# PROSTHESES LIST ADVISORY COMMITTEE

# COMMUNIQUE No. 3

The Prostheses List Advisory Committee (PLAC) met for the third time on 9 December 2016.

**Stakeholder Engagement**

The Committee agreed to convene stakeholder forums to enhance communication and broad engagement with stakeholders. These forums will provide opportunities for input to the reform process and will be conducted in the second quarter of 2017, once progress has been made on the reform options.

A medical device sponsor provided an overview of their experience with the existing prostheses process and suggested improvements for PLAC to consider, particularly in relation to the criteria for listing, innovation, administrative efficiencies, clinical evidence, listing reviews and international reference pricing.

**Prostheses Listings**

The Committee considered 114 applications to list new devices on the Prostheses List:

- 104 were recommended for granting
- 10 were not recommended for granting as insufficient clinical evidence had been provided to enable assessment of comparative clinical effectiveness.

The Committee considered 105 requests to change current listings on the Prostheses List:

- 89 requests were recommended
- 16 requests were not recommend (the grouping change requested was not appropriate or the changes were seeking to list new devices that require assessment against the listing criteria)

*Parallel application process*

In discussing applications to list new prostheses, the Committee noted that 22 of devices were not yet registered on the Australian Register of Therapeutic Goods (ARTG) and the TGA had not received an application to register on the ARTG.

The Committee agreed to review parallel processing to ensure that regulation and reimbursement applications run in parallel.

*Medicare Benefit Schedule (MBS) item for Goniotomy*

The Committee was informed that the MBS item for Goniotomy (42758) is being reviewed by the Medical Services Advisory Committee (MSAC). The current criteria for claiming the MBS item does not extend to allowing for the emerging practice of implanting eye stent devices listed on the Prostheses List. A communication and transition strategy for ongoing access to these devices listed on the Prostheses List will be developed.

*Transcatheter Aortic Valve Implantation (TAVI)*

The Committee noted that draft guidelines for assessment of transcatheter aortic valve implantation (TAVI) or transcatheter aortic valve replacement (TAVR) devices have been shared

with members of the Trans Aortic Valve Implantation Clinical Advisory Group (TAVICAG) and relevant stakeholders for comment. The TAVICAG has been established to consider applications to list TAVI devices on the Prostheses List, in parallel with the assessment of the technology by the Medical Services Advisory Committee.

**Reform Workplan**

*Targeted prostheses reviews*

The Committee discussed a proposed approach to review specific listings and benefits on the Prostheses List, as recommended by the Industry Working Group, including clearly setting out a framework that describes the aim, principles, processes and risks/impacts.

The process for each review will include opportunities for input and feedback by stakeholders. Other considerations should include a shared understanding of the clinical effectiveness, evidence requirements, value for money and consumer views. Advice to the Minister from the Committee will outline the proposed process, timing and priority categories for review.

*Superior Clinical Performance*

The Committee discussed a paper on the Superior Clinical Performance suffix and benefit premium, applied to 59 orthopaedic prostheses on the Prostheses List, including advice from a PLAC' SCP sub-committee.

The Committee discussed:

- whether the original policy intent of the SCP suffix is being achieved;
- if the existing criteria for eligibility are appropriate;
- data on performance of hip and knee prostheses;
- equity of the SCP benefit premium relative to the base benefit;
- expenditure on the SCP benefit premium.

*Benefit Setting Framework*

Professor Philip Clarke from the University of Melbourne presented research and feedback to date on his project about pricing models including price reference, price disclosure, tendering, external reference pricing, and market based strategies. He is continuing to meet with various stakeholders and medical device purchasing authorities in other jurisdictions to gather information.

Ms Adriana Platona presented to the Committee on the experience of price disclosure in the Government's subsidisation of pharmaceuticals.

*Minimise duplication and improve the listing process*

The Committee was briefed on the progress of work by the Regulation and Reimbursement of Medical Devices group. The Group comprises the MSAC Chair, the PBAC Chair, the PLAC Chair, Department staff from the TGA and the Medical and Pharmaceutical Benefits Divisions.

The Group has been exploring

- opportunities for timely collaboration between the HTA bodies, especially in relation to new and emerging health technologies;
- legislative provisions around information sharing between the HTA bodies, and how information could be shared without compromising security for stakeholders;
- collaboration on development of information technology systems to support parallel processing of applications;
- comparison of application processes; and

- comparison of clinical evidence requirements to identify similarities and differences.

The Committee was informed that new TGA medical device advisory committees will commence on 1 January 2017. The Committee agreed that the members of the PLAC and its clinical sub-committees should meet with the new TGA committees advisory committees to discuss assessment of medical devices.

**Next Meeting**

The next meeting is scheduled for 31 January 2017.