



**Australian Government**

**Department of Health and Ageing**

# **PROPOSAL FOR CHANGES TO THE MEDICAL SERVICES ADVISORY COMMITTEE (MSAC) PROCESSES FOR APPLICATIONS FOR PUBLIC FUNDING**

## **DISCUSSION PAPER**

This paper has been prepared by the Department of Health and Ageing (the Department) on behalf of the Medical Services Advisory Committee (MSAC) as a basis for further consultation with stakeholders on the implementation of changes to address recommendations in the Review of Health Technology Assessment in Australia (HTA Review).

This discussion paper outlines a broad framework for reform developed by MSAC in response to the recommendations agreed by government in the HTA Review report and seeks broader stakeholder comment on the key elements of the proposed changes as well as any issues for implementation.

This paper does not necessarily reflect the Minister's or the Government's views on the proposals outlined within.

Any queries in relation to the contents of this discussion paper should be directed via email to the Medical Services Advisory Committee secretariat at [msac.secretariat@health.gov.au](mailto:msac.secretariat@health.gov.au)

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# INTRODUCTION

By Chair of MSAC

Established in 1998 to advise the Australian Minister for Health and Ageing on evidence relating to the safety, effectiveness and cost-effectiveness of new medical technologies and procedures, the Medical Services Advisory Committee (MSAC) provides advice to the Australian Government to inform government decisions about public funding for new, and in some cases existing, medical technologies and procedures.

In providing advice to the Australian Government on the circumstances for public funding to improve health outcomes for patients, MSAC has instituted processes to allow the assembly and review of available evidence. MSAC's appraisal of evidence associated with medical services has, since 1998, been an integral part of the process for the listing of new medical technologies and services on the Medicare Benefits Schedule (MBS).

The MBS lists rebates payable to patients for private medical services provided on a fee-for-service basis and is a cornerstone of the Australian health care system, which facilitates patient access to general practice, specialist medical services, and allied health services. Many of the technologies and medical services appraised by MSAC for its advice to government also rely on funding, including public funding, outside of the MBS, for the delivery of that service to patients.

MSAC's role is to ensure that new and existing medical procedures attracting public funding, including under the Medicare Benefits Schedule, are supported by evidence of safety, clinical effectiveness and cost-effectiveness. MSAC's Terms of Reference also allow it to provide advice to government that interim public funding through the MBS be considered to enable specific data collection, within an agreed research framework, in order to broaden the evidence base for final definitive MSAC advice to government for either removal or ongoing MBS public funding.

In undertaking its role to provide advice to the Minister on the evidence for safety, clinical effectiveness and cost effectiveness, MSAC has up to now contracted an assessment of the health technology through a panel of health technology assessment specialists under contract to the Department of Health and Ageing. The compilation of the evidence has normally been guided by a specific MSAC Advisory Panel established for each application for public funding. Advisory Panel membership consists of a Chair and Deputy Chair (who are MSAC members), clinical experts relevant to the subject of the application, as well as consumer representation to provide advice to the contractors regarding appropriate comparators prior to the assessment being undertaken. The Advisory Panel 'signs off' the assessment report as suitable for MSAC purposes at the end of the evidence review and summation. The applicant has a right to respond to the draft protocol developed prior to evidence collection as well as to comment on the report produced for MSAC consideration as part of its role in providing advice to government on the circumstances for public funding.

Details of the application process, forms and Guidelines, as well as the status of application progress through the MSAC assessment process, Advisory Panel membership and the eventual report and MSAC advice are made available on the MSAC Website. Until early 2009, MSAC's advice was published within the contracted report along with the date of Government agreement to note the advice and release the report. Since that time, MSAC's advice and a public summary document outlining the rationale for MSAC's advice have been published separately to the contracted assessment report.

MSAC has regularly reviewed its processes and over the past 18 months the current MSAC has been undertaking an internal review of its processes in order to both focus its advice to improve transparency, timeliness, efficiency and effectiveness of its health technology assessment (HTA) processes.

During that time, MSAC has also seen an increase in the number of applications that are already supported by a systematic literature search, review and economic modelling prepared by the applicant.

In mid 2009, informed by issues discussed during the conduct of the Review of Health Technology Assessment in Australia (HTA Review), MSAC established a number of Working Groups to provide recommendations for reengineering the current MSAC one-size-fits-all approach to assessment to better align it with its needs in considering a range of options regarding the question of public funding for advice to government.

While MSAC's advice on the suitability of the technology for public reimbursement is in part guided by the outcome of the comparative assessment of evidence of the safety, clinical effectiveness and cost effectiveness of a new technology or service against an existing comparator, as presented in the assessment report, MSAC also has a responsibility to consider broader issues not necessarily addressed in each report.

MSAC's role currently ends at the stage of provision of advice to the Minister for Health and Ageing. The Minister, in acting on MSAC's advice, may direct the department to undertake further activity in scoping the impact of any potential funding implications. In making a final decision regarding public funding, the Government relies on the rationale behind MSAC's advice. In implementing a Government decision to fund a new service on the MBS, the Department relies on the level of clarity and detail in MSAC's advice as well as in the assessment report. Government may also direct the Department to undertake additional monitoring that it considers warranted.

One of the main drivers of MSAC's review of how assessment of evidence is developed and 'presented' to MSAC has been how to improve processes to ensure maximum transparency, participation, consistency and alignment to support MSAC's role in providing independent expert advice to government on the circumstances for public funding. There is a need to improve comprehensiveness, consistency and cohesion in MSAC processes to both facilitate the application to MSAC and to facilitate, where possible translation of that advice if the Government seeks to implement that advice.

A number of factors led to MSAC establishing a number of Working Groups to review MSAC processes. These included a revision of current MSAC Application, Economic and Diagnostic Guidelines, inconsistency in quality and comprehensiveness of Assessment Reports generated using the current MSAC Advisory Panel process, the increasing number of applications to MSAC and the increasing complexity of some applications especially the new generation of genetic diagnostic tests and other co-dependent or hybrid technologies. A combination of these factors has significantly impacted on the timeliness of the Advisory Panel contracted Assessment Report process and has led to delays and quality variation in deliverables for MSAC consideration in determining its advice to government. Delays in the MSAC advice process may mean delays in patients accessing publicly funded services.

MSAC positive reimbursement advice resulted in 7 new items being added to the MBS in 2008/09. The 7 new listings assessed by MSAC accounted for over 99% of increased MBS outlays resulting from the addition of a total of 15 new items to the MBS in that period.

Recent MSAC appraisals:

- 2006-07 15 applications 11 (73%) with support for public funding
- 2007-08 12 applications 10 (83%) with support for public funding
- 2008-09 9 applications 7 (78%) with support for public funding
- 2009-10 14 applications 10 (71%) with support for public funding
- 2010-11 20 applications currently in progress.

In mid 2009 MSAC tasked its then Economics Sub Committee (ESC) to establish a number of Working Groups to actively scope process improvements. Scoping included how best to:

- improve access to appropriate expert and consumer advice
- align the evidence collection to the question for public funding
- ensure appropriate data and economic modeling
- increase transparency, natural justice and consistency in each of the MSAC process steps

- increase timeliness of MSAC advice to government
- increase flexibility by introducing fit for purpose processes
- maintain overall cohesion so that core HTA principles were consistently applied through different process pathways.

The release of the HTA Review in February 2010 has provided a policy framework for MSAC process reforms to be progressed. The recommendations arising from the HTA Review require proposed improvements to MSAC processes to be as consistent as possible with other Commonwealth technology assessment. The release of the HTA Review has placed the MSAC process reform activity in the broader framework under which all Commonwealth HTA process improvement will occur.

MSAC progress to date is set out in this discussion paper for broader stakeholder comment. The proposals address MSAC's own reform agenda as well as specific MSAC related recommendations and broader HTA principles outlined in the HTA Review including alignment, where appropriate, with other Commonwealth health technology assessment processes for co-dependent technologies.

Over the past 18 months MSAC has been introducing and testing approaches to preparation and presentation of evidence at MSAC to improve transparency and reduce any perceived conflicts of interest. One of the early tangible outcomes has been the 2009 introduction of the *MSAC Public Summary Document* that outlines MSAC's advice to government and the rationale behind that advice, separate to the contracted assessment report.

MSAC has also undertaken a review of its role and its obligations to capture and provide both sufficient detail as well as a broadening its advice to indicate who pays when a specific new technology is likely to be introduced. As recommended in the HTA Review, MSAC has been given a new role in relation to advice to government with the inclusion of possible MBS fee and item descriptor scope/restrictions.

In addressing how its advice is provided to government, MSAC is proposing a new and different approach, moving from advice based mainly on a comparative assessment and analysis of all the evidence for a new technology to advice based on assessment and analysis focused on evidence for the question for public funding for the technology and best value for patient outcome.

While this may seem mere semantics, it represents a significant shift in how MSAC processes may operate in the future. An immediate outcome has been the removal of MSAC advice from the contracted Assessment Report. This rethink has resulted in a fresh approach to what the assessment report needs to address.

Under the current process, in many instances the existing approach to 'full' HTA process resulted in assessment reports that either did not fully address all the funding options that MSAC needs to take into consideration, or contained 'interpretation' of existing evidence that could be perceived as an MSAC responsibility. Review of MSAC processes has sought to ensure that the best use of expert advice and consumer perspectives is incorporated through clear and consistent processes that best support MSAC's role in providing advice to government.

The separate Working Groups have been tasked with reviewing parts of the total process but reporting back to MSAC through the MSAC ESC to ensure that the overall approach is consistent and addresses the clear goals – to increase transparency, participation, timeliness and effectiveness of the pre MSAC process and to better align it to MSAC's needs in providing independent expert advice to governments based on an appraisal of evidence for the circumstances of public funding.

MSAC is proposing to improve its timeliness by introducing different process pathways including a submission based application process as well as the introduction of abbreviated approaches to assessment including assessment of hybrid and/or codependent technologies. A more rigorous approach to agreed data collection requirements and a new approach to definitive evidence collection protocols are being proposed as well as an issues identification step prior to MSAC appraisal. These

reforms will improve the quality and consistency of evidence pathways prior to consideration by MSAC. Based on the on reviews of a number of previous MSAC-advised interim funded MBS items, reform of the process prior to any future MSAC advice to government on interim public funding is also being proposed. The proposed reforms will need to take into account both international and national HTA developments.

### **Current Commonwealth HTA Processes (including those undertaken by MSAC)**

In keeping with international practice, HTA in Australia has four broad elements: horizon scanning, market regulation, HTA for reimbursement, and post-implementation management.

- Horizon scanning activity allows early identification of new and emerging health technologies to inform governments and health systems for future planning purposes.
- Market regulation assesses the intrinsic safety and performance of therapeutic goods, as intended for use by manufacturers.
- HTA for reimbursement undertakes comparative assessment of safety, clinical and cost effectiveness of health technologies for consideration for public subsidy.
- Post-implementation management may take a number of forms including initial and longer term utilization monitoring, and in some instances where there may be a higher level of outcome concern, surveillance of outcomes, including adverse events, as new health technologies are introduced into routine clinical use.

### **Rationale for reform:**

Changes to MSAC process are required:

1. to explore innovative approaches to maximise health outcomes for patients, whilst promoting the most efficient use of limited health care resources
2. to align MSAC's approach to capturing relevant data and evidence with other major Australian reform and review agendas
3. to meet HTA Review deliverables for 2010 and 2011 including greater certainty in MSAC process timelines.

MSAC is seeking stakeholder comment on these proposed changes.

The following paper outlines MSAC's proposed approach resulting from some 12 months of intensive MSAC Working Group activity during which time many of these proposals have been trialed with agreement of applicants, contracted assessors and MSAC members MSAC Subcommittees, Working Groups and Advisory Panels. This MSAC review activity was foreshadowed in the MSAC 2008-09 Performance Report. The paper below outlines the broad framework for the reforms with the more detailed aspects of the re-engineering of processes provided in appendices. Where possible reference is made to current information available on the MSAC website related. Comment, on the broader framework and/or detailed processes would be welcome. In addition, an open call for expression of interest in participation in any of the new sub committees is also being sought via the MSAC Website.

I would like to take the opportunity to thank the many interested experts, contractors and members of the public who have already participated in development of the proposals to date as well as acknowledging the level of enthusiasm and support from the secretariat and relevant areas in department in both actively engaging in the reform agenda and for maintaining business as usual in what has been an extremely busy and productive 18 months.. It is expected that MSAC will agree final processes at its December 2010 meeting for introduction in 2011.

I would encourage all interested stakeholders to provide comment on the proposals outlined below.

Signature  
Professor Robyn Ward  
Chair of MSAC

# DISCUSSION PAPER

## **CONSULTATION ON PROPOSALS FOR CHANGES TO THE MEDICAL SERVICES ADVISORY COMMITTEE (MSAC) PROCESSES FOR SUBMISSIONS FOR PUBLIC FUNDING**

The discussion paper covers:

- MSAC and MSAC committee structures
- an overview of current and proposed approaches to process stages
- proposed MSAC subcommittee structures to deliver the new approach and calls for possible nominations for future sub committees
- provides attachments that detail the proposed sub committees and pathways to MSAC advice and stakeholder input.
  - Attachment 1: Protocol Advisory Sub Committee
  - Attachment 2: Evaluation Sub Committee
  - Attachment 3: Submission based (including MSAC codependent) pathway
  - Attachment 4: Contracted assessment and
  - Attachment 5: Stakeholder input.

Stakeholders are encouraged to provide written submissions including feedback on any issues, views, and suggestions regarding the proposed new MSAC processes at a concept and/or detailed step level.

The views of consumer organisations or individuals are particularly welcome. The consumer perspective is integral to MSAC processes. Suggestions for individual consumer and consumer organisation involvement in MSAC processes would be welcome.

### ***Written submissions***

All stakeholders are invited to provide written submissions addressing all, or selected issues, raised in this discussion paper, by **18 February 2010**.

Unless confidentiality is specifically requested and agreed justified all Submissions received will be made publicly available via the MSAC website

Written submissions should be emailed to [msac.secretariat@health.gov.au](mailto:msac.secretariat@health.gov.au) or sent in hard copy to the following address:

MSAC Secretariat  
Department of Health and Ageing  
MDP 853  
GPO Box 9848  
CANBERRA ACT 2601

For further information regarding this discussion paper please contact the [msac.secretariat@health.gov.au](mailto:msac.secretariat@health.gov.au)

### **MSAC WEBSITE**

The website <http://www.msac.gov.au> has details of the current MSAC processes and committee structure, terms of reference etc as well as MSAC Public Summary Documents and contracted assessment reports and MSAC Performance Reports.

Details of the MSAC Consultation process will be updated to include access to submissions to the Discussion Paper and subsequent implementation progress reports.

**MSAC will use its RSS and email alert process to provide advice of next steps.**

# OVERVIEW OF MSAC

The principal role of the Medical Services Advisory Committee (MSAC) is to advise the Australian Minister for Health and Ageing on evidence relating to the safety, effectiveness and cost-effectiveness of new medical technologies and procedures. This advice informs Australian Government decisions about public funding for new, and in some cases existing, medical procedures.

## Terms of Reference for the Medical Services Advisory Committee (21 June 2010)

### Purpose:

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 new medical service should be publicly funded 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.

### Roles and function:

MSAC is to:

- Advise the Minister for Health and Ageing on medical services that involve new or emerging technologies and procedures, in relation to:
  - the strength of evidence in relation to the comparative safety, effectiveness, cost-effectiveness and total cost of the medical service;
  - whether public funding should be supported for the medical service and, if so, the circumstances under which public funding should be supported;
  - the proposed Medicare Benefits Schedule (MBS) item descriptor and fee for the service where funding through the MBS is supported;
  - the circumstances, where there is uncertainty in relation to the clinical or cost-effectiveness of a service, under which interim public funding of a service should be supported for a specified period, during which defined data collections under agreed clinical protocols would be collected to inform a re-assessment of the service by MSAC at the conclusion of that period;
  - other matters related to the public funding of health services referred by the Minister.
- Advise the Australian Health Ministers' Advisory Council (AHMAC) on health technology assessments referred under AHMAC arrangements.

MSAC may also establish sub-committees to assist MSAC to effectively undertake its role. MSAC may delegate some of its functions to such sub-committees.

### Composition:

MSAC's size and composition is to be determined by the Minister for Health and Ageing. MSAC's composition is drawn from a wide range of experts constituted from time to time to address the likely type of applications for the committee's consideration. Membership appointments are generally for four year terms, with members able to nominate for consecutive terms. Appointments may be staggered to allow for continuity of the committee. Members may serve on the head committee (MSAC), and/or any of its sub-committees or ad-hoc working groups. MSAC may also

co-opt non-members to its sub-committees or working groups.

Members sign Deed of Confidentiality and Conflict of Interest Declarations upon appointment, and are required to declare potential, perceived or actual conflicts for each meeting/issue being addressed. The Chair will agree if and how an actual or potential conflict of interest needs to be managed.

### **Quorum:**

To enable a MSAC meeting to proceed, half the number of members plus one is required. Similarly, a MSAC decision, either in or out of session, requires a majority vote in favour of the resolution (MSAC's advice to the Minister). Members may abstain from voting. In the event of a tied vote, the Chair has the casting vote.

### **Meeting schedule:**

MSAC usually meets up to four times per year. Sub-committees and working groups may meet more frequently. Business may also be conducted out of session, usually via email or teleconference/videoconference, with face-to-face meetings held where/when required.

### **Deliverables:**

The rationale for MSAC's advice to the Minister (or AHMAC where the matter has been referred through AHMAC arrangements) is provided in the form of a Public Summary Document. Members are required to endorse the advice, Public Summary Documents and Minutes of Meetings, often out of session. Public Summary Documents are included in the public dissemination of the outcomes (both in hard copy and on the MSAC website), after the Minister (or AHMAC where appropriate) has noted MSAC's advice and agreed to its public release.

Members are also required to participate in sub-committees and/or other ad-hoc working groups as determined by the MSAC Executive from time to time.

### **Reporting:**

MSAC submits Performance Reports to the Minister annually.

## **Terms of Reference for MSAC Executive**

(21 June 2010)

### **Purpose:**

The MSAC Executive meets regularly via teleconference throughout the year to progress MSAC activity between formal MSAC meetings. Business may also be conducted out of session, usually via email.

### **Roles and function:**

In consultation with the MSAC Secretariat, to:

1. Regularly consider evaluation progress reports and key performance indicators and provide advice so that MSAC business is efficiently progressed between MSAC meetings.
2. Prepare advice to the Minister for Health and Ageing (the Minister) on applications or referrals where a full or partial Health Technology Assessment (HTA) evaluation is not warranted against an agreed risk based matrix and advice to the Minister is required prior to the next scheduled MSAC meeting. Executive advice to the Minister is to be reported to the next full MSAC meeting.
3. Endorse membership of MSAC sub-committees and ad-hoc working groups to facilitate MSAC activities.

4. Endorse the annual MSAC Performance Report to the Minister.
5. Nominate MSAC representation to external bodies as required.

**Composition:**

The MSAC Executive is appointed by the Department, and consists of the MSAC Chair, MSAC Deputy Chair, chair(s) of any MSAC sub-committee(s), and the Chief Medical Officer (or proxy).

**Deliverables:**

The MSAC Executive has input to/approves Draft Minutes, Public Summary Documents, other MSAC advice, and the annual Performance Report. The Chair provides MSAC's approval for the transmission of MSAC advice/reports to the Minister, which is then arranged by the Department.

The Chair and/or Executive may also be required to prepare and/or sign correspondence on behalf of the committee, usually responses to requests from stakeholders.

The Executive has input into the agendas for MSAC meetings.

**Reporting:**

The MSAC Chair reports to each MSAC meeting on activities conducted since the previous meeting and any Executive decisions taken.

The MSAC Executive clears the MSAC Performance Report that is submitted annually to the Minister.

# OVERVIEW OF CURRENT PROCESS

## Stage : Pre-lodgement

The Department requires a pre-lodgement meeting with applicants to ensure awareness of the process and requirements for consideration of eligibility to proceed. Where appropriate, representatives of relevant areas of the Department attend.

## Stage : Eligibility

This involves consideration by the Department of Health and Ageing to determine whether the application meets eligibility criteria making it suitable for commitment of Commonwealth funds to undertake the assessment. The principal eligibility criterion is whether the service constitutes a clinically relevant professional service within the meaning of the *Health Insurance Act 1973*. Any need for submission to the Therapeutic Goods Administration (TGA) is also confirmed at this stage. While an application may be eligible under the criteria, commitment of Commonwealth monies to undertake a contracted assessment is a separate step with the decision made on a value for money basis.

## Stage : LODGEMENT MSAC Advisory Panel / Contracted assessment report generation

For each eligible application the current process is to engage a contractor group to develop an Assessment Report of the evidence under the guidance of an expert Advisory Panel. The roles and responsibilities of each group is undertaken within formal Department contractual arrangements. MSAC, clinical experts and a consumer representative are involved. The report is managed as a contract deliverable by a department project manager.

Post agreement of a draft protocol by the Advisory Panel and consideration of comment from the applicant the Department contracted assessment group conducts an evidence-based assessment. This will include an economic evaluation with advice from the MSAC ESC on the appropriateness of the proposed economic evaluation approach from the MSAC perspective. The applicant is invited to comment on the draft report and that comment is provided to MSAC. At the end of this stage the applicant and department have an agreed upon a protocol for evidence collection and reporting.

## Stage : MSAC Appraisal

In formulating its advice MSAC considers a wide range of information, including the report assessing the evidence, critiques of the report by nominated non advisory panel MSAC members, rejoinder by the MSAC panel chair and advice from the MSAC ESC on economic issues in the report, comment on the report provided by the applicant, rejoinder from the assessment contractors on the applicant's advice and/or other relevant matters, as well as drawing on the individual expertise of MSAC members.

## Stage : MSAC Advice to Minister

MSAC prepares advice to the Minister on the strength of the evidence in relation to the comparative safety, clinical effectiveness and cost-effectiveness of the new technology or procedure and on the circumstances under which public funding should be supported.

Where the evidence is inconclusive, MSAC concludes that the evidence to definitively address whether the new service is likely to be safer, more clinically effective, and/or more cost-effective than currently funded services, MSAC may advise the Minister that interim funding to enable data collection and further evaluation is an appropriate funding option.

## Stage : Minister/Government Decision

The Minister for Health and Ageing notes MSAC's advice and authorises the publication of the advice and the assessment report. The Minister, in acting on MSAC positive advice may direct the Department to conduct further consultation leading to policy and costing advice on which the Minister may make a fully informed decision in relation to public funding.

## Stage : Implementation

Once a Government decision has been made to provide public funding to a new service the Department is directed to implement the decision. Where public subsidy is related to a new item on the MBS the necessary changes are made to the Medicare Benefits Schedule that describe the service and the fee on which Medicare benefits will be based. The Department undertakes routine reporting to government on MBS costs to the health care system. In some instances the government may also direct that further reporting requirements be established. This has been the case in the past for some MBS items established through the 3C determination process for interim MBS funding that were based on MSAC advice.

# OVERVIEW OF NEW PROCESSES

## Stage : Pre-lodgement

Prior to applicants submitting a request for eligibility consideration the Department holds a pre-lodgement meeting with them. Representatives from relevant areas of the Department (including other advisory committee secretariats) also attend. This ensures the applicant is aware of the process, the likely pathway and evidence expectations.

## Stage : Eligibility

MSAC eligibility criteria may vary depending on final requirements for fit-for-purpose pathways and approaches. This stage involves consideration by the Department to determine eligibility for a fit for purpose pathway and where required, protocol development. The principal eligibility criterion will remain whether the proposed service constitutes a clinically relevant professional service within the meaning of the *Health Insurance Act 1973*. Any need for submission to the Therapeutic Goods Administration (TGA) will also be confirmed at this stage. The Department will determine if all fit for purpose pathway requirements have been met and agree the pathway under which the application will be progressed.

## Stage : PASC Protocol development

Where indicated in a pathway, this stage requires the Protocol Advisory Subcommittee (PASC) to further develop decision analytic and resource usage templates submitted by the applicant. The PASC will undertake consultation with craft groups, the public and clinical experts. At the end of this stage the applicant and department and MSAC Executive will have an agreed protocol to undertake a systematic review of the evidence and generate an economic evaluation/model.

## Stage : Assessment – PASC protocol based

The agreed PASC protocol will be the basis for the applicant developing an assessment of the evidence for formal lodgement. The PASC protocol stage will be required for proposals for public funding and for submission based applications. With submission based application the applicant funds the review of evidence whereas in the case where a proposal for public funding is the agreed pathway, the department contracts an assessment group to undertake development of the assessment report. Reports must meet the requirements of an agreed template which will be the same for both submission based and for contracted assessment reports.

## Stage : LODGEMENT

## Evaluation - ESC

For submission based reports the department will commission a critique of evidence. In the case of a departmentally contracted report the applicant will be invited to comment, and that comment will be provided to MSAC. Following submission of protocol based review of existing evidence the report is provided to the MSAC Evaluation Subcommittee (ESC) which considers the report, critique or applicant comments. ESC's role is to review the report and comments against a pre-determined template for identifying the gaps and levels on uncertainty in the evidence and summarising issues mapped against the range of options MSAC routinely considers in formulating advice on public funding.

## Stage : MSAC Appraisal

In formulating its advice MSAC considers a wide range of information, including the report assessing the evidence, the critique of the report, ESC report on the evidence, any feedback on the report provided by the applicant and/or other relevant parties, as well as drawing on the individual expertise of MSAC members.

## Stage : MSAC Advice to Minister

MSAC prepares advice to the Minister on the circumstances under which public funding should be supported based on the strength of the evidence of safety, clinical effectiveness and cost-effectiveness of the new technology or procedure. Where current evidence is inconclusive, but MSAC considers the potential for health benefit to warrant Interim Funding MSAC may consider advising the Minister on interim funding.

## Stage : Minister/Government Decision

The Minister for Health and Ageing notes MSAC's advice and authorises the publication of the advice and the assessment report. The Minister, in acting on MSAC positive advice may direct the Department to conduct further consultation leading to policy and costing advice on which the Minister may make a fully informed decision in relation to public funding.

## Stage : Implementation

Once a Government decision has been made to provide public funding to a new service the Department is directed to implement the decision. Where public subsidy is related to a new item on the MBS the necessary changes are made to the Medicare Benefits Schedule that describe the service and the fee on which Medicare benefits will be based. The Department undertakes routine reporting to government on MBS costs to the health care system. In some instances the government may also direct that further reporting requirements be established. This has been the case in the past for some MBS items established through the 3C determination process for interim MBS funding based on MSAC advice.

## PROPOSED CHANGES

The new process is outlined below, with boxed comment on differences (if any) from the current approach. Details for each new proposal are provided in appendices to the paper

### Stage : Pre-lodgement

The main purpose is to provide the applicant with detailed information about the MSAC application process and potential pathways. This is usually undertaken via a face to face meeting or teleconference. This meeting must ensure the applicant can complete the application form with the required relevant and correct information. Any questions the applicant may have are also addressed at the meeting.

*This is essentially the same process but will now include representation from relevant secretariats and policy areas (and from the HTA Access Point for any nominated co-dependent applications that require advice from more than one advisory committee) to enable seamless management once the application has been provided with an agreed assessment pathway.*

*Pre-lodgement will now cover the period for PASC protocol development and the generation of a report. Lodgement will be defined as receipt of a PASC-informed assessment report that meets relevant requirements in the Guidelines.*

### Stage : Eligibility

An application to MSAC is eligible for assessment if it relates to a clinically relevant professional service as defined by the Health Insurance Act 1973 (a service that is generally accepted in the medical profession as necessary for the appropriate treatment of the patient).

Professional services that are covered by the MBS include diagnostic and imaging services, and surgical and medical procedures. Note that not all services related to health care are eligible for funding under Medicare.

The current MSAC application form requests applicant to provide evidence of clinical relevance, and attach a letter(s) from relevant college(s) or craft group(s) that represent(s) the appropriate section of the medical profession. The letter(s) should:

- describe the category of patients who would benefit from the service,
- certify that the service is generally accepted in the relevant profession as being necessary for the appropriate treatment of patients to whom it is rendered; and
- provide to MSAC names of relevant experts (who do not have a conflict of interest) who could provide expert advice to assist MSAC with any subsequent health technology assessment processes related to the application.

*This is essentially the same process but will now include input from relevant advisory committee secretariats and policy areas (and from the HTA Access Point for any co-dependent applications) to enable seamless management once the application has been provided with an agreed assessment pathway.*

*As well as evidence of clinical relevance and professional support, the MSAC secretariat will continue to seek policy and other relevant department advice prior to committing Commonwealth funds for evidence assessment.*

*Currently for MSAC timelines reporting, eligibility is the trigger for tracking time taken. In the new process to ensure equity in reporting, the trigger for tracking time-to-MSAC will be lodgment of the report generated as per an agreed PASC protocol. This will also assist in timing application advice for codependent technologies where more than one advisory committee is involved.*

## **Stage : Protocol development**

### **What is the role of PASC?**

To develop the question for public funding.

### **How will PASC undertake its role?**

By determining the question for public funding through a decision analytic and a table of resources for both the current and proposed clinical management algorithms.

### **Methods and process**

- identify the sensible decision options for MSAC to specify the likely question(s) for public funding
- develop the ensuing decision analyses
- portray these decision analyses as flowcharts to get wider input
- ensure adequate level of detail from the decision analyses on affected types of health care resources and on probabilities which are not determined by evidence relating to the proposed technology
- relate these outputs to the modelling questions faced by those compiling and assessing the evidence to address these decision options

### **Steps it takes to achieve it**

- Applicant protocol
- PASC examination
- Draft protocol for external comment
- Distillation and inclusion of public comment to protocol
- PASC deliberation
- Final protocol in the form of a decision analytic, a flow chart and a table of resources

*This step is a major change from current MSAC processes of seeking additional clinical and consumer input through the establishment of Advisory Panels.*

*The proposed changes are designed to improve the efficiency of the current process of establishing Advisory Panels to provide expert and consumer advice to inform the development of the research protocol for evidence collection. The changes include:*

*(a) improving consistency in approach across applications by having a standing committee rather than establishing panels on an ad-hoc basis*

*(b) facilitating access to subject matter expertise through an on-call list of interested subject matter experts available to attend 2 meetings at known dates to assist the PASC step compared to the current approach where panel members being asked to commit to a process where the duration number of meetings and dates are unknown. Consumer representation will be part of the standing committee membership*

*(c) reducing the number of instances where the research protocol and subsequent report development have been unnecessarily iterative because of the difficulty in sufficiently capturing broad and validated advice at the outset by seeking broader public comment*

*(d) transparently managing delineation between the role of the advisory panel in providing advice at the protocol development stage and the role of 'signing off' the subsequently generated assessment report by splitting the functions across PASC and ESC. This will also reduce the perception that panels could inadvertently influence interpretation of evidence prior to sign off*

*(e) revising documentation for current processes and report templates to address MSAC requirements for collection of and access to disaggregated resource use details to allow a range of funding options for MSAC consideration*

*(f) addressing the current mismatch between MSAC's decision options requirements and what is currently expected in the Executive Summary of assessment reports*

*(f) reviewing all Application Guidelines to be more applicant focused rather than evaluator focused. Addressing the lack of easily followed data and economic modeling guidelines and the subsequent inconsistency in evidence coverage in reports to allow MSAC to systematically consider the full*

range of funding options, and  
(g) ensuring that the assessment report itself, whether developed by an applicant or by a contracted assessment group will follow the same format to facilitate use by other HTA agencies, clinicians and consumers. The first step towards this has been the recognition that having MSAC advice in the report itself is inappropriate within an evidence assessment report. This has already been rectified by the introduction in 2009 of a separate MSAC Public Summary Document.

*In summary*

The previous AP role in drafting and agreeing a protocol prior to evidence review will be replaced by a standing sub committee (PASC) that may draw on particular additional clinical expertise as required on an ad hoc basis but whose core membership will allow development of protocol generation expertise and broader public participation prior to evidence review. All proposed protocols will be made available on the MSAC Website for comment and agreed PASC protocols will then be published on the Website as a process deliverable at this stage of the process.

It is expected that a proposed aggregate schedule fee range will be provided for comment at this stage. Disaggregated inputs will be part of the assessment report review process and subsequent economic evaluation. Specifics of the disaggregated fee inputs will only be available once the assessment report is agreed by the Minister to be made publicly available.

The intention of changes to this stage in the process is to increase the transparency, reduce any perception of possible conflict and increase the timeliness of this step by having a proposed protocol available for public comment with an agreed protocol to be made public within an agreed timeline.

This is seen as an essential component to allow submission based applications to address evidence review against an agreed protocol for that proposal thus reducing the risk of mismatch of evidence presentation and MSAC advice requirements based on a one size fits all approach as well as increasing the feasibility of management of timeliness for this step.

It both allows the development of a core group of subject matter experts with skills or interest in decision analytics as a tool for protocol development, and significantly increases the opportunity for participation by all relevant clinical, interest and consumer groups on a case by case basis.

The following diagram provides a comparison of the current Advisory Panel process to the proposed PASC process.

Comparison of Advisory Panel to proposed process for HTA

Current Advisory Panel	Proposed Process	
Advisory Panel (AP) with Assessment Group Preliminary meeting outlines research protocol	Applicant submits proposed protocol (includes items which reflect the AP's research and economic protocol)	
Assessment Group prepares draft research protocol	PASC reviews and modifies proposed protocol with ESC member and clinical expert involvement	
AP meeting with ESC member and clinical expert involvement confirms research protocol	PASC finalises draft protocol	
Applicant comment on research protocol	Draft protocol to web for external comment (public, applicant, expert(s), assessment group)	
	Close and collate all comments	
	PASC revise protocol with ESC member and clinical expert involvement including where accepted changes suggested by applicant, public, assessment group or expert(s)	
AP agree research protocol	PASC finalises protocol (includes research and economic)	
Assessment group prepare assessment report and prepare draft economic protocol including where relevant changes suggested by applicant	Assessment group prepares assessment report	Applicant lodges evidence
AP meeting agrees economic protocol		Assessment group or Department critiques submitted evidence against final protocol (includes economic and financial modelling)
Assessment group finalises assessment report		
Applicant comments on assessment report		
Assessment group provides rejoinder to applicant's comments		
AP accepts assessment report	Department accepts assessment report	Department accepts assessment critique
	Applicant comment on assessment report	Applicant comment on critique
	Assessment group provides rejoinder to applicant's comments	
ESC considers assessment report	ESC considers assessment report or critique of submission and resulting documents	
	Applicant comments on ESC report to MSAC and assessment group rejoinder	
<b>MSAC – Appraisal based on all previous documentation</b>		

## Stage : Assessment

### Assessment of international evidence within the Australian context

In undertaking HTA in Australia one of the complexities is interpreting cost effectiveness data within an Australian health care context. The current MSAC Economic Guidelines are due for review in 2010. The review will be informed by the reform activity currently being undertaken as well as by the new requirements for MSAC advice covering possible scope of MBS fee and item description. MSAC's economic modeling Working Group has undertaken extensive liaison within the Department to map the data requirements to ensure an appropriate level of detail to facilitate advice and any subsequent implementation of public funding. The proposal is to provide a spreadsheet available to applicants and contracted assessors to ensure consistency in approach and assumptions used for interpretation. The spreadsheet will be available on the MSAC website as part of the Application format. At different stages on the process figures will be required to be either aggregated or disaggregated depending on the process step and any agreed commercial-in-confidence requirements. For some applications to MSAC, particularly codependent technologies there will need to be consistency in assessment assumptions and costings. The approach to cost effectiveness and modeling will also need to be as consistent as possible.

*Essentially the same process in contracted generation of the review and assessment of the evidence will be followed as is currently the case once the Advisory Panel and the applicant have commented on and agreed the research protocol (in this case the PASC protocol).*

*The relevant systematic analysis skills currently being utilized by contracted assessments (and independently now by some applicants to MSAC) will continue to be required to produce an assessment report post an agreed protocol of the expected quality for MSAC's purposes.*

*To facilitate this step there will be an agreed MSAC report template, agreed MSAC Guidelines for evidence collation and economic evaluation (including worksheets with associated assumptions for economic modeling) that will be used by contractors for the Department and for applicants submitting a systematic review of the current evidence against the agreed PASC protocol.*

*The assessment report will be generated generally by HTA systematic review specialist contractors and will feed into an agreed Report Executive Summary that will better reflect MSAC's decision requirements in their use of the summarized evidence.*

*The main difference will be that once the PASC protocol is agreed then the previous role of the Advisory Panel in advising on interpretation of the evidence will no longer apply. The PASC process will stop once the protocol has been generated. Any subsequent clinical advice on interpretation is expected to be mainly related to clarification that the clinical setting is being interpreted correctly by the contractors.*

*MSAC is proposing that economic advice at the pre assessment (PASC) step will be provided by a nominated member of the MSAC ESC to PASC, and that at the post assessment (ESC) evaluation step a nominated PASC member will be available to ESC.*

*This process should increase the certainty that the effort put into reporting the evidence will be aligned to MSAC's needs. In addition it should also reduce the risk of unnecessary iteration and delay associated with commencing the report prior to final agreement by MSAC Executive of the PASC protocol.*

*The duration between PASC agreement and Lodgement of an application will be dependent on how long an applicant (in the case of submission based applications) or a contracted assessment takes to assemble the evidence for the agreed protocol. It is anticipated that submission based applications will in general take less time to have their already collected evidence assembled against the agreed PASC protocol than it would take a contracted assessment to commence from scratch. It may also become necessary to reduce the priority given to some MSAC applications that require a contracted assessment.*

## LODGEMENT OF EVIDENCE

*For formal reporting purposes this will now signal commencement of MSAC consideration of the evidence for the question for public funding.*

*Where possible MSAC will align its dates for lodgement with that of PBAC to facilitate concurrent codependent drug test assessment and will facilitate, where possible, alignment of codependent service device assessment that require advice from MSAC and the Prostheses List Advisory Committee (PLAC) a role previously undertaken by the PDC.*

*Codependent applications will be managed through a single access point to ensure that all relevant committees and secretariats are appropriately engaged.*

### **Stage : Evaluation**

#### **What ESC does**

Assess the evidence which addresses the question for public funding.

#### **How it does it**

By evaluating the weight, uncertainty, strength, and sensitivity of supplied evidence

#### **Steps it takes to achieve it**

- Evaluation of the evidence in the Assessment report
- Response to report by applicant
- Response by Assessment group to applicants comments
- ESC member discussant summary
- Summation of the areas of uncertainty remaining
- **Options for MSAC based on the areas of uncertainty**

**Applicants are able to comment on ESC documentation.**

**Report, and or applicant comment or critique, ESC summary document and the applicant comment on the ESC summary are made available to MSAC.**

*MSAC has recently expanded the terms of reference for its previous Economics Sub Committee to include a broader evaluation role as the MSAC Evaluation Sub Committee (MSAC ESC).*

*The new role for this committee will be to evaluate assessment reports and independent critiques of, or applicant comment on, reports. It will do so in order to provide comment to MSAC on any issues that may arise and the significance of those issues.*

*It will not have a role in providing options to MSAC for consideration but will advise of any issues that MSAC may need to consider when it addresses the range of public funding options available to it. ESC's summary of potential issues related to areas of remaining uncertainty will be made available to MSAC in written form and to applicants for comment directly to MSAC. The format will address the full range of funding options advice available to MSAC. The ESC approach will allow 'balance' at this step through the use of critiques of applicant generated reports and the parallel applicant comment on contracted reports.*

*Applicant comment on the critique of their report and the contractors comment on the applicant response to the contracted report will be provided separately and directly to MSAC.*

*ESC will continue to have an evaluation role in relation to overall review of MSAC process documentation and guidelines.*

## Stage : MSAC Appraisal

### **MSAC develops advice on under what circumstances public funding should be supported.**

Advice is developed by discussion among the expert members appointed to MSAC and take into account the following:

- Support for public funding is not conditional on finding ‘strong’ evidence but is based on strength of evidence
- Advice describes the ‘circumstances’ under which public funding is supported (or not) including advice on an item descriptor and fee
- Lack of evidence of effectiveness does not imply ineffectiveness

## Stage : MSAC Advice to the Minister

### **Full Funding with evidence**

MSAC may wish to consider the establishment of MBS item descriptors for the assessed technology with adequate evidence on clinical effectiveness, cost effectiveness and safety.

### **Full Funding with limited evidence**

MSAC may wish to consider the establishment of MBS item descriptors for the assessed technology with limited evidence on clinical effectiveness, cost effectiveness and safety.

### **Full funding requiring monitoring**

MSAC may wish to consider the establishment of MBS item descriptors, but with an accompanying request that the Department should monitor utilisation (as set out previously) and report back to MSAC on trends after 12-18 months of listing

### **Interim funding**

If MSAC proposes interim funding, MSAC must demonstrate how the technology meets the interim funding criteria, and what specific research questions should be addressed.

#### Primary criteria for Interim Funding

- Significant clinical need for the proposed service — is it likely to have a major effect on the morbidity and/or mortality of the disease treated?
- Some evidence of effectiveness, at least in the short term;
- Adequate evidence of safety, at least in the short to medium term; and
- Cost-effectiveness — is the new service likely to be as effective as, but less costly than, the comparator service, or more effective at a cost proportional to its increased effectiveness?

#### Secondary criteria for Interim Funding

- Potential for further studies to reduce uncertainty and to obtain relevant answers.
- Cost–benefit of conducting the study in relation to the value of the answer (in terms of likely utilisation under Medicare).
- Lack of information elsewhere (eg from overseas studies).
- Lack of alternative funding sources (eg commercial sponsors).

### **The circumstances for public funding**

MSAC may, where appropriate provide advice to the Minister proposing public reimbursement other than through the MBS.

MSAC may provide advice related to evidence identified during assessment and appraisal that it considers may need further review. This may include advice related to current MBS items where evidence may differ from accepted clinical practice, comment on the comparator items used in assessments or any other relevant matters.

#### *HTA Review recommendations specific to MSAC include:*

- *the use of a critique of submitted evidence as a pathway for MSAC advice*
- *a robust approach to data collection for interim funding*
- *addressing the scope for a MBS fee and descriptor in MSAC advice*

- *streamlining the process for seeking advice*
- *consideration of impact risk*
- *new approaches to concurrent assessment, and codependent and hybrid technologies*
- *new reporting requirements*
- *rigorous consideration of evidence consistently applied and with a view to sustainability*
- *processes to be guided by the principles and vision in the review report.*

*MSAC is aiming for increased certainty in assessment approaches and timelines and the discussion paper outlines MSAC's proposed approach to these recommendations.*

*To implement these changes MSAC is proposing establishment of new standing Sub Committees. The following proposals and governance arrangements are provided for comment.*

## **PROPOSED CHANGES TO MSAC SUBCOMMITTEES TO FACILITATE IMPLEMENTATION**

Formal mechanisms will be an important part of ensuring that recommendations of the HTA Review are successfully implemented. The arrangements will need to be flexible, to allow for the range of advice potentially required in relation to MSAC process and to incorporate any review and adjustments as the processes are bedded down. The proposed structures outlined below are aimed at facilitating the changes to MSAC processes. A change in scope to one existing sub committee and three additional new sub committees and being proposed, these are:

- MSAC Evaluation Subcommittee (ESC) - expanded role from economics to include evaluation of the suitability of evidence pre MSAC
- MSAC Protocol Advisory Subcommittee (PASC) to replace in part the previous role of Advisory Panels with the 'sign off' aspect being undertaken by ESC

Each committee will consist of an appropriate range of stakeholders. Members will contribute to developing and refining each component of the MSAC appraisal. This will ensure a comprehensive and effective streamline approach to managing the consideration of an application by MSAC can be conducted in a timely manner.

MSAC is able to establish sub committees and ad hoc working groups as it sees fit to support its functions. As this discussion paper indicates, a number of new subcommittees are likely to be established for commencement in 2011 and MSAC will review the requirement for additional committee support as new processes are implemented.

The MSAC appraisal process often leads to advice for inclusion of new technologies and procedures onto the MBS which then facilitates the rebate arrangements for patients. As such, consumers have a significant role to play in new MSAC processes and providing advice on specific consumer concerns with those processes. The creation of new subcommittees and structures provides the opportunity to explore constructive and broad consumer involvement. To help ensure consumer perspectives are actively considered, a consumer representative will be included in membership of each subcommittee.

### ***Expectations of MSAC subcommittees***

Committee members on all committees will be expected to:

- attend meetings whenever possible;
- participate fully in all committee work and provide technical input where relevant;
- actively play a role in reaching consensus on the item/s;
- be impartial and broadly represent Government interests;

- declare any vested or financial interests in the subject matter;
- be prepared to provide when casting a vote, clearly express technical and scientific reasoning; and
- work towards alignment with existing international evidence, wherever practical and relevant.

## **CALL FOR NOMINATIONS FOR PASC SUBCOMMITTEE**

### **PASC** (see Attachment 1)

The Department, on behalf of MSAC, is seeking suggestions from stakeholders for particular groups or individuals who would be suitable to participate on these committees. When considering suggestions for any of the committees, the following should be taken into consideration:

- the committees will require consistent representation for the period of the initiative;
- members will be appointed to the subcommittee only for their expertise and not as representatives of a particular organisation;
- members of subcommittees must have a background in evidence-based medicine, clinical medicine, health economic evaluations or consumer matters; and
- members must be:
  - conversant with relevant technical matters pertaining to a particular committee;
  - able to effectively represent the views of a particular area of expertise; and
  - be able to competently and actively participate in committee meetings and contribute to the development and implementation of the subcommittee.

All committee members will be required to adhere to agreed levels of confidentiality in relation to meeting discussions and declare any Conflicts of Interest on a meeting by meeting basis.

Subcommittees are expected to meet face to face 4-6 times per year. Members of subcommittees may have responsibility for overview on an application basis. Members may be eligible to be paid a sitting fee and have their incidental expenditure and travel arranged and paid for by the Department.

Suggestions or nominations can be emailed with “nomination for PASC” in the subject line to [msac.secretariat@health.gov.au](mailto:msac.secretariat@health.gov.au).

Email nomination to include

- name;
- contact details;
- evidence of nominee’s agreement to the nomination;
- the relevant advisory committee to participate on; and
- evidence to support nomination for a particular committee, for example their curriculum vitae.

## PROTOCOL ADVISORY SUBCOMMITTEE (PASC)

### Terms of Reference

#### **Purpose:**

The Protocol Advisory Sub-committee (PASC) is a standing sub-committee of MSAC with membership to include decision analysis, health economics, epidemiology, public health, consumer and clinical expertise. Its focus is on the task of determining Decision Analytic Protocols – that is, defining the decision option(s) or question(s) for public funding of a proposed new medical technologies and procedures prior to final lodgement of an application for its consideration by MSAC.

#### **Roles and functions:**

1. To describe in detail a limited set of decision option(s) for MSAC associated with the possible public funding of a proposed new medical technologies and procedures through the development of a Decision Analytic Protocol
2. To ensure stakeholders from the health profession, industry and the community have an opportunity to provide input into the construction of each set of decision option(s)
3. To ensure that each Decision Analytic Protocol accurately captures current clinical practice and reasonably reflects likely future practice with the proposed new medical technologies and procedures
4. To ensure that each Decision Analytic Protocol adequately describes all potentially impacted healthcare resources
5. To provide advice on the development and appropriateness of MSAC guidelines and associated documents in relation to developing decision options for applications
6. To provide advice on related aspects of broader MSAC issues particularly with respect to the development of decision analysis as requested by MSAC, the MSAC Executive or the Department
7. To create working groups as necessary to perform its roles and function.

#### **Composition:**

Members of PASC are appointed by the MSAC Executive according to a membership composition defined by MSAC.

- The Chair of PASC should be a member of MSAC and the MSAC Executive.
- Other members of PASC may or may not be members of MSAC.
- Where feasible, and as agreed by MSAC Executive, a PASC member may also be appointed as a member of another MSAC sub-committee.
- There are two types of PASC membership (a) a core membership expected to attend as many PASC meetings as possible and (b) an extended membership encompassing a wider range of clinical experts, each of whom is expected to attend a PASC meeting where an application relevant to the member's expertise is being considered.
- An additional member may be co-opted as necessary to inform PASC consideration of an application which requires input of clinical expertise from beyond the core and extended membership.

#### **Meeting schedule:**

PASC business may be conducted via teleconference/video conference and face-to-face where/when required. Where necessary, business may also be conducted out of session, usually via email. PASC meets face-to-face according to a timetable published at least 12 months<sup>†</sup> in advance in a cycle determined by scheduled opportunities for the public and other stakeholders to provide input on draft protocols and at other times as determined by the PASC Chair.

<sup>†</sup> Timetable published annually but may not be 12 month in advance during the implementation period of 2011/2012

### EVALUATION SUBCOMMITTEE (ESC)

#### Terms of Reference

##### **Purpose:**

The Evaluation Sub-committee (ESC) is a standing sub-committee of MSAC with membership to include health economics, epidemiology, public health, consumer and clinical expertise. Its focus is to provide advice on the quality, validity and relevance of internal and external assessments for applications being considered by MSAC.

##### **Roles and function:**

1. To review the evidence, expert opinion and assumptions integrated in the clinical comparisons, economic evaluations and financial analyses in each assessment for an application to be considered by MSAC
2. To ensure that the economic evaluations and financial/budgetary analyses in an assessment are presented from a healthcare system perspective, with disaggregation to the perspective of individual payers in the healthcare system (e.g. Commonwealth Government, state and territory governments, consumers, private health insurance)
3. To summarise and provide advice as necessary on draft item descriptors and fees for the subject of an application (full and disaggregated)
4. To advise MSAC on each review of an application, by summarising the essential facts, identifying any important issues to be considered by MSAC, including equity of access issues, and advising on their applicability for MSAC's advice in response to the application
5. To provide advice on the development and appropriateness of MSAC guidelines and associated documents in relation to evaluating assessments
6. To provide advice on broader aspects of MSAC issues particularly with respect to evaluation of clinical, economic and financial evidence as requested by MSAC, the MSAC Executive or the Department
7. To create working groups as necessary to perform its roles and function.

##### **Composition:**

- Members of ESC are appointed by the MSAC Executive according to a membership composition defined by MSAC.
- The Chair of ESC should be a member of MSAC and the MSAC Executive.
- Other members of ESC may or may not be members of MSAC.
- Where feasible, and as agreed by MSAC Executive, an ESC member may also be appointed as a member of another MSAC sub-committee.

##### **Meeting schedule:**

ESC business may be conducted via teleconference/video conference and face-to-face where/when required. Where necessary, business may also be conducted out of session, usually via email.

ESC meets face-to-face seven weeks before each MSAC meeting according to a timetable published at least 12 months<sup>†</sup> in advance and at other times as determined by the ESC Chair.

<sup>†</sup> Timetable will be published annually but may not be 12 months in advance during the implementation period of 2011-12

### SUBMISSION BASED APPLICATION/ASSESSMENT (SBA)

All applications to MSAC will need to go through the PASC step to ensure that the question for public reimbursement is adequately addressed from the commencement of the process. This will ensure the evidence collected and assessed is relevant to MSAC's advice for public funding.

PASC agreed protocols will be published on the MSAC website.

Post the PASC step there are a series of options for applicants that will require formal advice, within an agreed period, from the applicant as to the option being pursued.

- Option 1: applicant continues a Submission Based Assessment after protocol development.
- Option 2: applicant continues a contracted assessment after protocol development (noting the timing of assessment will be dependent of relative priority and resources available).
- Option 3: submission based applicants may choose to opt out at this stage, in which case the PASC agreed protocol may be used by other applicants as the basis for a submission based approach or by MSAC for a contracted assessment. (noting the timing of assessment will be dependent of relative priority and resources available).

PASC protocols will remain valid for an advised period unless other significant evidence is published that would impact on the basis of the protocol.

### CO-DEPENDENT APPLICATION/ASSESSMENT

Codependent applications particularly for applications seeking advice from both MSAC and PBAC are considered to be submission based. Post the PASC step, applicants seeking co-dependent reimbursements advice will be encouraged to lodge with both PBAC and MSAC at the same time. MSAC meeting dates will be scheduled to facilitate coordination of advice from the two advisory committees. MSAC will endeavor to provide a critique of the evidence for the associated test/service requiring MBS reimbursement within the time frame for PBAC advice. A similar approach will be considered for codependents devices/services item applications that require advice from both MSAC and PLAC.

Where a co-dependent application is to be lodged the pre-lodgement process will be coordinated through the HTA Health Technology Taskforce who will also manage the coordination of advice at completion of the process.

The following steps will apply to the MSAC assessment component of a co-dependent application that seeks MSAC advice on public reimbursement for a co-dependent MBS listing either in relation to co-dependent advice sought through the PBAC or co-dependent advice through the Prostheses List Advisory Committee.

**The following lists each step in the submission based pathway to MSAC advice on public reimbursement.**

## **Steps in the Application Process for a Submission Based Assessment (SBA)**

### **Optional pre-lodgement opportunity preceding an application**

Informal meeting(s) *with applicant* and MSAC Secretariat, Medical Officer, implementation area and other policy area(s) as relevant to ascertain the basis for potential submission.

### **Eligibility phase**

1. *Applicant submits eligibility documentation*
2. MSAC Secretariat consideration of eligibility
3. Medical Officer, implementation area and/or policy area comments on eligibility documentation
4. Clarification sought from applicant or referring area by MSAC Secretariat if necessary on any area of the eligibility documentation
5. Formal/mandatory meeting *with applicant* and MSAC Secretariat, Medical Officer, implementation area and other policy area(s) as relevant to ensure that the applicant is aware of the requirements for PASC. (May be waived with the agreement of the MSAC secretariat if a pre-lodgement meeting is considered satisfactory)
6. Applicant notified of eligibility

### **PASC Protocol Development phase**

7. *Applicant submits proposed protocol.* Secretariat checks suitable to proceed to PASC.
8. DOHA contracts review of proposed analytic, protocol and healthcare resources table(s)
9. PASC review draft protocol with ESC member involvement
10. Call for public comment on reviewed draft protocol
11. Final protocol developed by PASC with ESC member involvement taking into consideration public comments
12. PASC seeks MSAC Executive endorsement on the PASC Protocol, its development documentation, suitability for future lodgement (based on MSAC eligibility requirements), and advice on the level of assessment required. MSAC Executive's endorsement of suitability to progress to lodgement and level of assessment required, along with the final protocol, will be provided to the applicant by the Secretariat.
13. Applicant agrees to the final protocol, suggested level of assessment (assessment report or abbreviated evidence requirement) and agrees to lodge a submission. A time limit will apply to this step. NOTE: the applicant may opt out of a submission based approach at this stage or seek further comment from PASC through the MSAC Executive. At the completion of this step the final protocol will be made available on the MSAC Website whether the applicant continues or opts out. If the applicant opts out the agreed PASC Protocol would then be available either for another applicant to use for a submission based approach or for contracted assessment.

### **Assessment**

14. *Applicant submits evidence to address agreed protocol (Submission)*
15. Medical Officer, implementation area and policy area comments on Submission
16. Clarification sought from applicant if necessary on any area of the application
17. DOHA contracted critique of submission conducted (SBA Critique). Where possible this would be the same groups contracted at Step 8.
18. *Applicant response to SBA critique*

### **ESC's Evaluation**

19. Evaluation of Submission and SBA critique by ESC with PASC member involvement (ESC Report to MSAC)
20. *Opportunity for applicant to comment on ESC Report to MSAC and SBA Critique (Applicant Comment)*

### **MSAC Appraisal and Advice to Minister**

21. MSAC appraisal of Submission, SBA Critique, ESC Report to MSAC, and applicant's comments on ESC Report to MSAC & SBA Critique
22. MSAC advice to Minister on submission including suitability for funding and suggestion of MBS item descriptor and fee if relevant

### **Minister's Decision on MSAC advice**

23. Noting of MSAC advice
24. *Applicant notified of Minister's noting of MSAC advice and MSAC Public Summary Document of facts and rationale behind decision*
25. Implementation and policy areas notified of Minister's noting of MSAC advice and MSAC Public Summary Document of facts rationale behind decision
26. Public dissemination of MSAC Advice, Submission, SBA Critique, ESC Report to MSAC and MSAC Public Summary Document of facts and rationale behind decision

### **Post MSAC Implementation**

27. Implementation area and policy area progress work including negotiation with DoFD for MBS item listing, if relevant

### **CONTRACTED ASSESSMENT (CA)**

MSAC will continue to offer contracted assessment as an alternative to submission based applications, noting that relative priority may influence when these are conducted. The following steps will apply.

#### **Steps in the Application Process for a Contracted Assessment (CA)**

##### **Optional pre-lodgement opportunity preceding an application**

Informal meeting(s) *with applicant or referring area* and MSAC Secretariat, Medical Officer, implementation area and other policy area(s) as relevant to ascertain the basis for potential submission

##### **Eligibility phase**

1. *Applicant or referring area submits eligibility documentation*
2. MSAC Secretariat consideration of eligibility
3. Medical Officer, implementation area and/or policy area comments on eligibility documentation
4. Clarification sought from applicant by MSAC Secretariat if necessary on any area of the eligibility documentation
5. Formal/mandatory meeting *with applicant* and MSAC Secretariat, Medical Officer, implementation area and other policy area(s) as relevant (May be waived with the agreement of the MSAC secretariat if a pre-lodgement meeting if considered satisfactory).
6. Applicant or referring area notified of eligibility

##### **PASC Protocol Development phase**

7. *Applicant submits proposed protocol*
8. DOHA contracts Assessment group for review of proposed analytic, protocol and healthcare resources table(s)
9. PASC review draft protocol with ESC member involvement
10. Call for public comment on reviewed draft protocol
11. Final protocol developed by PASC with ESC member involvement taking into consideration public comments
12. PASC seeks MSAC Executive endorsement on the PASC Protocol, its development documentation, suitability for future lodgement (based on MSAC eligibility requirements), and advice on the level of assessment required. MSAC Executive's endorsement of suitability to progress to lodgement and level of assessment required, along with the final protocol, will be provided to the applicant by the Secretariat.
13. Final protocol given to applicant. Contracted assessment agreed to be the only option available to progress the application. (This may be the fall back position if an applicant for submission based assessment opts out at this step). A time limit will apply to this step. NOTE: At the completion of this step the final protocol will be made available on the MSAC Website and would then be available for another applicant to use for a submission based approach if the application has not been prioritised for contracted assessment..

## **Assessment**

14. DOHA contracted Assessment Group to submit the evidence as Contracted Assessment Report or as an abbreviated assessment as advised by PASC and agreed by MSAC Executive. Where possible this will be the same group contracted at step 8.
15. **Original applicant** or referring area contacted for comment on Contracted Assessment (Applicant Comment on the Contracted Assessment)
16. Assessment group reply to applicant(s) or referring area's comment on Contracted Assessment (Assessment Group Rejoinder)
17. Medical Officer, implementation area and policy area comments on Contracted Assessment

## **ESC's Evaluation**

18. Evaluation of Contracted Assessment, comments by applicants or referring area and reply by assessment group by ESC with PASC member involvement (ESC Report to the MSAC)
19. **Opportunity for applicant** or referring area to comment on ESC Report to the MSAC (Applicant Comment on ESC Report to MSAC)

## **MSAC Appraisal and Advice to Minister**

20. MSAC appraisal of Contracted Assessment, ESC Report to the MSAC, Applicant Comment on ESC Report to MSAC & Applicant Comment on the Contracted Assessment and Assessment Group Rejoinder
21. MSAC advice to Minister on Contracted Assessment including suitability for funding and suggestion of MBS item descriptor and fee if relevant

## **Minister's Decision on MSAC advice**

22. Noting of MSAC advice
23. Applicant notified of Minister's noting of MSAC advice and MSAC Public Summary Document of facts and rationale behind decision
24. Implementation area notified of Minister's noting of MSAC advice and MSAC Public Summary Document of facts and rationale behind decision
25. Public dissemination of MSAC Advice, Contracted Assessment, ESC Report to the MSAC and MSAC Public Summary Document of facts and rationale behind decision

## **Post MSAC Implementation**

26. Implementation area and policy area progress work including negotiation with DoFD for MBS item listing, if relevant

## **ABBREVIATED ASSESSMENT**

In some instances the PASC agreed protocol may not necessarily require the extensive collation of evidence normally expected for either a submission based or contracted assessment report. Post PASC it may be clear that, especially for previously unsuccessful applications coming back to MSAC or for MSAC consideration of an amendment to an existing MBS items to include new indications or new technologies that the evidence needed may be more targeted than that for an application in an area not yet considered by MSAC. In these cases MSAC Executive agreement to an abbreviated assessment approach would be sought.

Abbreviated assessments may only be undertaken post PASC advice and MSAC Executive endorsement. The evidence may be submitted by the applicant or contracted, and will progress to

the usual Assessment and ESC evaluation steps. The steps that would be required for an abbreviated approach would be as consistent as possible with the normal pathway to MSAC advice on public funding. All applications would go through the PASC Step and the ESC step.

For some agreed abbreviated assessments, ESC advice may be provided directly to the MSAC Executive.

### **MSAC Executive Appraisal and Advice to Minister**

1. MSAC Executive appraisal will include the Abbreviated Assessment, the ESC Report to MSAC, Applicant Comment on the Abbreviated Assessment, Assessment Group Rejoinder and Applicant Comment on the ESC report as well as any relevant comment and policy advice on the Abbreviated Assessment provided by the Principal Medical Officer, implementation areas and policy areas of the Department.
2. MSAC Executive under its Terms of Reference will prepare advice to Minister on Abbreviated Assessment including suitability for funding and suggestion of MBS item descriptor and fee if relevant.
3. In exceptional circumstances, MSAC Executive may a Abbreviated application to the next meeting of MSAC for a formal decision.

### **Minister's Decision on MSAC Executive advice**

4. Noting of MSAC Executive advice
5. Referring area notified of Minister's noting of MSAC Executive advice and MSAC Public Summary Document of facts rationale behind decision
6. Implementation area notified of Minister's noting of MSAC Executive advice and MSAC Public Summary Document of facts and rationale behind decision
7. Public dissemination of MSAC Executive Advice, Abbreviated Assessment, ESC Report to MSAC and MSAC Public Summary document of facts and rationale behind decision

### **Post MSAC Implementation**

8. Implementation area and policy area progress work including negotiation with DoFD for MBS item listing, if relevant

### STAKEHOLDER INPUT

The dedicated website to support the MSAC, <http://www.msac.gov.au> will provide a central source for changes and access for stakeholders.

A range of information will be available through the website about the reviews, including:

- list of applications that are in progress;
- draft protocols;
- final assessment reports; and
- Public summary document

In addition, a website portal is being developed to provide a mechanism for stakeholders to nominate review topics, having regard to the proposed prioritising criteria.

Stakeholders can provide input or raise issues about applications through the MSAC website ([www.msac.gov.au](http://www.msac.gov.au))

Stakeholders will have a range of opportunities for specific input and involvement in the review process including:

#### *Opportunities for Applicant Input*

Applicants will have to opportunity to have input into their submission at the following stages of the consideration process

1. Pre-lodgement Eligibility
2. Draft protocol development
3. Application lodgement
4. Comment on ESC evaluation of submission and critique of submission ( In the case of an SBA)
5. Comment on the draft assessment report or Abbreviated Report

#### *Opportunities for Consumer Input*

Consumers will have to opportunity to have input into their submission at the following stages of the consideration process:

1. As Consumers' Health Forum representative on each subcommittee
2. On the draft protocol as disseminated through the MSAC website
3. Direct to the MSAC secretariat on notification 6 weeks out from an MSAC appraisal of the intent to consider and application

### REVIEW OF HEALTH TECHNOLOGY ASSESSMENT (HTA REVIEW)

On 27 February 2010, the Minister for Health and Ageing, Nicola Roxon, and the Minister for Finance and Deregulation, Lindsay Tanner, released the report on the Review of Health Technology Assessment (HTA Review). The report recommended improvements to the way new health products, procedures and services are assessed for public funding, in line with international best practice.

The report on the HTA Review can be found at: <http://www.health.gov.au/htareview>

## DEFINITIONS

1. *Cost* of MBS items (as distinct from specific costs discussed in the fee section of the paper) is a broad term that encompasses but is not exclusive to:

- the rebate cost of the item for Government;
- the amount spent by the Government on the item per episode of service (including safety net costs); and
- the amount spent by the Government over a forward estimates period.

*Schedule fee* means the amount the Government considers appropriate as a recommended fee for an MBS item. Rebates are paid to patients receiving the service described in an MBS item at a proportion (75%, 85% or 100%) of the Schedule fee. A Schedule fee does not determine the amount a health professional can charge for providing the service.

### Methods of ESC deliberations

#### Cost Effectiveness

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.

#### Cost Benefit

An economic evaluation that compares therapy involving the proposed drug with therapy involving its main comparator(s) in which both costs and benefits are measured in monetary terms to compute a net monetary gain/loss or benefit gain/loss.

#### Cost Minimisation

A type of economic analysis that compares health care services that have a common health outcome, to find the least costly one. Used when the proposed service has been shown to be no worse than the comparator.

#### Cost Utility

A type of economic analysis that compares health care services that have a common health outcome in which costs are measured in monetary terms and outcomes are measured in terms of extension of life and the utility value of that extension (eg quality-adjusted life years).

## QUESTIONS FOR CONSIDERATION

1. Did you find the discussion paper useful?
2. Were the principles of the proposed MSAC processes clear and understandable?
3. Is there any terminology that needs further exploration or explanation?
4. Are there any concepts that need further exploration or explanation?
5. Would any of the approaches or strategies outlined in the discussion paper be particularly suitable or unsuitable for you or your organisation?
6. Are there additional significant Australian or international initiatives or strategies that need to be highlighted in the discussion paper?
7. Are there barriers to implementing the proposed processes in the Australian context that need to be explored in the discussion paper?
8. How do the contents of the discussion paper apply to your organisation?

### Future directions

9. Are there any areas that you believe you or your organisation could support MSAC proposals?
10. How does MSAC promote greater consumer and stakeholder input? Who needs to be involved?
11. Is there more work that needs to be done in the HTA field, specific to the Australian context?
12. What type of tools or support would you need to improve your participation in MSAC processes?
13. Are there activities, frameworks, strategies or protocols that could be provided that would help?

*Submissions do not have to address these questions and may respond to other issues raised in the discussion paper.*