The MTAA submission to the Senate Committee on Community Affairs Inquiry into the Prostheses List Framework

MTAA Medical Technology ASSOCIATION OF AUSTRALIA

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Executive Summary

The Medical Technology Association of Australia (MTAA) welcomes the opportunity to make a submission to inform the Senate Committee on Community Affairs with respect to its inquiry into the Prostheses List (PL) framework. This submission clarifies existing arrangements for prostheses and addresses concerns about their impact on Private Health Insurance (PHI) affordability.

We offer suggestions to improve existing arrangements to ensure patients with PHI have timely access to a range of contemporary clinically and cost-effective technologies which have been recommended for them by their physician.

The MTAA is the national association representing 71 manufacturers and suppliers of medical technology used in the diagnosis, prevention, treatment and management of disease and disability. MTAA works with all stakeholders to ensure the benefits of innovative and reliable medical technology are delivered effectively to provide better health outcomes to the Australian community. Over 80% of MTAA members are small-medium enterprises (SMEs) (less than 200 employees) and only around 15% are subsidiaries of large multinational companies.

The PL framework contributes to the value proposition of PHI whilst suppressing benefit inflation and should therefore be retained.

Specifically, the value proposition of private hospital insurance over the public hospital system relates to patients having their choice of physician and prostheses, a greater capacity for individualised care and shorter waiting times for elective surgery. The PL framework supports the value proposition relating to choice as it ensures that patients receive the prostheses chosen by their treating physician, based on individual clinical need, with no out of pocket cost.

In considering options for reform, it should be noted that the proportion of benefits paid by PHI in relation to PL benefits is only 14% of the total, and the rate of growth in the average PL benefit has been zero for a number of years. This means that extracting savings from the PL to support the affordability of PHI is likely to have very limited impact.

The key areas of growth in benefit expenditure have related to hospital costs. These costs have continued to rise and as these represent 70% of PHI benefit payments, a review of these costs is likely to generate more substantial savings.

Notwithstanding the above, there are various opportunities to strengthen existing PL arrangements.

The MTAA supports PL reforms which ensure a sustainable, value-based funding mechanism for the supply of medical technology that delivers improved health outcomes and operational efficiencies to the Australian healthcare system. Reform should also support access to innovative technologies which improve patient outcomes and quality of life.

In this context, the MTAA supports reforms to refine the existing value-based mechanism to set prostheses benefit levels and the existing reference pricing system whereby prostheses with the same therapeutic value are grouped and priced similarly. It also supports the introduction of mandatory price disclosure based on the following principles:

- Benefits set with reference to competition should be bounded to the appropriate competitive environment that is subject to the same policy settings and same economic dynamics. This excludes international benchmarking and public pricing as relevant factors

and is consistent with how the Pharmaceutical Benefits Scheme (PBS) price disclosure model operates.
- The benefits model should foster and encourage innovation by providing economic incentives to allow Australia to be world leaders in adopting new and improved medical technologies.
- Data sourced to investigate market competition must be derived from a credible source and commercial sensitivity must be secured in operation.
- Benefit reviews should have an appropriate cadence and allow stakeholders/market appropriate time to adjust.
- Physician choice of prosthesis should be maintained.
- Costs of operating any model must be sustainable into the future and ensure equity of costs incurred.

This will efficiently address Government's desire for savings and pricing transparency whilst minimizing risks to patients and the healthcare system from reforms based on inappropriate data.

There are also other opportunities for improvement to the framework which will maximise efficiency, reduce red-tape and ensure PL benefits support contemporary models of care and advances in technology.

The MTAA considers that initiatives to achieve the above reform elements would strengthen the sustainability of the PL, improve the value of PHI to consumers and assist in generating savings in the context of PHI.

Government has already commenced a range of activities to reform the PL framework. The MTAA has been and continues to be, a collaborative and active participant to support and inform this process.

MTAA suggestions for Prostheses List reform

1. ***Introduce mandatory price disclosure based on private market data only and in accordance with MTAA's principles.***

Rationale:
This would ensure PL benefits are adjusted to reflect true market prices for prostheses and leverage existing competition in a market bounded by the same policy parameters and market dynamics. This is also consistent with how price disclosure for pharmaceuticals operates.

Additionally, a price disclosure system based on private hospital data builds on existing infrastructure rather than requiring the implementation of new infrastructure. This reduces implementation delays and generates savings earlier than other systems. It also maximises the sustainability of a price disclosure system and limits risks to consumers.

If prostheses benefit reductions are conducted arbitrarily or using inappropriate data, there is a risk of significantly skewed benefit reductions which could see patients having:

- to meet additional costs for their prostheses as gap payments are introduced to assist industry manage the quantum of the reductions;
- reduced choice of prostheses as some prostheses will no longer be viable for supply;
- reduced access to manufacturer support for prostheses implanted in the private sector as manufacturers reduce or cease such support and patients are transferred to the public system for ongoing post-implantation care;

- reduced access in private hospitals to procedures associated with medical devices that are not currently covered by the PL if rebates to private hospitals reduce given that hospitals use these to subsidise such medical devices; and
- reduced access to innovative technologies.

The above could be counterproductive to Government's desire to support PHI and its stated policy to support innovation.

2. ***Amend the existing administrative arrangements under Part C of the PL to allow the inclusion of devices that are not implantable or are not included on the Australian Register of Therapeutic Goods (ARTG) but have been approved by the Therapeutic Goods Administration (TGA) under other mechanisms.***

Rationale:
This will ensure that the PL keeps pace with advances in technology and privately insured patients have access to new in kind prostheses or those which represent significant technological advances over other prostheses available on the market. This maximises the value of PHI for consumers.

3. ***Improve the efficiency of the Health Technology Assessment (HTA) process and reduce duplication between the Prostheses List Advisory Committee (PLAC) and the TGA. This includes allowing devices of a kind already approved by the TGA to be added to an existing PL group without review by the PLAC and reviewing the fees and charges associated with obtaining and maintaining inclusions on the PL and the ARTG.***

Rationale:
Minimised duplication and a more rational approach to HTA assessment would reduce operating costs to all parties and can be passed on through the supply chain. This will provide earlier access to clinically effective and cost-effective therapies and would maximise the value of PHI to consumers.

1. Background

1.1. The Prostheses List arrangements

The PL offers a mechanism to regulate the level of benefit insurers should pay and enhance the choice of prostheses based on an objective and transparent assessment linking improved health outcomes with the value of the prosthesis. There are over 10,000 prostheses currently listed on the PL.

The existing PL framework is established in legislation under Division 72 of the *Private Health Insurance Act 2007 (the Act),* which sets out the benefit requirements private health insurance policies covering hospital treatment must meet. This includes the provision of a defined value benefit for prostheses that are used as part of hospital or hospital-substitute treatment for which a Medicare benefit is payable.

The Act also provides for the Prostheses List (known as the *PHI (Prostheses) Rules*) and for the Minister to make decisions about including prostheses on that List and the level of benefit that should apply, taking into advice the recommendations of the PLAC.

There are three parts to the Prostheses List and different listing criteria apply. Part A of the Prostheses List lists prostheses; Part B lists human tissue products; Part C lists medical devices that do not meet the criteria for listing under Part A.

	Legislated criteria
Part A	1. Are included on the Australian Register of Therapeutic Goods[1]; AND 2. Are provided to a person as part of an episode of hospital or hospital-substitute treatment; AND 3. A Medicare benefit is payable for the professional service associated with the provision of the prostheses; AND
	Administrative criteria
	4. The product should be surgically implanted and be designed to replace an anatomical body part; or combat a pathological process; or modulate a physiological process OR 5. Be essential to and specifically designed as an integral single-use aid for implanting the prostheses described above OR 6. Be critical to the continuing function of the implanted product to achieve the outcomes described above. 7. The prostheses has been compared to alternative products on the Prostheses List or alternative treatments and: (a) assessed as being, at least, of similar clinical effectiveness; and (b) The cost of the product is relative to its clinical effectiveness.

[1] This requirement applies to all therapeutic goods, including medical devices, which are approved for marketing in Australia and is a provision of the Therapeutic Goods Act 1989.

1.2. Prostheses in private hospitals compared to public hospitals

The PL arrangements ensure that patients in the private sector have access to a greater range of prostheses, including those that represent more complex technologies than those offered in the public sector. This enables physicians to determine the best prostheses to use to meet individual patient needs. Given the range of anatomical differences in patients (different sizes and weights, different levels of physical health and functional / structural deterioration), the capacity to individualise treatment is important.

Public hospitals rely on block funding as well as Activity Based Funding (ABF) to manage their operations. Under ABF, the incentive is to increase efficiency and drive down operating costs. State-based procurement activities for medical devices form an integral part of ABF where purchasing arrangements focus on bulk purchasing of a limited range of products to receive the lowest price.

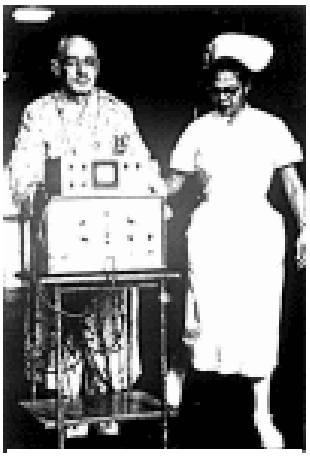
The way that the current PL arrangements operate mean that patients in private hospitals generally have to wait longer to access technologies that are used to support new models of care compared to patients in public hospitals. This diminishes the value of PHI to consumers.

However, once a technology is established and incremental improvements are made to it, patients in private hospitals have greater access to these more technologically advanced products. Patients are the ultimate beneficiaries of incremental innovation, and access to more technologically advanced prostheses in the private sector enhances the value of PHI to consumers.

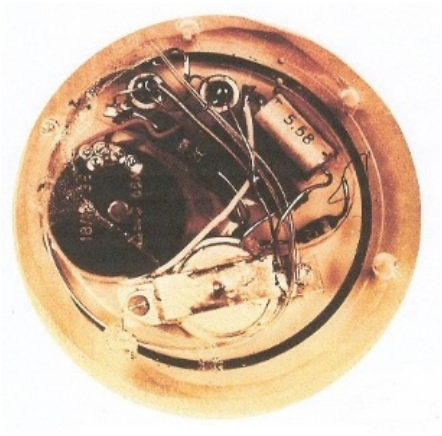
It is therefore important that any reform initiatives encourage (or at least do not actively discourage) innovation.

Medical devices are generally subject to a high rate of incremental innovation as the design of devices is improved to ensure greater or better functionality and patient or user acceptability. For example, incremental innovation has seen the development of pacemakers evolve from the first mains powered pacemaker in the 1950's to the range of pacemakers we have now.

The first mains powered pacemaker was a large box that had to be carried on a cart and would allow patient mobility as far as the length of the electrical cord from the power point. This evolved to the first implantable pacemaker in 1958.



First mains powered pacemaker



First implanted pacemaker

Source: Images Paediatr Cardiol, v.8 (2); Apr-Jun 2006 PMC3232561

However, pacemakers experienced issues including faulty batteries and broken leads. Incremental improvements to this technology resulted in shifting the therapeutic endpoint from saving life to enhancing quality of life and simplifying follow-up.
Incremental improvements made to pacemakers include:
• Introducing steroid-eluting cardiac leads to reduce the body's inflammatory response to the insertion of the pacemaker which aids patient comfort and tolerability;
• Reducing the current necessary to capture the heart, thereby improving patient comfort;
• Introducing capacity for adjustment pacing to allow the pacemaker to respond to a patient's activity level or physical changes;
• Introducing microprocessor-driven pacemakers able to detect and store information about cardiac events which can be used to monitor a patient's condition;
• Introducing biventricular pacing for heart failure which improves patient symptoms and survival;
• Introducing pacemakers where data can be uploaded on the internet and enable remote cardiac monitoring of the patient in order to detect emerging clinical issues early.

Source: Images Paediatr Cardiol, v.8 (2); Apr-Jun 2006 PMC3232561

1.3. Why was the Prostheses List established?

Prior to 1985, private insurers made individual decisions on which prostheses they would cover and the value of the benefit. This led to uncertainty of access and cost of prostheses for physicians and patients. Consequently, in 1985, the Government intervened and introduced Schedule 5. This Schedule listed the prostheses and the benefits that should be paid by private health insurers.

Changes were made to the Schedule 5 arrangements in February 2001 to allow private health insurers to negotiate prostheses benefits in an effort to address inflation. However, this accelerated inflation to the point that by 2003-2004, the average price paid per benefit under the revised Schedule 5 arrangements had doubled[2].

The Government then introduced the PL framework in 2005 where the prostheses and associated benefits were included on a list based on an assessment linking improved health outcomes with the value of the prosthesis.

The introduction of the PL framework has successfully addressed the earlier policy failures relating to certainty, cost and inflation. The final report from the Industry Working Group (IWG) on Private Health Insurance Prostheses Reform 2016, acknowledges the value of the PL by stating that *'a PL be maintained to ensure consumers and clinicians can access a reasonable choice of clinically relevant prostheses, reimbursed by insurers, preferably without a consumer co-payment*'.

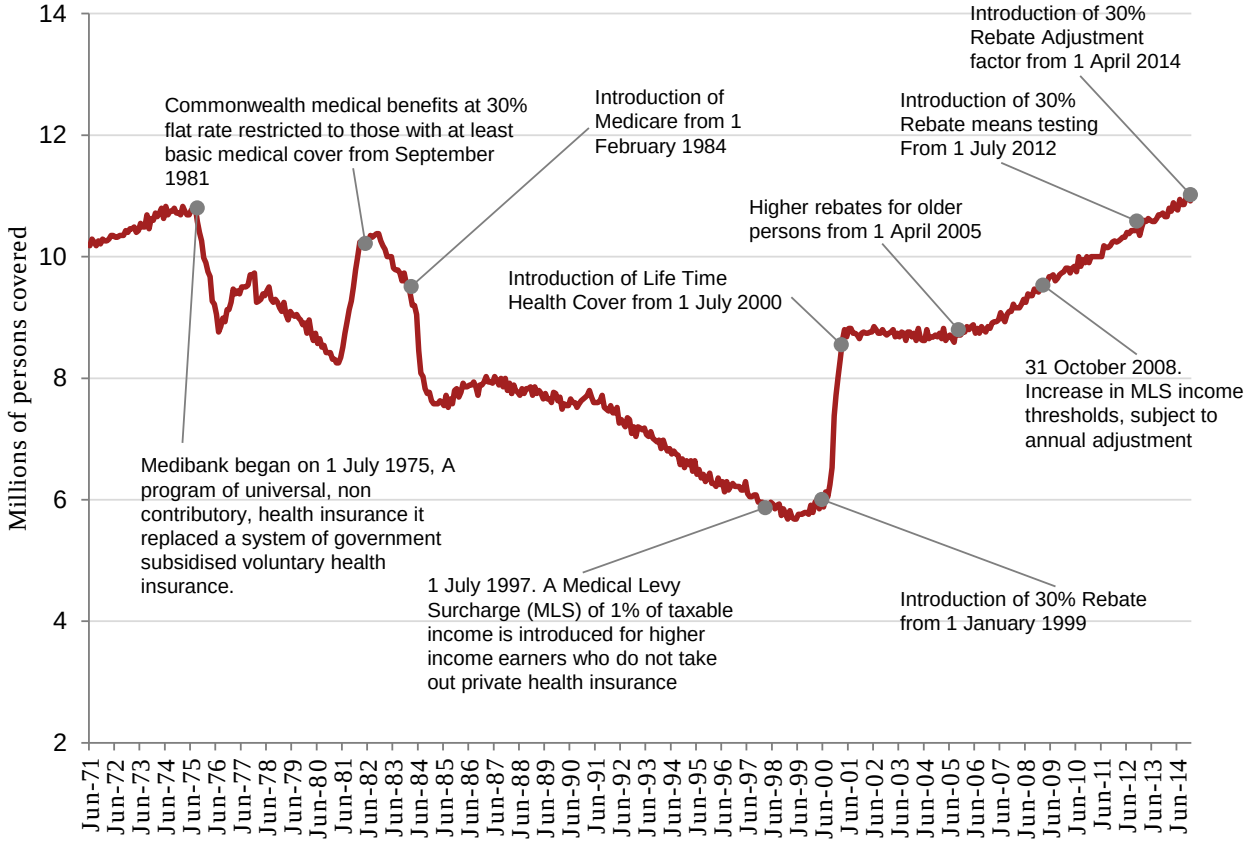
[2] Report of the Review of Prostheses List Arrangements October 2007 – Robert Doyle on behalf of the Australian Government

1.4. The value of the Prostheses List framework to Private Health Insurance

History has shown that the uptake of PHI responds to Government implementing policy levers to support PHI product engagement at a consumer level. In the absence of these incentives, consumers revert to the public system.

Reforms which limit the incentive to innovate and provide a suitable range of therapies may be problematic as they will diminish the value of PHI.

Figure 1: Private Health Insurance uptake in Australia over the last 40 years[3]



1.5. History of reviews into the Prostheses List arrangements

There have been numerous reviews of the PL Framework since its inception in 2005, the latest being conducted by the IWG on PHI Prostheses Reform in 2016.

The IWG terms of reference were to assess the PL system, including the PLAC and its supporting committees, and advise on:

- Creating a more competitive basis for purchase and reimbursement of prostheses and devices, including options for new pricing mechanisms;
- Products/categories which present opportunities for immediate benefit reductions;
- Refining the scope of products listed on the PL without adversely impacting on access; and
- Opportunities for deregulation.

[3] PHIAC (2015) - Competition in the Australian Private Health Insurance Market - Research Paper 1.

The key IWG recommendations to Government / the Department included:

- Retaining the PL to ensure consumers and clinicians can access a reasonable choice of clinically relevant prostheses;
- Implementing a price disclosure mechanism to obtain benefit reductions over the medium term encompassing public and private sector medical device pricing;
- Price referencing be set by taking into account domestic and international prices to set the PL benefit;
- Immediate benefit reductions could apply to the following device categories: cardiac, intraocular lens, hips and knees;
- Refine the scope of products on the PL by removing some products and amending the PL criteria to include innovative medical technologies which are demonstrably safe, effective and cost-effective but do not meet the PL criteria;
- Revising operational arrangements to reduce duplication of assessment between HTA bodies; and
- Revising roles and expertise of PLAC and its advisory committees.

The PLAC's terms of reference were amended in September 2016 to continue the work of the IWG to include:

- Developing options for improving application and assessment processes as recommended by the IWG to drive improved cost effectiveness of new and current medical devices;
- Revising its governance structure including its sub-committees to ensure alignment with the purpose of the Committee and reform directions outlined by Government;
- Making recommendations to the Minister on moving to a benefit setting mechanism that reflects real market dynamics for medical devices, such as price disclosure and/or reference to pricing in other markets; and
- Assisting the Department of Health to advise the Minister on any other policy matters pertaining to the medical device listing arrangements.

On 7 December, the PLAC released its workplan which outlines the following tasks:

- Undertaking a targeted review of benefits and categories;
- Developing a longer term benefits setting framework;
- Reviewing the criteria for listing;
- Reviewing the listing process to minimise duplication and make the assessment system more effective; and
- Minimising duplication.

This work has already commenced and the PLAC workplan is available at www.health.gov.au.

Additionally, in October 2016, Government announced a benefit reduction of 7.5% for hip and knee prostheses and 10% for cardiac and intraocular lenses effective from February 2017. These reductions are arbitrary and were not based on evidence.

1.6. The role of the Prostheses List Advisory Committee

The PLAC is a non-statutory committee whose members are ministerially appointed on the basis of their expertise and whose primary function is to advise and make recommendations to the Minister about new and existing listings on the PL. It remit has recently been extended to progress the work of the IWG.

The composition of the PLAC and its predecessors has featured in the three reviews into the PL arrangements. Membership was broadened in October 2016 to include additional health economics expertise and an expert member of the MSAC to ensure alignment of related activities.

2. Response to Terms of Reference

The basis of this Inquiry appears to be predicated on the following:

a) the perception that the cost of prostheses in the private sector is having a significant impact on the affordability of PHI and therefore the benefit setting system should be reformed; and
b) the possibility of improving the other elements of the system to better meet consumer needs.

These themes are addressed below.

2.1. Affordability of Private Health Insurance

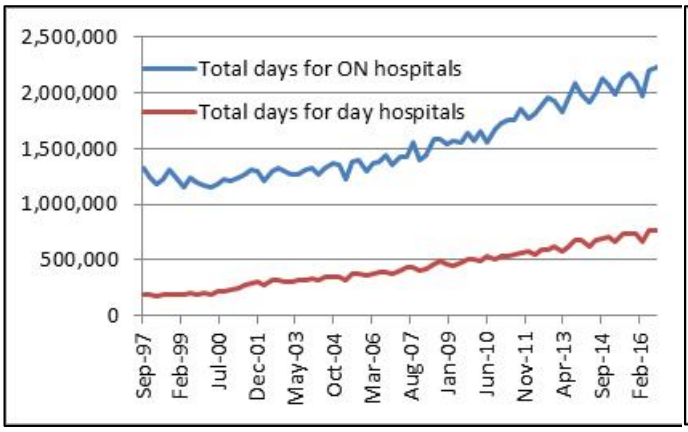
Based on the data below, reducing the value of the PL benefit is likely to have a minor impact on the affordability of PHI. Additionally, with recent industry profits at around 28%, it is difficult to understand how private health insurers are under financial stress.

Based on published data from the Australian Prudential Regulation Authority (APRA), the average benefit growth for prostheses between 2005 and 2015 was 1.4%, while the average benefit growth for medical services was 2.3% and 3.2% for hospitals services. The data also show that **the average benefit growth for prostheses between 2010 and 2015 was zero percent** while the benefit growth rates were approximately 1.7% for medical services and 2.6% for hospital services.

Analysis of quarterly PHI data from APRA ranging from Sep 1997 to May 2016 (see Figures 2-4 below) shows the overall trends in number of services and average benefits paid. The data indicate that the number of hospital and medical services and prostheses services continues to grow. However, the average benefits paid for private hospital services are continuing to increase whereas the average benefit paid for prostheses has almost flat-lined.

Figure 2: Number of hospital days and average hospital benefit paid

Total number of hospital days for day and overnight hospitals



Average benefit per day for day and overnight hospitals

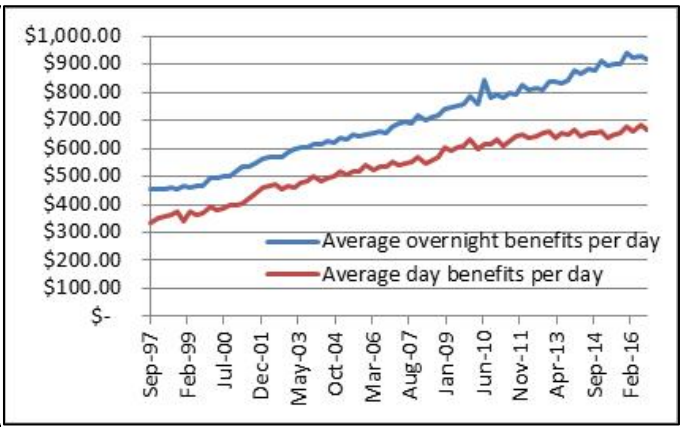
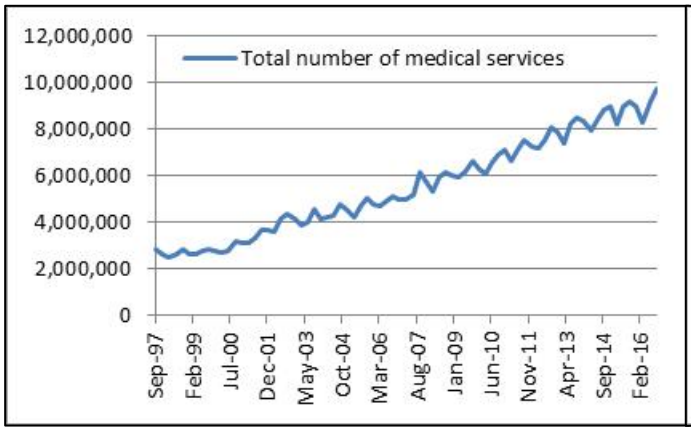


Figure 3: Number of medical service items and average benefit paid

Total number of medical service items



Average benefit paid for medical services

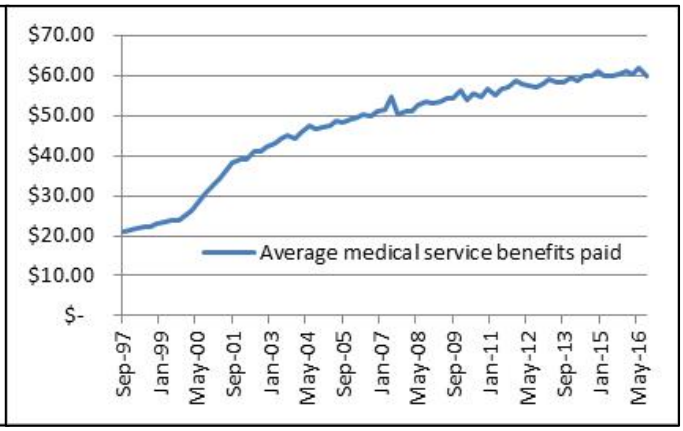
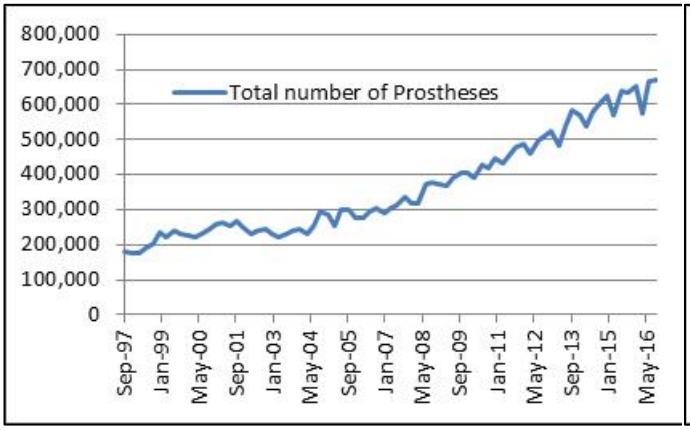
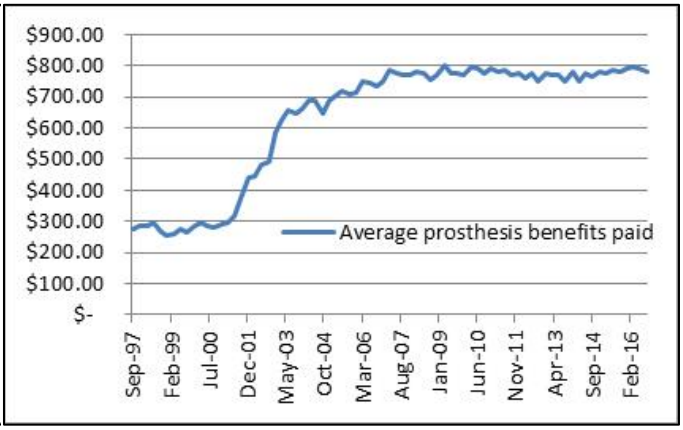


Figure 4: Number of prostheses items and average benefit paid

Total number of prostheses items



Average prostheses benefit paid



In 2015, prostheses accounted for only 14% of the total paid in reimbursements by private health insurers under their hospital cover policies compared to medical benefits which accounted for 16% and hospital costs (accommodation, theatre fees, and nursing care) which accounted for 70%[4].

In the quarter ending September 2016, private health insurers paid the following[5]:

Benefit type	Benefit paid	Percentage of hospital treatment cover benefit	Percentage of general and hospital treatment benefit combined
Prostheses	$521 million	14%	10%
Medical	$583 million	16%	12%
Hospital	$2.57 billion	70%	53%
Hospital treatment cover	$3.68 billion	Not applicable	76%
General treatment cover	$1.17 billion	Not applicable	24%

[4] APRA PHI statistical trends December 2015, March 2016, June 2016 and September 2016; http://www.apra.gov.au/phi/publications/pages/statistical-trends.aspx

[5] APRA PHI quarterly statistics September 2016; http://www.apra.gov.au/PHI/Publications/Documents/1611-QPHIS-20160930.pdf

Recent data indicates that the PHI industry increased its net profit after tax by 28.3 % in the 12 months ending September 2016 compared to the 12 months ending September 2015.

Figure 5: PHI Performance Statistics[6]

	September 2015	September 2016	Change
Total revenue	$21.5 billion	$22.9 billion	+6.5%
Total benefits	$18.3 billion	$19.2 billion	+4.9%
Net profit after tax	**$1.064 billion**	**$1.365 billion**	**+28.3%**
Net margin	**4.5%**	**5.3%**	**0.8%**

Given the flat-lining of average PL benefit growth and the low contribution that PL benefit payments make to the total benefits paid by PHI, it is difficult see how prostheses costs are impacting significantly on the sustainability and affordability of PHI.

The above data indicates that the impact of reforming the PL arrangements is unlikely to generate significant savings for PHI. Additionally, the data seems to indicate that the PHI industry is quite profitable.

2.2. Cost drivers for prostheses

There are many factors which influence the costs of prostheses, resulting in pricing variability across markets. In considering any reforms, it is important to understand these factors as they show that direct price comparisons across markets are not as straight forward as they may appear and may not be appropriate.

The key drivers influencing price differentials across markets include:

- The purchasing arrangements and level of segmentation of the market through capacity to discount;
- How the PL benefit level has been set and whether patient benefits have been considered rather than only cost efficiencies to meet efficiency and funding targets;
- The level of technical manufacturer support required ; and
- The level of regulatory hurdles and market delays.

The MTAA considers that pursuing pricing reforms using public hospital data or international pricing data as reference points or in price disclosure calculations is not appropriate and is associated with risk.

The difficulty of comparisons across international jurisdictions was acknowledged by Bupa, one of the largest PHI companies in Australia, in an article published in The Age on 21 September 2016[7]. When asked why Australian families are paying up to $400 more a month for private health insurance than consumers in comparable countries like Britain, a Bupa spokesperson said that the 'private health market in Britain was "very different", with insurers able to pick and choose customers and force patients to seek their approval before being referred to a specialist'. In Australia, old and sick patients cannot be turned away by insurers and they cannot be charged higher premiums.

[6] APRA PHI quarterly statistics September 2016; http://www.apra.gov.au/PHI/Publications/Documents/1611-QPHIS-20160930.pdf

[7] http://www.theage.com.au/federal-politics/politica;-news/australians-pay-thousands-more-for-private-health-cover-20160921-grly1.html

In addition to the above, MTAA is concerned that introducing international reference pricing can be counterproductive to healthcare and overall savings. The European International Centre for International Political Economy[8] found that international reference pricing (IRP) for pharmaceuticals was effective in lowering the prices of drugs in the short-term but was associated with long term unintended consequences which were contrary to the overall purpose of reducing healthcare costs. There appears to be no reason why this finding should not apply to prostheses.

Extracts from the European International Centre for International Political Economy Policy Briefs No 04/2013 ISSN 1653-8994'

"The problems are rooted in the fact that IRP is underpinned solely by the idea of reducing costs rather than enhancing productivity or providing value for money in the healthcare sector. Policymakers may rejoice as the prices of medicines become lower almost overnight. However, lower costs in the short-term must be juxtaposed with negative long-term ramifications which may result from the fact that IRP sets the operation of the price mechanism out of play. ***This might entail serious consequences on the innovation, competition, market structures, and prices as well as the availability of drugs, ultimately affecting patients".***

"…all efforts should not be devoted to reducing the costs of medicines. A vast array of inefficiencies must be addressed, including the administration of hospitals and medical services"

The factors which influence price differentials are discussed below.

a) Healthcare financing and prostheses purchasing decisions

The incentives created through the funding arrangements, who makes the purchasing decision, and their sensitivity to the cost of the prosthesis will influence the purchasing arrangements and ultimately the market price.

Figure 6 shows that the public hospital sector is predominantly funded by the Commonwealth Government (54%) and State/Territory Governments (36.8%). Private hospitals are predominantly funded by private health insurers (48.6%), the Commonwealth Government (30.2%) and individuals (11%).

Under the public sector, prostheses are mostly purchased through tendering arrangements by State/Territory Governments with a focus on bulk purchasing of prostheses. This is because over time, Commonwealth funding received by States and Territories is moving towards activity based funding where hospitals are paid a set amount for the number and mix of patients they treat. This incentivises the provision of patient care at the lowest possible cost that will adequately meet the healthcare needs of patients.

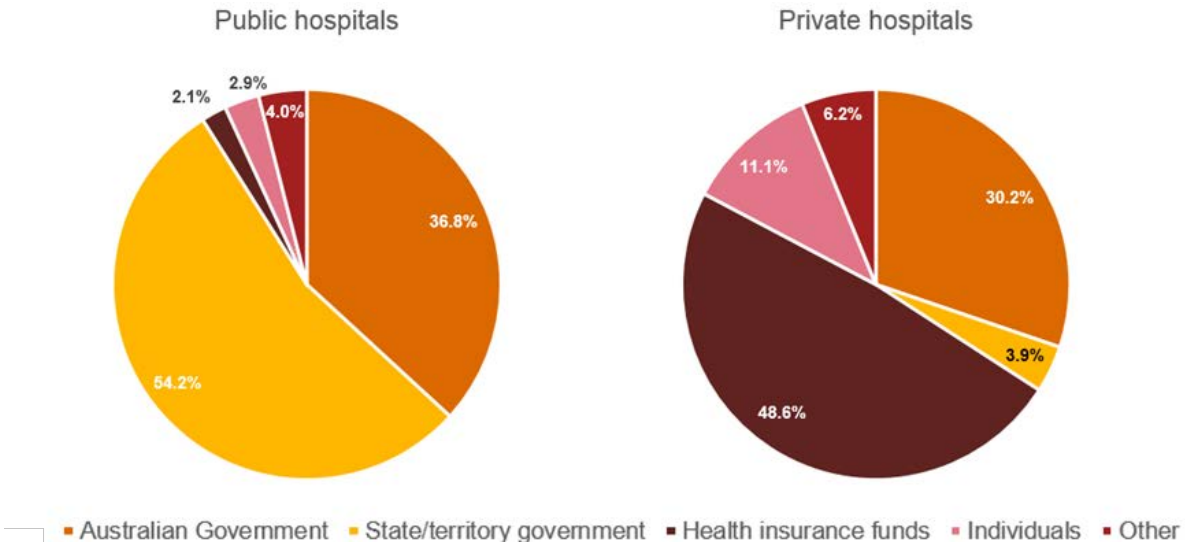
Tendering reduces the choice of prostheses available and public hospitals tend to purchase the most basic prostheses which will meet the patient's needs and decisions on patient care are influenced largely by cost considerations. Many public hospitals have criteria that need to be met to justify the patient receiving a more technologically advanced prosthesis. These criteria are absent in the private sector.

In the private hospital sector, surgeons and specialists are reimbursed for their services directly by the Commonwealth Government via the Medical Benefits Schedule (MBS). Private insurers pay for the cost of accommodation, theatre and prostheses costs for private procedures. Patients pay for any out of pocket costs incurred.

[8] ECIPE Policy briefs No 04/2013 ISSN 1653-8994 – Price tagging the priceless: International reference pricing for medicines in theory and practice

The current arrangements for private hospitals do not incentivise surgeons to consider cost when determining which prosthesis to use for their particular patient as the cost of PL prostheses is borne by the private health insurer. However, choice of surgeon and choice of prosthesis are fundamental benefits of private healthcare cover and reduced choice could impact on the consumer's perception of the value of their insurance.

Figure 6: Source of funds for public and private hospitals 2013-14[9]



b) The HTA assessment system for prostheses

The level of HTA assessment and whether it has taken into account the value of the patient outcome will influence the market price of the prosthesis.

Prostheses are approved for marketing in Australia by the TGA if they are found to be of acceptable quality, safety and efficacy. Once regulatory approval is obtained from the TGA, the prosthesis is immediately available for purchase in the public sector.

However, once TGA approval is obtained, further assessment needs to be conducted to enable a prosthesis to be available through private hospitals and this may take several years. This is because not only is an assessment of the comparative effectiveness and sometimes the comparative cost of a prosthesis required to be undertaken by the PLAC, but an MBS item must also be available to cover the service or procedure associated with that prosthesis. MBS items are issued following successful evaluation by the Medical Services Advisory Committee (MSAC).

Delaying entry to the private market come at significant costs to the medical device industry especially as the effective market life of a device is relatively short due to the high rate of incremental innovation. If assessments are significantly delayed, the technology being assessed has been superseded and private patients are not receiving access to the latest technologies which may already be available in the public hospital.

There are examples in the orthopaedic and cardiac sector where MSAC approval for an MBS item was finally granted after four years. However, by the time the recommendation to grant an MBS

[9] Australian Institute of Health and Welfare (2016). Hospital resources 2014–15: Australian hospital statistics. Health services series no. 71. Cat. no. HSE 176. Canberra: AIHW.

item was made, the prostheses used in the procedures in question had already been superseded by more advanced models which were already being used in public hospitals.

Additionally, the private sector requires data that are not required by the TGA for approval and may require conducting additional clinical trials and economic analyses to support reimbursement.

Delayed access to the private sector and the cost associated with meeting the unique evidentiary requirements of the private sector can ultimately be reflected in the PL benefit for these products. Any savings from efficiencies gained through the HTA assessment process would be able to be passed down the supply chain.

c) How benefits are set in the private sector and what is included

In general, the benefit takes into account the cost of the prostheses and the cost of additional support services provided by the supplier. Many of these services are essential to ensure the best health outcomes for patients and are discussed under subsection d) below. These are not taken into account in the pricing of prostheses in the public hospital sector.

Prostheses with similar clinical outcomes are grouped and allocated the same benefit amount on the PL. Where a prosthesis demonstrates superiority over other PL listed products and the proposed benefit level has been validated, it may be included in a new group.

d) Additional support services and complexity of device

The level of service and support required from suppliers for individual prostheses is generally higher in the private sector compared to the public sector and are include as part of the PL benefit and consequently, the prices in the public sector and the private sector may not align.

Supplier support services may be required before, during or following implantation and are associated with real costs to the supplier. Any reform to significantly reduce the benefit levels is likely to result in these support mechanisms being reduced or abolished or costs being transferred to other parts of the supply chain (including the patient).

These support services are explained further below.

- ***Theatre support***

Private hospitals require greater in-theatre support because:

- the private sector offers a greater range of devices (as the prostheses is based on individual surgeon choice) and it is difficult for hospital staff to have the necessary expertise to support the utilisation of every prostheses and associated instrumentation that the hospital may use; and
- private hospitals tend to use more advanced technology which requires a greater level of expertise to implant and therefore greater supplier support is required.

For example, intraocular lenses (IOLs) are most commonly used to replace a natural lens during cataract surgery but can also be used for refractive lens exchange which is a type of vision correction. There are three main types of IOLs which include monofocal, multifocal and toric lenses.

Monofocal lenses are the most common type and provide corrected vision at either near, intermediate or far distances and may require spectacles for additional vision correction. Multifocal lenses allow changes in focus providing vision correction for varying distances, allowing spectacle

independence. Toric lenses are mostly monofocal IOLs that correct astigmatism and may still require spectacles.[10]

Public hospitals tend to use monofocal lenses over the other IOLs as these are the cheapest technologies.

More complex IOLs and services require more in-depth preoperative ocular and optical assessment of cataract patients compared to procedures using more basic models. Intraoperatively, there are also additional considerations to ensure optimal outcomes when using these IOLs. Monofocal lenses do not require specific orientation in the eye whereas the other IOLs do due to their specific design. This means that a representative from the supplier is present to assist the surgeon during surgery.

- ***Post-implantation monitoring and follow-up***

Suppliers of certain devices (e.g. implantable cardiac defibrillators [ICDs]) need to provide support services to patients and clinicians post-implantation for the life of the device or the life of the patient to ensure ongoing patient safety.

In the public sector, such support costs are borne from within the hospital's funding envelope as they generally have the infrastructure to provide similar, but lower, levels of support. For example, ICD manufacturers can provide up to around $15,000 of post-implantation services to patients for around 10 years (usually the lifetime of the patient or the device). This cost is included in the PL benefit as it is uniquely incurred in the private sector.

Supplier services for implantable defibrillators are Australia wide and include:

- technical support during all surgical procedures;
- 24/7 technical support by highly qualified and trained individuals and this may include call-out services to remote locations;
- device testing to ensure the device is working appropriately;
- routine patient follow up in clinics to read the data collected and stored by the defibrillator which provides an indication of the patient's condition and disease progression and informs ongoing treatment options;
- turning devices off post-mortem; and
- temporarily deactivating devices for oncology and MRI treatments.

- ***Transport and maintenance cost of heavy instrumentation for orthopaedic surgery***

In relation to orthopaedic devices, the purchasing power of public hospitals and the contractual arrangements make it viable to supply heavy instrumentation associated with the safe implantation of a particular an orthopaedic prosthesis for each surgery.

The instrumentation supplied may be up to 1 cubic meter in volume and weigh around 100 kg as illustrated in Figure 7 below. It requires checking, calibration and maintenance by manufacturers before and after each use.

The fact that private hospitals do not have bulk supply and purchase arrangements in place means that suppliers have to pay for the transportation of this instrumentation on an individual case basis. This is costly and is built into the value of the PL benefit.

[10] Boyd, K (2016). IOL Implants: Lens replacement and cataract surgery. American Academy of Ophthalmology

Figure 7: Instrumentation trays supplied to hospitals for every knee replacement procedure

The above show the diversity of ancillary services included in the value of a PL benefit. A significant reduction in PL benefits may compromise the ongoing level support for private patients in the private sector.

e) How prices are set in the public sector and what is included

Prices in the public are determined through tender arrangements between State/Territory Governments on behalf of their hospitals and medical device companies. This means that the prices of prostheses across States/Territories will vary.

The prices in the public sector may be different to those in the private sector as they do not take into account in the value of the health outcome and they also exclude the support services provided by the supplier. This means that the prices across the public and private sector may not be identical and can vary significantly for some prostheses.

f) Purchasing arrangements between device companies and hospitals

Purchasing arrangements are generally subject to contracts between device suppliers and private hospitals or State/Territory Governments on behalf of their public hospitals. These specific requirements will result in different prostheses prices across States/Territories and private hospitals.

Contracts exist between suppliers and:

- State/Territory Governments;
- individual public hospitals where purchasing occurs for individual prostheses outside the State tender process;
- private hospital groups; and
- individual private hospitals.

These contracts contain requirements legally or administratively required by purchasers.

Private hospital purchasing is generally based on a single purchase at a time based on surgeon preference whereas public hospital contracts are based on bulk purchases with contractual

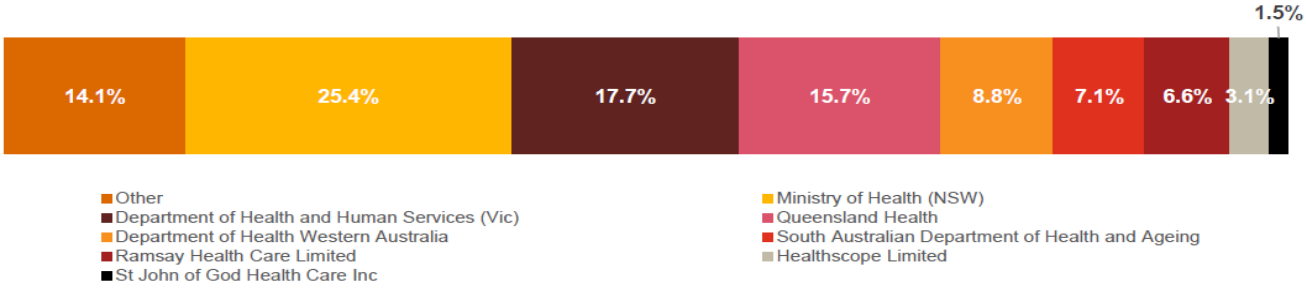
arrangements of 2 -3 years, locking in minimum purchase volumes at specific prices for that time. The current arrangements impact on the capacity of device suppliers to reduce the price of prostheses supplied in the private sector.

Additionally, the segmentation of the healthcare sector influences how prostheses are purchased - the higher the segmentation, the lower the capacity to exert market power to reduce prices.

OECD Health at a Glance 2013 data indicates that around 70% of health financing comes from the public funding with the remainder from private sources including 8% from private health insurance and 20% from patient out of pocket payments. This indicates that the private healthcare sector is highly segmented in comparison with the public healthcare sector. Additionally, the private healthcare sector is subject to different policy drivers and settings than the private healthcare sector, which influences market dynamics and pricing.

The figure below provides an overview of the major players in the Australian health system in terms of overall spend for the 2015-16 financial year. This highlights the purchasing power of the three most populous state health services compared to the larger private hospital groups.

Figure 8: Overview of hospital market share in Australia 2015-16[11]



Overall, the current purchasing mechanisms advantage the public sector which has the capacity to centralize the purchase of prostheses for 698[12] public hospitals through the existing tendering systems with the 8 States and Territories. In contrast, many of the 624[12]private hospitals have to enter into individual contractual agreements and purchase on an ad-hoc basis.

2.3. Opportunities for improvement

a) Benefit setting

The introduction of price disclosure based on private market data only will efficiently improve transparency of pricing, maximise savings from current market competition and reduce the risks to patients and the healthcare system arising from reforms based on inappropriate data.

Additional benefits are that such a model can be implemented using existing data and infrastructure. This allows price disclosure to be implemented faster than under other models and also ensures the system incurs minimal set up and maintenance costs, making it sustainable for the longer term.

Following extensive consultation with its members, the MTAA considers that the following principles should apply to a mandatory price disclosure system:

[11] IBISWorld (2016). General hospitals in Australia
[12] Australia's Hospitals at a glance 2014-15 – AIHW Health services series no. 70 July 2016

- Benefits set with reference to competition should be bounded to the appropriate competitive environment that is subject to the same policy settings and same economic dynamics. This excludes international benchmarking and public pricing as relevant factors and is consistent with how the PBS price disclosure model operates.
- The benefits model should foster and encourage innovation by providing economic incentives to allow Australia to be world leaders in adopting new and improved medical technologies.
- Data sourced to investigate market competition must be derived from a credible source and commercial sensitivity must be secured in operation.
- Benefit reviews should have an appropriate cadence and allow stakeholders/market appropriate time to adjust.
- Physician choice of prosthesis should be maintained.
- Costs of operating any model must be sustainable into the future and ensure equity of costs incurred.

If prostheses benefit reductions are conducted arbitrarily or using inappropriate data, there is a risk of significantly skewed benefit reductions which could see patients having:

- to meet additional costs for their prostheses as gap payments are introduced to assist industry manage the quantum of the reductions;
- reduced choice of prostheses as some prostheses will no longer be viable for supply;
- reduced access to manufacturer support for prostheses implanted in the private sector as manufacturers reduce or cease such support and patients are transferred to the public system for ongoing post-implantation care;
- reduced access in private hospitals to procedures associated with medical devices that are not currently covered by the PL if rebates to private hospitals reduce given that hospitals use these to subsidise such medical devices; and
- reduced access to innovative technologies.

Any diminution of the value offering of private insurance to patients could see a further attrition in privately insured patients and this will increase pressure on public hospitals. In turn, waiting times for elective surgery may be increased for patients in the public sector.

Given that 80% of MTAA members are SMEs and include companies which manufacture in Australia, benefit reductions that are inappropriately skewed could see their withdrawal from the market as they do not have the capacity to absorb significant reductions. Additionally, such reductions could see a significantly reduced investment in research and development in Australia and is contrary to the Government's stated agenda to support innovation.

MTAA proposed option for reform:
Introduce mandatory price disclosure based on private market data only and in accordance with MTAA's principles.

b) Outdated criteria for Prostheses List

While the current PL Framework has been successful in supporting choice and containing costs, it has not been updated to reflect advances in technology and models of care. This is due to the administrative criteria which have been set regarding the definition of prosthesis and also the requirement that the prosthesis should be included on the ARTG.

The administrative definition of a prosthesis requires the product to be surgically implanted and left in the patient. Advances in technology mean that medical devices that are used in effective and clinically proven surgical procedures are not eligible for listing on the PL because they are not implanted.

A clear example of this is the use of ablation catheters used in cardiac ablation procedures to treat atrial fibrillation (AF). AF affects around 460,000 Australians and places them at higher risk of stroke, heart failure and death than the general population. Patients can be treated with life-long treatment with medication or, if they do not respond to medication, may undergo a cardiac ablation procedure which destroys small areas of the heart tissue where abnormal heartbeats may cause an arrhythmia to start.

During catheter ablation, a series of catheters (thin, flexible wires) are put into a major blood vessel and are guided into the heart where radiofrequency signals are transmitted into the heart to destroy cardiac tissue.

Cardiac catheter ablation is endorsed as a treatment by the Cardiac Society of Australia and New Zealand and its efficacy has been substantiated by a systematic review and meta-analysis into the long term outcomes of catheter ablation of AF[13].

Ablation catheters such as 3-D mapping catheters (which map the location of the catheter to more precisely ablate the cardiac tissue) and irrigated catheters (which assist control the temperature and contain ablation to a specific area) may cost from $7,000 to $10,000, whereas the more basic catheters that are used in less complicated cases of AF may cost 30%-40% less.

Ablation catheters do not meet the criteria for being included on the PL as they are not permanently left in the body. Therefore, patients receiving cardiac ablation in private hospitals have to either pay for the cost of these devices themselves or the hospital has to meet these costs. For these reasons, some private hospitals do not offer this procedure at all and patients are either referred to a public hospital for treatment or they remain on life-long pharmacological treatment. Patients in public hospitals are offered this treatment for free.

Other devices that are excluded from the PL as they are not implantable include drug coated balloon catheters used for artery widening to treat peripheral arterial disease and blood clot retrieval devices.

These devices offer clinical an economic advantages over other therapies but are not available through the PL.

[13] Journal of the American Heart Association DOI: 10.1161/JAHA.112.004549 – Long term outcomes of catheter ablation of atrial fibrillation: A systematic review and meta-analysis, Anand N et al

Case Study *Mr X was given just a 15 per cent chance of survival after suffering an ischaemic stroke. The clot removal device helped restore blood flow to the brain, saving his life and limiting side-effects.*

The Royal Melbourne Hospital Neurointervention Service director Associate Professor Y said the 67-year-old had a complete blockage in the basilar artery, which he said supplies blood to the brain and it was normally "not survivable".

Mr X began to feel dizzy on December 2. He went numb down the right arm and side and his face lost shape and his speech slurred. He was taken to the hospital where they threaded the device, about 4mm in diameter, inside a tiny tube on a wire into his brain artery. The tube was pulled back so the retriever expanded.

"As it expands, it grabs the clot and you can pull it out, unblocking the artery," he said.

Associate Prof Y said he was ecstatic with Mr X's outcome. The day after the procedure he could move his right arm and leg, and even managed a short walk. Although Mr X is still recovering, he said he felt extremely lucky.

"At the same time I feel grateful and humble that the procedure became available at the time when I needed it," he said.

Unlike other devices, doctors can actually see this device expand inside the artery, potentially allowing quicker retrieval. He said it was vital to clear the blockage and restore blood to the brain quickly to minimise damage. This could be the difference between a patient left with subtle gait or fine motor problems, or someone who struggled to walk and talk. He said most clot retrieval procedures were performed on conscious patients, which increased speed and potentially led to better outcomes.

http://www.heraldsun.com.au/news/victoria/blood-clot-catcher-saves-lives-at-the-royal-melbourne-hospital/story-fni0fit3-1226837639434

The requirement that a product must be included on the ARTG is also problematic as this means that prostheses that are custom made for patients are not able to be included on the PL. This is because custom made devices and products that are approved by the TGA for individual patient use or individual practitioner use are exempt from being included on the ARTG.

With the evolution of 3D printing and therapies that are more uniquely manufactured for an individual, continuing this requirement will be problematic and means that the PL is not reflecting advances in technology. It should be sufficient for PL purposes that the TGA has approved the device. PL inclusion should not be predicated on whether a product has been included on the ARTG as this reflects only one of the types of approvals TGA can provide.

The existing infrastructure can be used by formalising the administrative processes to include such products under Part C of the PL rather then reviewing the criteria for inclusion under Part A. The risk of revising the current criteria to suit todays' technologies is that a lot of effort will be undertaken to devise criteria which are likely to quickly become outdated given the pace of technological advancements.

MTAA proposed option for reform:
Amend the existing administrative arrangements under Part C of the PL to allow the inclusion of devices that are not implantable or are not included on the ARTG but have been approved by the TGA under other mechanisms.

c) Cost of the regulatory system

Another issue with the current arrangements is the cost imposed by Government through cost-recovery which is compounded by significant delays in approving products for marketing in Australia followed by delays in assessment for access to the private market through the PL arrangements.

Improved efficiencies in the administration and operation of the PL could result in savings which can flow on to other areas of the supply chain.

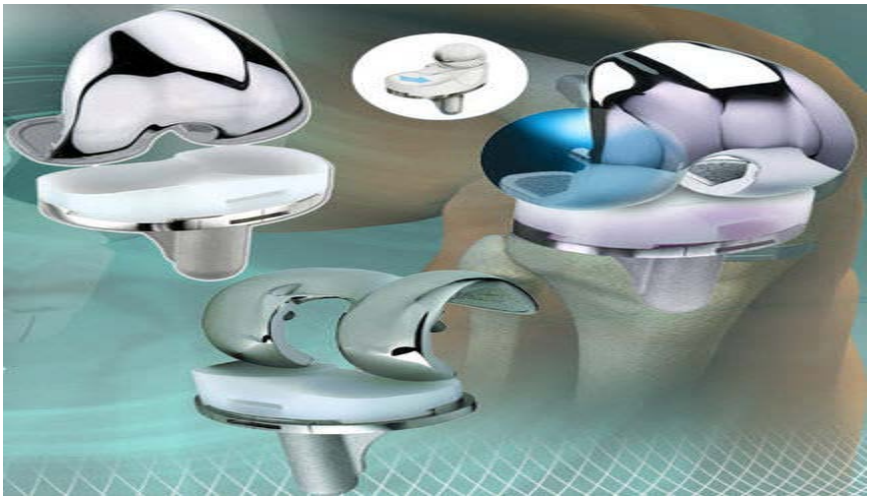
At present, the device industry meets the following costs associated with bringing and maintaining products on the Australian market:

- Application fees for TGA assessment / approval for new ARTG entries and changes to existing ARTG entries (ranging from $980 to $85,000 (when a full assessment of the device design and the quality management system of a Class III device is undertaken);
- Annual fees for maintaining ARTG entries (ranging from $80 – $1,200 per ARTG entry);
- Application fees for PL assessment ($600 per billing code);
- Annual fees for maintaining PL entries ($200 per billing code); and
- The cost of the National Joint Replacement Register (NJRR) which is a Government and Australian Orthopaedic Association initiative to collect post-marketing data that provides a prospective case series on all joint replacement surgery undertaken in Australia. The total costs to industry for funding these arrangements for 2015-16 were $2.24 million and are estimated to increase to $2.38 million over the forward estimates.

Examples of where and how the current arrangements are adding considerable costs to medical device companies are outlined below.

- The ARTG and the PL individually list every device, irrespective of whether the device in question is a component of a larger device (such as a patella in a total knee replacement system or a screw and wedge that is part of such a system). A fee is payable for the listing of each of these components. A more reasonable approach to the fee charging structure should be considered such as around the assemblage of components that is supported by the clinical evidence. Figure 9 below illustrates the number of components that may comprise a knee prosthesis and for which separate PL and ARTG fees are payable.

Figure 9: Components of a knee replacement



- There are overlaps in the assessments conducted by the TGA and the PLAC. This has been recognised by the various reviews conducted into the PL arrangements and recommendations have been made to reduce duplication and streamline the arrangements as much as possible[14]. A specific example relates to medical device sponsors being able to add medical devices under an existing ARTG entry providing that the device is of the same kind. However, the PLAC requires an application for assessment be made for these 'me too' devices. Despite review recommendations that PLAC should not assess 'me too' devices, these recommendations have not been implemented.

- There are significant delays in assessments by the TGA, the MSAC and the PLAC. While marketing approval by the TGA is sufficient to supply devices to public hospitals, there are significant delays in supplying devices in the private system through delays in MSAC and PLAC evaluations. While the MSAC assesses the services and procedures that will be subsidised under Medicare (rather than a specific prosthesis), a prosthesis cannot be listed on the PL without an MSAC recommendation to list a service or procedure which utilises that prosthesis.

- These delays come at significant costs to the industry especially as the effective market life of a device is relatively short due to the high rate of incremental improvement. There are case examples where by the time an MSAC recommendation was made four years after the original application was submitted that the relevant prostheses were superseded by other prostheses which were being supplied in the public sector.

MTAA proposed option for reform:
Improve the efficiency of the HTA process and reduce duplication between the PLAC and the TGA. This includes allowing devices of a kind already approved by the TGA to be added to an existing PL group without review by the PLAC and reviewing the fees and charges associated with obtaining and maintaining inclusions on the PL and the ARTG.

3. Conclusion

The MTAA recognises the public health system pressures and the important role that PHI has in alleviating these, particularly in light of the increasing burden of chronic disease and the ageing population.

The PL framework has played a significant and successful role in supporting PHI but there is scope for improvement to ensure that privately insured patients obtain best value from their contributions towards PHI.

In considering initiatives to reform the PL framework, particularly with respect to setting benefit levels, it is important that the implications for patients across the public and private hospital sectors

[14] The Industry Working group on Private Health Insurance Prostheses Reform Final Report – 2016 recommendation 4 states that 'the Government should consider opportunities for enhanced co-operation between the PLAC and the TGA to ensure activities are not inappropriately duplicated'.

are considered given the linkages and interdependencies between these two separate elements of the Australian healthcare system. As this submission shows, there are risks associated with implementing reforms in an arbitrary and segmented manner which ignore the whole of the system as the balance between public and private healthcare is delicate with Government relying on the implementation of policy levers to incentivise consumers to take up PHI.

In this submission the MTAA has offered its options for reform for the Committee's consideration. The MTAA believes these options will ensure that savings are delivered whilst strengthening a key element of the PHI system and supporting the value proposition PHI offers.

The MTAA looks forward to collaboratively working with Government to further progress the reform process that commenced in 2016 in order to ensure that patients are the ultimate beneficiaries of reform in the short, medium and long-term.