



Australian Government
Department of Health

HEALTH TECHNOLOGY ASSESSMENT FOR MEDICAL DEVICES

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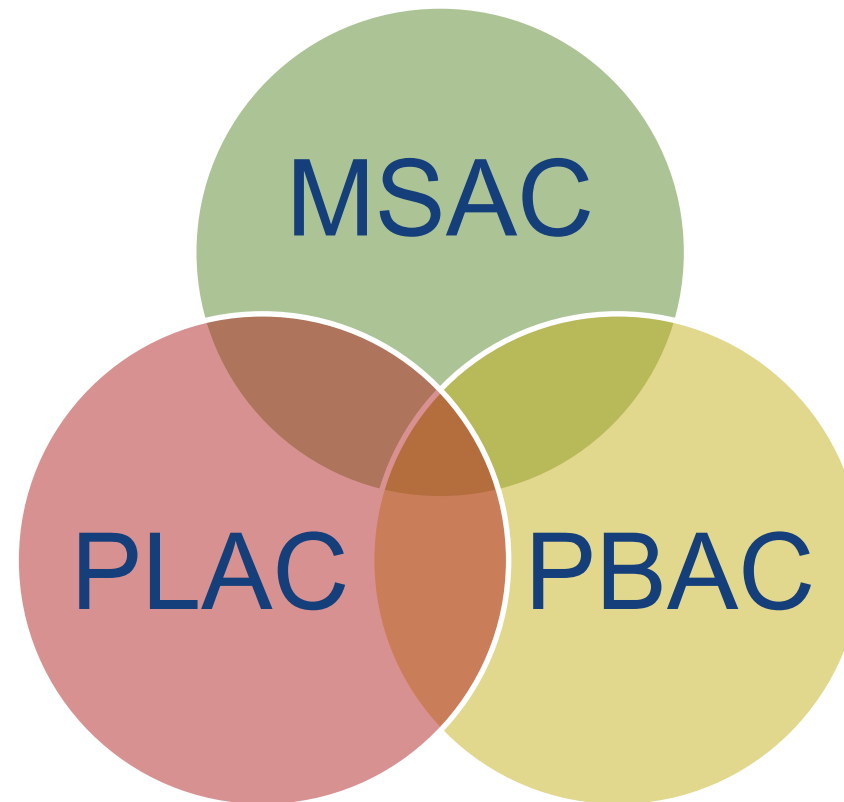
Context – Technology Assessment & Access Division

- Responsible for providing reliable, timely and affordable access to medicines, medical devices and other health services, including through the Pharmaceutical Benefits Scheme, Medicare Benefits Schedule, the Prostheses List, Life Savings Drug Program, and targeted assistance programs.



Office of Health Technology Assessment

- Three principal reimbursement committees with responsibility for Health Technology Assessment of medical devices, medical services and medicines.



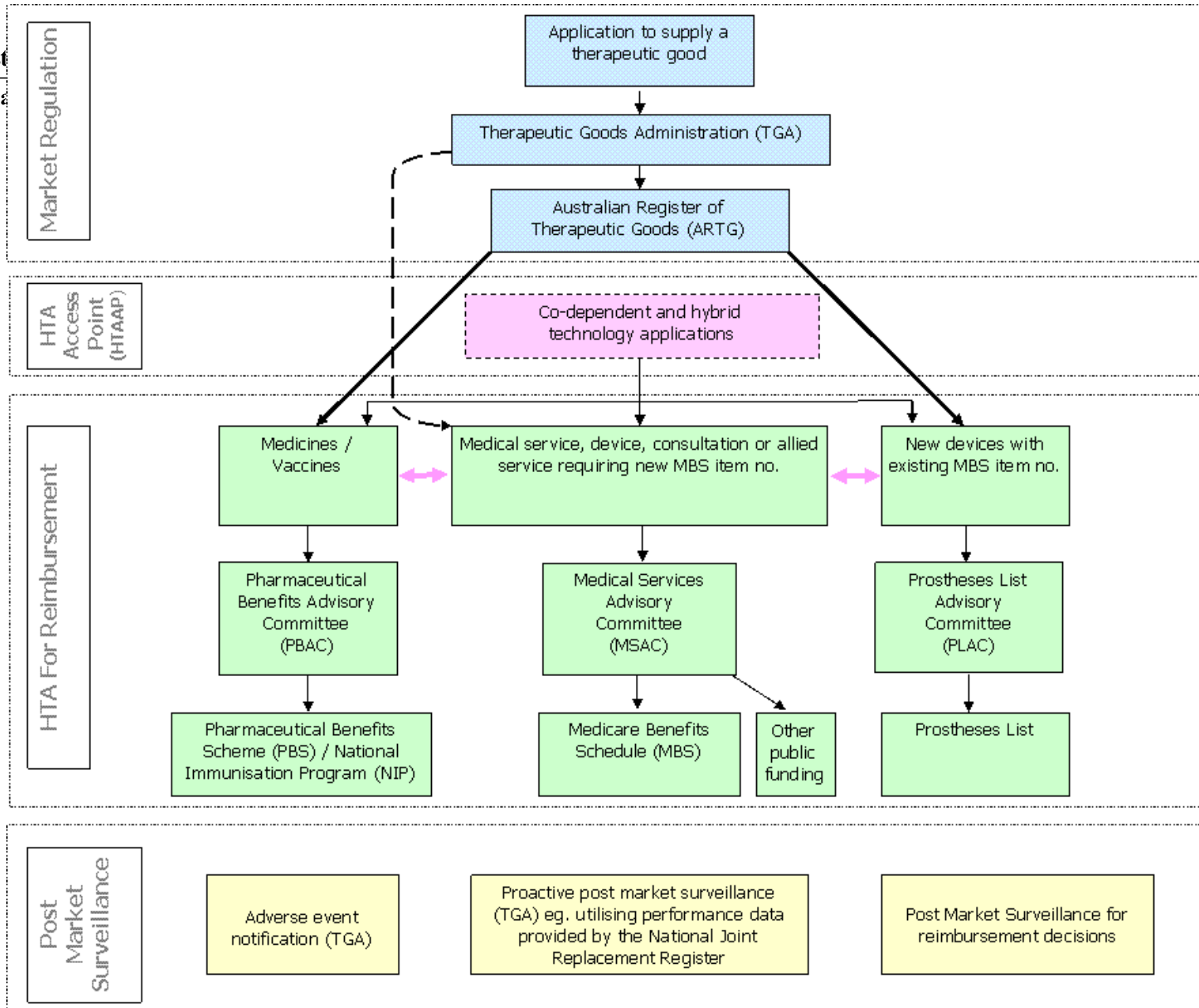


What is HTA?

- A Health Technology Assessment (HTA) involves a range of processes and mechanisms that use scientific evidence to assess the quality, safety, efficacy, effectiveness and cost effectiveness of health services.
- The key questions that a HTA aims to answer for each new health technology, in comparison to alternative interventions, are:
 - Is it safe?
 - Does it improve health outcomes, if so, what is the size of the treatment effect?
 - Is it cost effective?
 - Budget impact?



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Why HTA?

- One of the key tasks of government is the efficient allocation of resources. HTA assists in determining which health services, pharmaceuticals and medical devices should be funded.
- For devices, any product used on the Prostheses List has a cost to private health insurers, government, hospitals – and consumers.
- In 2009, the Government accepted the following recommendation from the Health Technology Assessment Review:
 - *That the rigorous consideration of evidence be consistently applied across all Australian Government HTA processes to ensure sustainability of the Australian Government's health financing arrangements*



What is the Prostheses List?

- The *Private Health Insurance (Prostheses) Rules* provide the legal basis on which the Prostheses List operates.
- A list of surgically implanted prostheses, human tissue items, and other medical devices that private health insurers must pay benefits for when they are provided:
 - to a patient with appropriate health insurance cover,
 - as part of hospital treatment or hospital substitute treatment, and
 - where there is a Medicare benefit payable for the service.



What is the Prostheses List (cont.)

- Part A:
 - Prostheses that satisfy the criteria for listing
 - Over 10,000 items including joints, screws, pacemakers
- Part B:
 - Human tissue items, including products substantially derived from human tissue
 - Over 750 items
- Part C:
 - The listing of items on Part C of the Prostheses List are at the discretion of the Minister for Health
 - Currently, items must be:
 - insulin infusion pump
 - implantable cardiac event recorder
 - cardiac home/remote monitoring system
 - cardiac ablation catheters/patches
 - surgical cardiac ablation systems
 - 58 items



Agreement with the MTAA

- October 2017 – agreement between Government and the MTAA.
- **Agreed principles:**
 - **Improved value** of private health insurance for consumers through benefits that enable access to safe, effective and cost-effective medical devices supplied within a competitive market.
 - **Support for innovation** of healthcare through incentives to develop and deliver new clinically effective and cost effective medical devices that improve health outcomes.

**Improving access to breakthrough medical technology and
affordability of medical devices for privately insured Australians:
Agreement between the Government and the Medical Technology
Association of Australia (MTAA)**

Purpose:

A commitment by the Government and the MTAA, as advocates for Australia's innovative medical technology sector, to:

- promote the sustainability of privately insured health care through rebalancing the costs of medical devices to privately insured patients, to help keep private health insurance affordable for all Australians;
- support a viable, innovative and diverse medical technology sector in Australia and local jobs; and
- improve the value of private health insurance for consumers by reducing benefits for prostheses on the Prostheses List.

The Government recognises the role of the Prostheses List in supporting the value proposition of private healthcare to Australian consumers, and how the medical technology sector contributes to this.



Priority Areas

Ensure Australian patients have access to safe, effective, and cost effective innovative medical devices in the private sector

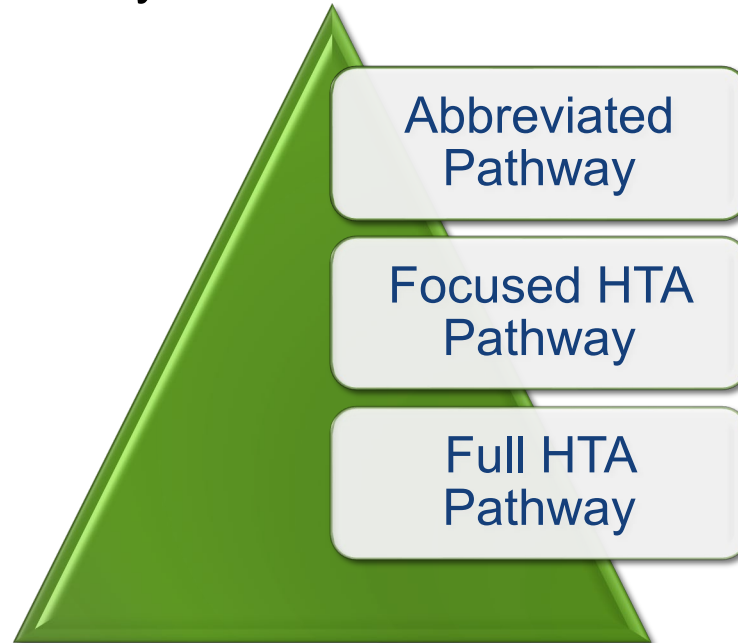
Improve the transparency and efficiency of the Prostheses List arrangements

Reduce the time to market for medical devices



Revised application and assessment process

- Designing three pathways:





Abbreviated Pathway

- ✓ Meets criteria for listing on Part A of the Prostheses List
- ✓ Class IIb (or lower) devices – approved by CAGs and PLAC
- ✓ Existing PL Group to which it can be listed
- ✓ Comparator – same purpose, same benefit

Approximately 70% of applications *could* go through this pathway, subject to other criteria being met.



HTA Pathways

- Full HTA / MSAC Pathway for new or novel devices or devices where there is likely to be a substantial cost to the health system
 - Applications likely to follow this pathway
 - Applications to Part C where there is no existing category
 - No appropriate Medicare Benefit Schedule item
 - Comparator not on Prostheses List
 - Some claims of superiority
- Focussed HTA pathway has a number of options which will be fit for purpose for the application
 - Some devices will go through a process similar to the existing process (e.g. clinician → CAG → PLAC)
 - For those devices that are seeking a higher benefit, a cost effective analysis will likely be required depending on complexity
 - Initial consideration can require escalation to full HTA and MSAC



Reviews

- Under the Agreement, the Government stated its intent to continue with targeted reviews of prostheses but not implementing any changes to benefit levels without agreement of the MTAA during the life of the Agreement
- Review framework being developed to look at items already on the Prostheses List
 - Administrative reviews / review of groupings
 - In-depth reviews, looking at clinical or cost effectiveness
- PLAC has considered a few ideas for future reviews
 - Skeletal reconstruction items
 - Wound closure
 - Catheters and microcatheters
 - Cemented vs uncemented hips
 - Drug eluting stents



Reviews (continued)

- These are being considered for a number of reasons, including:
 - inconsistency of items between and within groups
 - new evidence
 - large financial outlays
 - questions around the meeting of listing criteria
- Reviews are anticipated to be fit-for-purpose and will differ in scale and complexity
- Each review is expected to take a number of months, with opportunities for sponsor, and public consultation

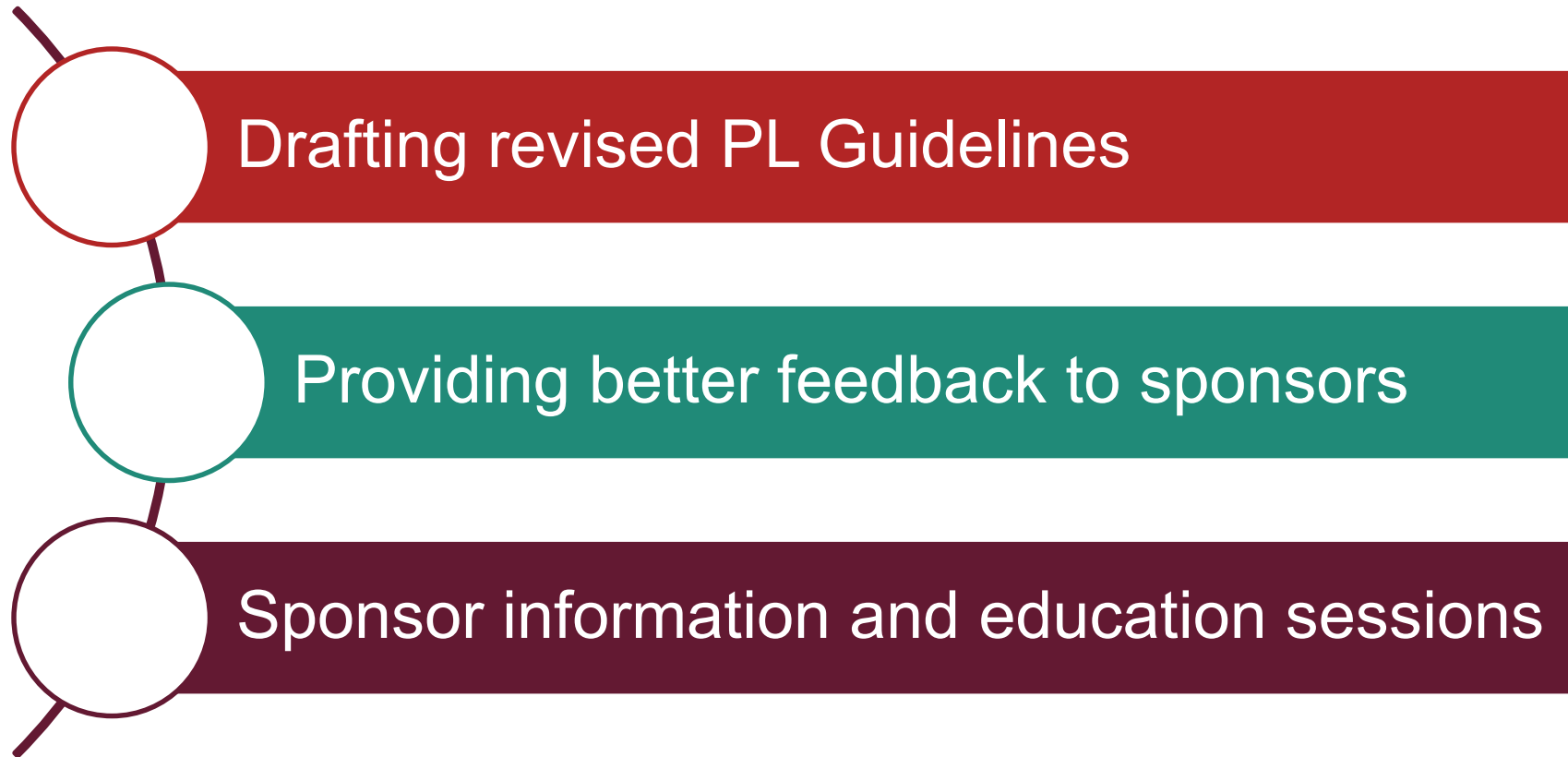


Review process

- Topics for review may be raised through a number of avenues –
eg PLAC, CAGs, sponsors and others
- Once identified, PLAC will consider and decide whether to commence a review, the public will be notified and a call for submissions will be made
- Sponsors will be consulted on the development of the draft report prior to it being provided for PLAC's agreement to release for public consultation
- Following public consultation the finalised report will be provided to PLAC for approval and consideration of report outcomes



What else are we doing?





More Information

- Department of Health website:
 - <http://www.health.gov.au/internet/main/publishing.nsf/Content/health-privatehealth-prostheses-reform>
- PHI Circulars
- prosthesesreform@health.gov.au