PROSTHESES LIST ADVISORY COMMITTEE

COMMUNIQUE No. 6

The Prostheses List Advisory Committee (PLAC) met for the sixth time on 30 March 2017 in Sydney.

Committee management

PLAC welcomed Ms Robyn Kemp to her first meeting as the Advisory Member representing the Department of Veterans' Affairs. PLAC noted the appointment process is underway for a new advisory member representing the Australian Private Hospitals Association.

Conflict of interest management and member appointment process

The Committee agreed to the revised Conflict of Interest and Declaration of Interest templates that strengthen the process and improve transparency for identifying and managing conflicts. The templates will be published on the website. The Committee also discussed revisions to the appointment process for members of clinical sub-committees to allow more timely filling of vacancies.

Redevelopment of website

The Committee noted a project had commenced to improve the PLAC and Prostheses List websites. Improvements such as providing further guidance to applicants, a list of questions and answers, links to other relevant websites and key messages for when consultation on reform activities occur would be included.

Prostheses listings

A report on the status of applications was noted, including any delays or issues associated with assessments being completed.

The Committee endorsed the Guidelines for the Evaluation of Transcatheter Aortic Valve Implantation (or replacement) devices, agreeing the next steps to commence the assessment process.

The Committee noted the implementation of the change to MBS item 42758 – Goniotomy and agreed that the existing devices on the prostheses list associated with this item not be removed, but that sponsors and private health insurers be notified of the restriction of use.

The Committee considered 77 applications to list new devices on the Prostheses List:

- 74 were recommended for granting
- 3 were deferred pending further advice.

The Committee considered 23 requests to change current listings on the Prostheses List (PL):

- 21 requests were recommended
- 2 requests were deferred pending further advice.

Reform Workplan

- *Targeted benefits and category reviews*

The Committee endorsed the document "Approach to targeted reviews of prostheses" and agreed to its presentation to the Minister for consideration. It was noted that most categories of

prostheses and their benefits had not been systematically reviewed since they were established in 2005-06. A process for seeking feedback on the approach from stakeholders would need to be agreed. Reviews would consider the appropriateness of the categorisation as well as the benefits paid. The Committee also reflected on the Industry Working Group's recommendations as to which categories could be reviewed initially, and other suggestions made by clinical advisory groups. A key input for the reviews would be access to data and collaboration and feedback from the medical device industry and other stakeholders. Data from the Independent Hospitals Pricing Authority would be considered in the reviews.

- *Superior clinical performance*

A presentation from Professor Graves of the National Joint Registry on revision rates and data collected by the registry on hip and knee prostheses prompted discussion on the policy intent of the Superior Clinical Performance (SCP) suffix. The Committee noted that any changes to prostheses listing arrangements should not negatively impact consumer access to quality devices.

- *Longer Term Benefit Setting Framework*

The Committee noted the University of Melbourne's Centre for Health Policy had finalised its research on possible benefit setting models and how they could be applied to the prostheses listing arrangements. In summary the report noted: regulations outside Australia, options for setting benefits for existing items on the PL, potential for rationalising the PL, evaluating new technologies and implementation considerations of new benefit setting arrangements.

The Committee noted input from a range of stakeholders was reflected in the report to ensure a broad understanding of potential impacts of potential models. Whilst the research was a good starting point, significant further consultation and more detailed comparative analysis and implementation considerations needed to occur. The Committee noted a public release strategy was being developed.

- *Review the Criteria for Listing*

The Committee discussed the implications of including essential consumables and/or consumable components on the prostheses list, noting that the criteria for listing do not currently support these listings. The Committee also discussed the appropriateness of low cost items and whether the criteria for listing should be limited to high cost and/or complex prostheses. There may be better value achieved if these low cost items were part of other processes, for example, negotiations between private health insurers and hospitals. The Committee noted the implications of various options and agreed further input from relevant stakeholders will be required to inform this work further.

- *Minimising duplication and improving the prostheses listing process*

The Committee noted two streams of work are progressing; identifying opportunities from a sponsors' perspective to streamline application processes for listing on the ARTG and PL, and utilising clinician expertise across health technology assessment processes. It was recognised that whilst there were different assessment purposes being undertaken for regulatory and reimbursement; there was some common information that could be provided once (e.g.: name of sponsor, manufacturer details, device details) and other information that was specific to the assessment being done (i.e.: for ARTG purposes vs PL purposes). The use of clinician expertise in ARTG assessments, particularly class 3 devices and linking with the Medical Services Advisory Committee (MSAC) processes earlier could result in faster and more efficient listings.

- *Clinical evidence requirements*

The Committee noted the TGA had released its evidence requirements for medical devices, which relate to quality, safety and performance - *Clinical Evidence Guidelines for Medical Devices.* A comparison of evidence requirements for ARTG, MBS and PL had also been undertaken, identifying where possible synergies and collaborative approaches could be investigated.

TGA advised that an expedited pathway for assessment of technologies for listing on the ARTG was expected to commence in 2018. It was noted that limited feedback had been received from industry on the public consultation paper.

Other Business

The Committee noted progress of the Senate Inquiry into Price regulation associated with the Prostheses List Framework, including submissions being available on the Parliament of Australia website. The Committee noted that many of the matters raised with the Senate Committee were generally reflected in the Committee's Reform Work Plan. The Inquiry report is due to be released on 10 May 2017.

The Committee was provided with a presentation from a medical device manufacturer and from the Director of the Australian Orthopaedic Association's National Joint Replacement Registry.

The Chair confirmed that a meeting with the chairs of each of the clinical advisory groups had been scheduled for 30 March to discuss their role and contribution to the reform work, consistency in application assessments, improvement to processes through development of additional guidance and evidence requirements documents for sponsors.

The Committee also received updates on:

- the Senate Inquiries into the TGA Amendment Bill and Transvaginal Meshes.
- The Health Technology Assessment (HTA) Consumer Consultative Committee (a collaboration of all consumer representatives on all advisory committees in Health).
- The release of a report on HTA from the Organisation for Economic Co-operation and Development (OECD).

The next meeting is scheduled for 11 May 2017.