A. Focus of the Roundtable

The Health Technology Assessment of Medical Devices Roundtable (HTA Roundtable) was held in Sydney on Friday 9 June 2017.

The HTA Roundtable was attended by expert members of the Prosthesis List Advisory Committee (PLAC) and the Medical Services Advisory Committee (MSAC), and their subcommittees, and members of the Therapeutic Goods Administration (TGA) Advisory Committee on Medical Devices (ACMD).

The objectives of the Roundtable were to:

- identify opportunities to share information and clinical expertise in relation to Health Technology Assessments (HTAs):
  - to best utilise limited resources
  - reduce duplication of effort
  - streamline processes, and
- identify issues that would benefit from a cross-committee approach.

Roundtable participants were encouraged to use the HTA Roundtable as an opportunity to share ideas, learn about the roles of the various committees, and discuss areas of common interest, focusing on HTAs and particularly HTAs involving devices.

B. Context

Professor Terry Campbell (Chair of the PLAC) welcomed participants to the Roundtable and noted the initial impetus for the Roundtable (specifically, at a PLAC meeting in 2016, the PLAC requested that the Department of Health organise a roundtable to enable experts to come together to discuss the assessment of devices and opportunities for minimising duplication and aligning processes).

Tracey Duffy (Assistant Secretary of the Private Health Insurance Branch, Department of Health), noted a number of recent changes/developments in relation to HTA processes and committees including:

- that the PLAC was reconstituted in October 2016 with a new Chair and additional members
- the four components of the PLAC reform work plan, including:
  - reviewing the criteria for listing on the prostheses list
  - minimising duplication and improving the listing process
  - targeted category (device groupings) and benefit (pricing) reviews
  - establishing a longer-term benefit setting framework
- Departmental activities in parallel with the HTA activities, including:
  - reviewing processes to identify duplication and opportunities for streamlining
  - working with device sponsors comparing data submission requirements across the three assessment processes (PLAC, MSAC, TGA)
  - compiling evidence requirements across assessment processes
  - establishing a regulation and reimbursement senior executive group
  - working with Departmental IT divisions on possible IT solutions for the future
developing more streamlined processes between Secretariats in relation to management of medical device applications, and
examining how to best make use of existing clinical expertise across all committees and HTA processes.

Ms Duffy also noted the relevance of the Industry Working Group recommendations of 2016 which support the HTA Roundtable, including that:
• HTA expertise should be utilised as appropriate for cost effectiveness assessment, and
• the Government should consider opportunities for enhanced cooperation between the PLAC and TGA to ensure that activities are not inappropriately duplicated.

C. Office of Health Technology Assessment

Andrew Stuart (Deputy Secretary, Health Benefits Group, Department of Health) explained some of the key changes being made within the Department, and the Department’s vision for improved HTA processes, including for medical devices.

Mr Stuart discussed the establishment of the Office of Health Technology Assessment within the Department which:
• combines the secretariats of the various HTA committees into one Office
• provides a single-entry point for applications
• enables work to be more effectively undertaken on co-dependent technologies
• will include an HTA policy unit which would enable time and resources to be focused on policy issues relating to HTAs
• will be advised by a Committee of Chairs (comprising the Chairs of MSAC, PLAC, PBAC and ACMD) that will meet regularly to discuss and resolve cross-committee issues.

Mr Stuart emphasised that the Office of Health Technology Assessment was not intended to reduce resources, nor change the application cycle for sponsors, but instead to enable strengthened focus on improving systems and processes for application management, and addressing both emerging and long standing policy issues.

D. Strengths and limitations of HTA processes

Throughout the HTA Roundtable, participants discussed the strengths and limitations/challenges of the existing system of HTAs.

Some of the key strengths included:
• the strength of the clinical assessments undertaken, and
• the role played by Clinical Advisory Groups (CAGs).

Some of the challenges identified included:
• that many of the new technologies are innovative and hybrid (or designed for small populations with modest evidence to support their efficacy) posing assessment challenges
• the process for removing devices from the Prostheses List in the event that they are poorer performing or no longer cost effective
• the limitations of post-marketing monitoring and surveillance to review efficiency and cost effectiveness of listed devices
• impact of international changes and reduced scrutiny of some devices overseas
• some misunderstanding within the sector about the difference between Australian Register of Therapeutic Goods (ARTG) listing and the availability of devices in public and private hospitals (noting that a device may be TGA approved and have an ARTG listing
but if the device is not on the Prostheses List, private health insurers are not mandated to reimburse for it

• that there is rigidity in both assessment systems and approval processes, with committees working in silos and not always cross referencing information
• the artificial boundaries between HTA processes where such boundaries do not support better assessment of either safety or cost effectiveness, and
• indication creep (use of a therapy/device in an untested or poorly defined population to determine its benefit).

E. Outcomes sought

Noting the strengths and limitations/challenges posed by the existing systems, participants discussed the outcomes sought through potential improvements to existing HTA processes. It was generally agreed that improvements would be desirable in the following areas:

• applications – It was noted that some applications include irrelevant information or do not include necessary or focused information, thereby drawing unnecessarily on the resources of the Department and its experts. Many of the suggestions (detailed below) focused on improving the quality of applications and enabling the rejection of inadequate applications;
• reducing duplication of assessment and greater co-ordination of effort – Various examples were given whereby different committees or experts provide advice on the same or similar matters. Examples were also given of circumstances in which it would be desirable to have the clinical input of CAG members into other committees or processes such as TGA (including ACMD) and MSAC processes. As one participant described, the optimal approach to clinical assessments – we need to ‘do it once, do it properly’;
• harmonising TGA/PLAC/MSAC assessment processes wherever possible;
• to learn more from experience – For example, by better utilising information from previous assessments, reviews, registries and post-market surveillance, to continuously improve HTAs and increase capacity to take rapid action in the event that devices are not safe or are deemed not cost efficient;
• capacity to pre-empt changes in industry and in technologies - for example assessment processes are well adapted to dealing with the applications that are submitted (e.g. for novel applications, combination devices/medicines etc); and
• improve post-market surveillance (including better utilisation of committee expertise with respect to post-market reviews of devices, including registry data).

F. Improving applications

Some participants suggested that in the longer term it would be desirable to have a single application and assessment process (such that the sponsor submits one package of evidence that is used variously by different bodies depending on whether that body is undertaking a clinical safety assessment, cost effectiveness assessment etc.).

A number of barriers to this were also identified, including that not all sponsors seek approval of both the TGA and PLAC, the TGA is subject to specific legislative constraints, and sponsors do not always share information across committees for commercial reasons.

Most of the discussion focused on the quality of applications and how applications could be improved in the short term.

It was suggested that:

• better instructions and guidance could be provided to sponsors about how to complete applications
• this guidance for sponsors could better define minimum evidence requirements for applications
• the Secretariats should reject an application if it does not meet the application requirements including the minimum evidence requirements
• sponsors should have the opportunity to attend a pre-submission meeting to ensure their applications are adequate/appropriate (comparable to the current MSAC process)
• greater filtering of applications could be undertaken by Secretariats so that only pertinent information is sent to CAG members and other experts (i.e. to prevent marketing and irrelevant material being provided to CAG members, and to reduce the time taken by CAG members and committees to review applications and provide advice), and
• information should be collected once for multiple assessments and shared between committees.

G. Coordinating effort and reducing duplication

There was general consensus that:

• CAG members are a limited resource and their expertise should be shared across HTA committees and with the TGA
• Clinical expertise of CAG members should be accessed and utilised early in assessment process, and
• there should be flexibility in terms of how clinical advice is accessed (i.e. sometimes informal advice to short timeframes is required, while in other circumstances detailed written advice is required, or full committee consideration of an issue is necessary).

It was suggested that CAG expertise could be utilised across all HTA processes, not just by PLAC. For example:

• ACMD could seek advice from specific CAGs depending on assessment requirements
• MSAC could ask questions of CAG members to explore/test clinical matters raised in applications, and
• the TGA could seek advice from CAG members on:
  – Device applications that should be triaged for in-depth review including Class 2b device applications (noting that the TGA has only 20 working days in which to decide whether or not to undertake an in-depth assessment and that the TGA receives over 600 of these applications per year), and
  – Class 3 device applications that are assessed by TGA and considered by ACMD.

Roundtable participants noted that there may be some barriers to the sharing of information and expertise in the way described above including, for example, legislative limits on information that may be shared outside the TGA, time constraints, limits inherent in the terms of reference for the various committees, and the cost recovery arrangements (noting that each committee has different cost recovery arrangements).

It was agreed that that Department should examine these matters further, with a view to finding a solution to enable sharing of expertise and information so as to improve assessments and reduce duplication.

It was also suggested that consideration could be given to the 2-year evidence rule (applicable to applications considered by CAG/PLAC) where greater harmonisation of HTAs was desirable.

H. Improvements to post market surveillance

Participants emphasised the importance of post-market surveillance and, in particular:
noted a number of registries and other sources of information already exist that could be used to inform selection of devices for post-market monitoring and further assessment. The Department noted that it is currently looking at the role and use of registries

• the need for prompt action to be taken when clinical problems with devices are identified

• provided various suggestions for how the TGA could better utilise CAG experts in relation to post-marking monitoring including, for example:
  – seeking CAG advice as part of its postmarking monitoring program
  – seeking advice on conditions that could be applied (at the time of initial assessment for entry on the ARTG) with respect to devices assessed by the TGA
  – identifying the areas that should be targeted for post-market monitoring

I. Other comments/suggestions

Other comments and suggestions that were made during the HTA Roundtable included:

• the potential value in undertaking case studies and reviews of:
  – the circumstances in which the TGA has approved a device, but the PLAC has not recommended its listing, and
  – devices that have proven not to be safe, including how these could have been identified earlier in the assessment process

• identifying incentives for sponsors to share information and evidence (i.e. faster listing)

• confirming with private health insurers about the operation of the Prostheses List and assessment processes of PLAC (i.e. views about evidence rules)

• the value of a stable secretariat for the committees, and

• the importance of managing any conflicts of interest.

Participants also suggested various long term reforms that could be considered including:

• a single assessment process/assessment body;
• removing the Prostheses List;
• removing ineffective and/or low cost devices from the Prostheses List;
• how provisional approvals for some devices could work.

J. Close

Professor Campbell thanked participants for their contributions to the HTA Roundtable. He noted that the Committee of Chairs would further consider the issues raised at the Roundtable and would continue to explore ways to improve HTA processes, in conjunction with the Department.