
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<tbody>
<tr>
<td>Phone</td>
<td>(02) 6289 7550</td>
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<tr>
<td>Post</td>
<td>Department of Health and Ageing HTA Access Point (MDP 854) GPO Box 9848 CANBERRA ACT 2601</td>
</tr>
<tr>
<td>Street address</td>
<td>Department of Health &amp; Ageing, 23 Furzer St, Phillip ACT 2606</td>
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Role and Function of the Health Technology Assessment Access Point (HTAAP)

The December 2009 *Review of Health Technology Assessment in Australia* (HTA Review) recommended there be a single point of contact to assist applicants navigate Australian Government health technology assessment (HTA) for reimbursement processes for co-dependent and hybrid technologies.

The Health Technology Assessment Access Point (HTAAP) is the entry point for applicants with co-dependent or hybrid technologies seeking reimbursement through:

- the Medical Services Advisory Committee (MSAC) for listing on the Medicare Benefits Schedule (MBS)
- the Pharmaceutical Benefits Advisory Committee (PBAC) for listing on the Pharmaceutical Benefits Scheme (PBS)
- the Prostheses List Advisory Committee (PLAC) for listing on the Prostheses List

The HTAAP will:

- provide relevant background information and forms
- organise initial meetings with HTA secretariats
- provide an ongoing point of contact between the applicant and the relevant secretariats for the duration of the assessment process

The HTAAP can advise on:

- whether the application will be treated as co-dependent
- what pre-lodgement steps will be required
- the progress of your application

This HTAAP Information Pack provides basic information to potential applicants to assist them in early discussions with the Department about potential applications:

- the Australian Government’s HTA system including the expert advisory committees that provide advice to government on applications for HTA for reimbursement
- the role and function of the HTAAP
- the arrangements for HTA of co-dependent technology applications
- frequently asked questions

Current Australian Government processes for market entry and HTA for reimbursement

The attached diagram provides a high level overview of the current Australian Government processes for market entry and HTA for reimbursement. Further information about these processes, the funding programs and the expert advisory committees can be found on the HTA website.

The diagram is split into four sections. A brief description of the key committees follows.

The first section, ‘Market Regulation’ illustrates that an application to supply a therapeutic good must be submitted to the Therapeutic Goods Administration (TGA) to be approved for listing on the Australian Register of Therapeutic Goods (ARTG).

The second section ‘HTA Access Point (HTAAP)’ manages co-dependent and hybrid technology applications where the technology needs to be considered by more than one committee.

The third section is HTA for reimbursement which illustrates various pathways for assessment for funding under an Australian Government health funding program. Applications may be made concurrently to each of these programs, noting that applicants will be expected to comply with the eligibility criteria for each program.

For medicines or vaccines, applications for new items or amendments to an existing item can be made to the Pharmaceutical Benefits Advisory Committee (PBAC). If successful, new items or amendments will be included in the Pharmaceutical Benefits Scheme (PBS) or the National Immunisation Program (NIP).

For medical services (including medical consultations or allied health services) requiring a new Medicare Benefits Schedule (MBS) item number or an amendment to an existing item, applications need to be made to the Medical Services Advisory Committee (MSAC). If successful, the new service or amendment will be included on the MBS.

For prostheses that are implanted as part of a medical service listed on the MBS, applications need to be made to the Prostheses List Advisory Committee. If successful, the device is listed on the Prostheses List for private health insurance purposes.

The fourth section is Post Market Surveillance. Post market surveillance can occur through adverse event notification to the TGA, proactive post market surveillance by the TGA for example utilising performance data provided by the National Joint Replacement Register and through post market surveillance for reimbursement decisions through the 2011-12 Budget Measure “Comprehensive Management Framework for the MBS” (CMFM). The CMFM continues the rolling departmentally-managed reviews of the quality, safety and fee levels of existing MBS items to examine the evidence of the clinical quality and appropriateness of existing MBS items and MBS fees in order to maximise health outcomes for patients.
Therapeutic Goods Administration (TGA)

The Therapeutic Goods Administration (TGA) is Australia's regulatory authority for therapeutic goods. The TGA carries out a range of assessment and monitoring activities to ensure therapeutic goods available in Australia are of an acceptable standard with the aim of ensuring that the Australian community has access, within a reasonable time, to therapeutic advances.

The TGA has six statutory expert committees it may call upon to obtain independent advice on scientific and technical matters.

Committee members are appointed by the Minister and must have expertise in relevant clinical or scientific fields or appropriate consumer issues.

Pharmaceutical Benefits Advisory Committee (PBAC)

The role of the Pharmaceutical Benefits Advisory Committee (PBAC) is to assess applications for and provide advice to the Minister for Health and Ageing on listing of medicines on the Pharmaceutical Benefits Scheme (PBS) to ensure that all products listed as benefits meet the criteria specified in the National Health Act 1953.

Medical Services Advisory Committee (MSAC)

The Medical Services Advisory Committee (MSAC) is an independent scientific committee comprising individuals with expertise in clinical medicine, health economics and consumer matters. It advises the Minister for Health and Ageing on whether a medical service (which meets the eligibility requirements under the Health Insurance Act 1973) should be publicly funded through listing on the Medicare Benefits Schedule (MBS), by amending existing items on the MBS, or through other funding arrangements, based on an assessment of its comparative safety, effectiveness, cost-effectiveness and total cost, using the best available evidence. In providing this advice, MSAC may also take other relevant factors into account. This process ensures that Australians have access to medical services that have been shown to be safe and clinically effective, as well as representing value for money for the Australian health care system.

Prostheses List Advisory Committee (PLAC)

The primary role of the Prostheses List Advisory Committee (PLAC) is to advise the Minister for Health and Ageing about the listing of prostheses and their appropriate benefits in the Prostheses List. The List is made under the Private Health Insurance Act 2006 and the Private Health Insurance (Prostheses) Rules which require private health insurers to pay benefits for those prostheses in specified circumstances.

Co-Dependent and Hybrid Technologies

Health technologies are co-dependent if their use needs to be combined (either sequentially or simultaneously) to achieve or enhance the intended clinical effect of either technology. For example, a drug/test combination where a new medicine seeking listing on the PBS may have a related pathology test that helps to determine the population group for that medicine.

Hybrid health technologies combine the characteristics of different health technologies in one entity. An implantable device that also releases a medication such as drug eluting stents is an example of this type of technology. The assessment pathway for hybrid health technologies is informed by its classification established by the Therapeutic Goods Administration (TGA).
Arrangements for health technology assessment of co-dependent technology applications

The assessment of co-dependent and hybrid technologies is coordinated, managed and monitored through the Health Technology Assessment Access Point (HTAAP).

The following diagram outlines the arrangements for health technology assessment (HTA) of co-dependent technology applications consistent with the requirements of the HTA Review, including:

a. an integrated front door to Australian Government HTA processes with the HTA Access Point (HTAAP) assisting applicants to initiate and navigate the different HTA processes (for changes to the Medicare Benefits Schedule (MBS), the Pharmaceutical Benefits Scheme (PBS) and the Prostheses List);

b. coordinated but modular assessment of applications, which reflects agreed HTA processes and timeframes and the individual responsibilities and accountability to the Minister of each of the expert advisory committees (that is, the Medical Services Advisory Committee (MSAC), the Pharmaceutical Benefits Advisory Committee (PBAC) and the Prostheses List Advisory Committee (PLAC); and

c. integrated advice to the Minister for Health and Ageing which incorporates the committees’ advice to take account of each technology’s co-dependence and the consequent implications for government should the listing of the co-dependent technologies be approved.

MSAC appraises medical services where there is an impact on public expenditure, whether the service is directly subsidised by the MBS or through an alternative funding mechanism such as a deed of agreement associated with a PBS listing. It is expected that the majority of co-dependent technology applications will include an MSAC appraisal.

Potential applicants considering submitting an application for a co-dependent technology are encouraged to familiarise themselves with the MSAC arrangements which can be found at: http://www.m sac.gov.au/

Potential applicants are also encouraged to make early contact with the HTAAP about their proposed application so that evidence and assessment processes can be clarified.

The new arrangements for the assessment of co-dependent technologies are intended to reduce the overall assessment timeframe for such applications by ensuring that MSAC assessments occur concurrently with those of other committees (instead of sequentially). As well, if an applicant chooses to lodge a submission-based assessment to MSAC, it will have greater control over the assessment timeframe.

The number of co-dependent technology applications is expected to comprise only a small percentage of overall applications to Australian Government funding programs. The department, through the HTAAP, will work with applicants to ensure the transition to the new arrangements is as seamless as possible. The department is also working with all relevant committees to facilitate the coordination of advice to the Minister.
Arrangements for Health Technology Assessment of Co-Dependent Technology Applications

Integrated front door for Australian Government HTA

- HTAAP - Case Manager Role
  - Brief industry on new processes
  - Encourage early industry notification of upcoming applications
  - Conduct initial meeting between DoHA and applicant
  - PASC (MSAC)

Submission lodged

Coordinated but modular HTA

HTAAP Monitoring
- Separate funding program
- Separate HTA of applications
- Separate advisory committee
- Coordinated advice to government
- Coordinated Government decision
- Coordinated listing

- Prostheses List
- Cost Recovery
- FLAC
- MBS
- Not Cost Recovery
- MSAC
- Advice
- Decision
- PBS
- Cost Recovery
- FBAC
- MBS
- PBS
- Prostheses List
Key Steps in HTA

The key elements in the diagram are:

- The HTAAP encourages applicants to engage early with the department in order to understand the processes required.

- Applicants may contact the HTAAP directly for advice or the matter may be referred to the HTAAP by an existing secretariat (PBAC, PLAC or MSAC) where a potential co-dependent technology application is identified through usual pre-assessment or application lodgement processes.

- The HTAAP will convene an internal Technology Discussion Meeting with relevant secretariats, medical and other technical advisers at which broad agreement is reached on whether the proposed application is co-dependent and the likely assessment pathway(s) and methodology(ies).

- The HTAAP will contact the applicant to confirm the expected co-dependent assessment across technologies and provide relevant background information and forms, with an offer to set up an initial meeting with relevant secretariats and advisers to further discuss the proposed application and to brief the applicant on the HTA processes should the applicant proceed.

- Following the initial meeting, the HTAAP will continue to coordinate the pre-assessment steps in the MSAC process, as well as the subsequent lodgement of the integrated (but modular) co-dependent technology application and its assessment through the relevant HTA processes.

- The applicant will need to complete the pre-assessment documentation required by the agreed assessment pathways (that is, PBAC, MSAC or PLAC) and meet all necessary eligibility and pre-assessment requirements including payment of fees where appropriate.
  - The data information requirements set out in "Draft Information Requests for assessing co-dependent technologies" will also need to be addressed, alongside the existing PBAC and MSAC Guidelines.
  - Advice is available through initial or pre-assessment meetings on more complex co-dependent scenarios.
  - It is preferable where possible for applicants to submit integrated evidence in their co-dependent technology application.

- Each committee will continue to be responsible for assessing and providing advice to the Minister for Health and Ageing under its terms of reference or legislation.

- Where necessary and appropriate to ensure integrated and coordinated advice to the Minister about the implications of a co-dependent pairing, the committee secretariats will share information as part of informing and coordinating committee deliberations.

- The department will prepare integrated, coordinated advice to the Minister which will include the advice of relevant committees and the costing and financial implications for the different funding programs to enable the Government to make a decision about the listing of one or both technologies.
Frequently Asked Questions

What are Co-Dependent and Hybrid Technologies?

Health technologies are co-dependent if their use needs to be combined (either sequentially or simultaneously) to achieve or enhance the intended clinical effect of either technology. For example, a drug/test combination where a new medicine seeking listing on the PBS may have a related pathology test that helps to determine the population group for that medicine.

Hybrid health technologies combine the characteristics of different health technologies in one entity. For example, an implantable device that also releases a medication such as drug eluting stents.

The assessment pathway for hybrid health technologies is informed by the classification established by the Therapeutic Goods Administration (TGA).

What is the Health Technology Assessment Access Point (HTAAP)?

The Health Technology Assessment Access Point (HTAAP) is the initial entry point to identify and coordinate the appropriate assessment pathways for co-dependent and hybrid technology applications/submissions and applications to the Medical Services Advisory Committee (MSAC). The HTAAP will:

- provide relevant background information and pre-assessment documentation to initiate an application;
- organise any initial meetings with HTA secretariats; and
- provide an ongoing point of contact with the applicant and the secretariats.

The HTAAP can advise on:

- whether the application will be treated as co-dependent;
- what pre-assessment steps will be required (particularly the MSAC PASC process); and
- progress of your application

What is the Therapeutic Goods Administration (TGA)?

The Therapeutic Goods Administration (TGA) is Australia's regulatory authority for therapeutic goods. The TGA carries out a range of assessment and monitoring activities to ensure therapeutic goods available in Australia are of an acceptable standard with the aim of ensuring that the Australian community has access, within a reasonable time, to therapeutic advances.

The TGA has six statutory expert committees it may call upon to obtain independent advice on scientific and technical matters.

Committee members are appointed by the Minister and must have expertise in relevant clinical or scientific fields or appropriate consumer issues.
How do I apply for reimbursement for co-dependent or hybrid technologies?

Contact the Health Technology Access Point (HTAAP) via phone (02) 6289 7550 or email hta@health.gov.au.

Co-dependent technologies that require new listings or amendments to both the Pharmaceutical Benefits Scheme (PBS) and the Medicare Benefits Schedule (MBS) will require assessment by both the Pharmaceutical Benefits Advisory Committee (PBAC) and the Medical Services Advisory Committee (MSAC).

Co-dependent technologies that require new listings or amendments to the Prostheses List where an eligible MBS item number has not been confirmed will require assessment by the Prostheses List Advisory Committee and MSAC.

The HTAAP will assist applicants with co-dependent technologies to ensure timely assessment by each relevant assessment process.

All applicants seeking MBS listing (including where a co-dependent technology is not involved) should also contact the HTAAP on the above or the MSAC Secretariat via phone (02) 6289 7550.

What is the Pharmaceutical Benefits Advisory Committee (PBAC)

The role of the Pharmaceutical Benefits Advisory Committee is to assess applications for and provide advice to the Minister for Health and Ageing on listing of medicines on the Pharmaceutical Benefits Scheme (PBS) to ensure that all products listed as benefits meet the criteria specified in the National Health Act 1953.

What is the Pharmaceutical Benefits Advisory Committee (PBAC) Economic Sub Committee (ESC)?

The Pharmaceutical Benefits Advisory Committee (PBAC) established the Economic Sub Committee (ESC) in December 1993 under section 101A of the National Health Act 1953 to:

- 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.

What is the Prostheses List Advisory Committee (PLAC)?

The primary role of the Prostheses List Advisory Committee is to advise the Minister for Health and Ageing about the listing of prostheses and their appropriate benefits in the Prostheses List. The List is made under the Private Health Insurance Act 2006 and the Private Health Insurance (Prostheses) Rules which require private health insurers to pay benefits for those prostheses in specified circumstances.
**What is the Medical Services Advisory Committee (MSAC)?**

The Medical Services Advisory Committee (MSAC) is an independent scientific committee comprising individuals with expertise in clinical medicine, health economics and consumer matters. It advises the Minister for Health and Ageing on whether a medical service (which meets the eligibility requirements under the *Health Insurance Act 1973*) should be publicly funded through listing on the Medicare Benefits Schedule (MBS), on amendments to existing items on the MBS or other arrangements based on an assessment of its comparative safety, effectiveness, cost-effectiveness and total cost, using the best available evidence. In providing this advice, MSAC may also take other relevant factors into account.

This process ensures that Australians have access to medical services that have been shown to be safe and clinically effective, as well as representing value for money for the Australian health care system.

**Why do I need to seek appraisal by the Medical Services Advisory Committee (MSAC)?**

Most co-dependent technology applications include a medical service which means that the application will include an MSAC appraisal. MSAC appraises medical services where there is an impact on public expenditure, whether the service is directly subsidised by the MBS or through an alternative funding agreement such as a deed of agreement associated with a PBS listing.

Potential applicants considering submitting an application for a co-dependent technology are encouraged to familiarise themselves with the MSAC arrangements which commenced on 1 January 2011 and can be found at: [MSAC Application Process](#). They are also encouraged to make early contact with the HTAAP about their proposed application so that evidence and assessment processes can be clarified.

The MSAC arrangements allow applicants to lodge a submission based application (for critique by an external evaluator), and reduce overall assessment timeframes. Applicants are still able to seek a contracted assessment, if that is the preferred pathway.

A more detailed diagram for MSAC processes is included in this information pack.

**What is the Protocol Advisory Sub-Committee (PASC)?**

The Protocol Advisory Sub-Committee (PASC) is a standing sub-committee of MSAC with membership which includes decision analysis, health economics, epidemiology, public health, consumer and clinical expertise. Its primary role is to determine the Decision Analytic Protocol – that is, define the decision option(s) or question(s) for public funding of proposed new or amendment services and procedures prior to final lodgement of an application for consideration by MSAC. This step includes a 4-6 week public consultation phase. Further information can be found on the MSAC website at [http://www.msac.gov.au](http://www.msac.gov.au).

**What is a Decision Analytic Protocol (DAP)?**

The Decision Analytic Protocol defines the decision option(s) or question(s) for public funding of proposed medical services prior to final lodgement of an application for its consideration by the Medical Services Advisory Committee (MSAC). Applicants must address all of the requirements of the agreed protocol. Additional protocols for submission based applications must be advised to MSAC and agreed prior to commencement of evidence collection. Evidence assessment reports must use the required MSAC format.
What is the Medical Services Advisory Committee (MSAC) Evaluation Sub-Committee (ESC)?

The Evaluation Sub-Committee (ESC) is a standing sub-committee of MSAC with membership which includes health economics, epidemiology, public health, consumer and clinical expertise. Its role is to provide advice on any gaps or areas of uncertainty in the quality, validity and relevance of evidence provided in critiques or assessment reports for applications being considered by MSAC.

How will expert advisory committees communicate with each other?

Each relevant expert advisory committee will consider the co-dependent technology submissions within their current processes and timeframes. For MSAC/PBAC co-dependent submissions, MSAC will consider the medical service component as well as any overlapping co-dependency issues with the medicine, and PBAC will consider the medicine component as well as any overlapping co-dependency issues with the medical service. For MSAC/PLAC co-dependent technology submissions MSAC will consider the medical service component as well as any overlapping co-dependency issues with the device and PLAC will consider the device component as well as any overlapping co-dependency issues with the medical service.

The timing of committee communications depends on when a submission of evidence is made and when committees are scheduled to meet for example:

- if you submit evidence to MSAC first using the PASC agreed protocol, MSAC will provide its advice to the next PBAC/PLAC meeting;
- if you submit evidence to PBAC/PLAC first, that committee will most likely need to wait until MSAC next meets to receive advice from MSAC. This means that PBAC/PLAC may need to defer finalising its advice until the next PBAC/PLAC meeting so that it can take MSAC’s advice into consideration in finalising its assessment; and
- if you submit concurrently to both PBAC/PLAC and MSAC, then it will depend on which committee meets last to enable the appraisal of the different elements of the co-dependent technology to be finalised.

It should be noted that either committee may, following their appraisal, defer finalising its advice to request specific further information from the other committee. It is unlikely that the committees will consider matters out of session, and will not meet jointly.

How long will it take to process co-dependent technology applications?

Each committee will consider co-dependent technology submissions within their existing processes and timeframes.

The amount of time taken by each committee to consider a co-dependent technology submission, and request or respond to issues raised during that consideration, will be determined by each committee.

Timeframes will be specific to each submission and will be dependent on the complexity of the submission elements including co-dependent issues. This makes it difficult to predict at which exact meeting either committee would provide final advice on any given submission.

Government expects coordinated advice on co-dependent technologies from the relevant committees to be provided at the same time so that it may make fully informed funding decisions.
Will the arrangements for assessing co-dependent technologies increase assessment timeframes?

The arrangements for the assessment of co-dependent technologies are intended to reduce the overall assessment timeframe for such applications by ensuring assessments occur concurrently across committees and the Therapeutic Goods Administration (TGA) (instead of sequentially).

While the Medical Services Advisory Committee (MSAC) requires a Protocol Advisory Sub Committee (PASC) agreed Decision Analytic Protocol (DAP) prior to submission of evidence using the DAP, the duration between submission to and appraisal by MSAC and the Pharmaceutical Benefits Advisory Committee (PBAC) is not substantially different.

Applicants are advised to seek a PASC agreed DAP early. If an applicant chooses to lodge a submission-based assessment to MSAC, it may have greater control over the assessment timeframe. The timing of when to submit an application is ultimately the applicant’s decision. While the MSAC PASC step will provide greater certainty for submission-based assessments to MSAC, it should be noted that the arrangements also may need to address other aspects of the HTA Review recommendations, such as improvements in procedural fairness and transparency, and these can add to the overall processing timeframe. For example, MSAC allows a 10 day response time for each applicant input step compared to a five day response time provided by PBAC.

Co-dependent technology applications are expected to comprise only a small percentage of overall applications to PBAC, MSAC and PLAC. The department, through the HTAAP, will work with applicants to ensure that these arrangements operate as seamlessly as possible.

The department is also working with all relevant committees to facilitate the coordination of advice to the Minister.

Are the arrangements for cost recovery, the same for Medical Services Advisory Committee (MSAC) submissions as they are for Pharmaceutical Benefits Advisory Committee (PBAC) submissions?

There is no proposal at this stage for applications to the Medical Services Advisory Committee (MSAC) to operate under cost recovery arrangements. That is, the department will not be charging a fee, and will cover the costs of the critique of a submission based application for MSAC consideration or of the contracted assessment. Where an applicant opts to present a submission based application, the applicant would be responsible for the costs of preparing the application. Applicants who submit evidence to MSAC do so on the basis that it will be made publicly available once MSAC advice has been noted by the Minister for Health and Ageing.
What are the key steps in the Medical Services Advisory Committee (MSAC) arrangements?

The process map relating to the consideration by MSAC of medical services is found at:


outlines the key steps for applications being considered by the Medical Services Advisory Committee (MSAC). These include:

1. an initial meeting with the department to provide information about the eligibility, application and assessment processes.
2. an application to determine whether the proposed medical service meets the eligibility requirements of the MBS.
3. a pre-submission of evidence which outlines the intent and scope of the proposed medical service. This informs the development and agreement of the Decision Analytic Protocol (DAP) which sets out the question for public funding through the Protocol Advisory Sub Committee (PASC). This step also includes public consultation on the proposed new medical service.
4. development of a submission based application to MSAC or request for the department to fund a contracted assessment based on the PASC agreed DAP.
5. review of the submission based application or the contracted assessment by the Evaluation Sub Committee of MSAC.
6. MSAC appraisal and advice to the Minister for Health and Ageing.

What are the stakeholder feedback options during the MSAC process?

Applicants have several opportunities to contribute to the MSAC processes including the development of the Decision Analytic Protocol. These opportunities are outlined in the MSAC process diagram included in this information pack.
Processes relating to the consideration by MSAC of Medical Services

From Initiation to Listing

Expression of Interest stage

- **Initiation of process**
  - Applicant submits Part A & Aii

- **Technical Discussion Meeting**
  - Dept

- **Initial meeting**
  - Dept and applicant

- **Eligibility check**
  - Dept
  - Applicant submits Part B

- **MBS Management Committee**
  - Dept

Determination of Approach to Assessment stage

- **Proposed DAP**
  - Applicant submits Part C and D

- **Public notification of PASC agenda**
  - Dept

- **PASC 1**
  - Reviews draft DAP
  - Preparers consultation DAP
  - Applicant comment

- **Public comment**
  - Dept seeks specific input for revised DAP
  - Applicant comment

- **PASC 2**
  - Reviews revised DAP
  - Reviews comments on consultation DAP
  - Finalises DAP
  - Applicant advised

Consideration of Evidence stage

- **Assessment**
  - Applicant Submission
  - Applicant comment

- **Assessment review**
  - Assessment Group
  - Applicant comment

- **ESC evaluation**
  - Focuses issues
  - Prepares report
  - Applicant comment

- **MSAC appraisal**
  - Deliberates
  - Prepares advice and rationale

- **Minister**
  - Notes MSAC Advice
  - Applicant advised
  - Report & MSAC advice published

Implementation stage

- **Pre implementation of new items or changes**
  - Dept

- **Advice to Minister on item**
  - Dept

- **Costing of item**
  - Agreed across Depts

- **Advice to Government**
  - Makes funding decision

- **MBS listing**
  - Dept