PROSTHESES BENEFIT SETTING FRAMEWORK

Comparative analysis of benefit setting models
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Executive Summary

A fundamental aim of the Prostheses List is to ensure choice and coverage of prostheses and devices for patients with private health insurance that need surgically implanted prostheses, human tissues or other medical devices. The Prostheses List now covers a wide range of devices where the total annual benefit paid has grown by almost tenfold since 1997 and currently totals around $2 billion per year.

The Private Health Insurance Act 2007 provides that private health insurers pay minimum benefits for appropriately insured policy holders for hospital treatment cover including prostheses listed in the Prostheses Rules.

The Prostheses Rules lists more than 11,000 devices and respective minimum benefits to be paid. The listing of prostheses occurs following assessment by the Prostheses List Advisory Committee upon meeting the regulatory and clinical requirements.

In late 2016, the Prostheses List Advisory Committee established a Reform Work Plan that progresses the recommendations of the Industry Working Group. One of the early pieces of work for the Committee is defining models that will create a more transparent basis for purchase and reimbursement of prostheses, including the consideration of options for new benefit setting mechanisms.

Prostheses regulation employed outside Australia

There is considerable variability in the pricing and reimbursement strategies between countries and the strategy employed is highly dependent on the structure of the healthcare system. Among the selected countries considered, France appears to have a healthcare system most similar to that of Australia where it has universal public health coverage and complementary private health cover.

Benefit setting strategies for existing items

This report focuses on the proposed benefit setting strategies for existing items on the list that are deemed most viable:

- Price disclosure
- Reference pricing
- Tendering – market based approach

It is important to recognise that these mechanisms are not mutually exclusive. These can be implemented in different stages of the reform, or can be used to set benefits for different types of items. For example, price disclosure or reference pricing could be used for existing items and tendering could be used for new classes of devices, when similar products are applying for listing at the same time.

In developing this report, the views and expertise from stakeholders of organisations impacted by the reform were sought and taken into consideration to ensure a broad
understanding of the potential impact. The relationships between key stakeholders were mapped to obtain a better understanding of each party’s value and incentive to participate in the prostheses market. Additionally, recognition of the composition of the Prostheses List benefit which represents a bundled benefit covering not only the device, but also the costs of additional services such as technical support and transportation is also an important consideration when deliberating the most appropriate benefit setting mechanism. In this respect, there needs to be greater transparency in the justification and costing of these additional services. This also highlights the potential differences between the private market prostheses price, the public sector and international prices.

Table ES1 provides a summary of the comparative analysis of the three main benefit setting models. Whilst all three approaches may have their advantages as well as disadvantages in setting benefits for devices, the relative success of implementation is largely based on the willingness of all key stakeholders to agree and commit to the chosen approach or approaches. Each of these models will require an injection of fresh resource or an expansion of currently available resources by all parties involved. Other potential considerations include the timeline on which reduction is expected to take into effect, for instance pharmaceutical price disclosure required numerous rounds of adjustments before substantial reductions were realised and in the case of simvastatin, this took over a decade.

**Potential for rationalising the List**

It is important to recognise that the size of the list will have an impact on the cost of implementing and administering any new benefit setting arrangements and a way to reduce the potential costs would be to rationalise the list. The two proposed options to achieve this are through:

- Removal of low cost items
- Exclusion of low volume items from ongoing benefit setting arrangements

Close to a quarter of the items on the Prostheses List have a benefit of less than $250, this includes items such as infusion sets, clips, screws and catheters. These low value items are used in high volumes and while there could be some variation between procedures it is likely that over time stable patterns of utilisation will be observed at a hospital level for many of these items. In these circumstances there is a case for treating these like surgical consumables and incorporating the cost into a revised theatre band or Diagnosis Related Group (DRG) fee.

Low volume items may include older generation items which remain on the list to ensure benefits are paid when these items need to replaced or adjusted. It is likely to be difficult to apply any of the proposed benefit arrangements to these items, as there is likely to be very little market competition and it will be difficult to find relevant comparators for regulatory processes such as reference pricing.

Both these options can lessen the administrative and regulatory burden to manage items on the list as well as to individually assessed benefits via any future benefit setting revisions.
Evaluating new technologies

There is considerable overlap in the types of technologies considered by the Medical Services Advisory Committee (MSAC) and the Prostheses List Advisory Committee (PLAC). The MSAC considers the cost of the device or prostheses in evaluating cost-effectiveness and setting the professional services fee, but is not directly involved in funding or setting benefits for the devices themselves. Therefore, there should be considerations to formalise a role for MSAC in assisting with setting of benefits for new prostheses on the basis cost-effectiveness information already submitted by sponsors and assessed by MSAC. This would require establishing a clear working relationship and communication mechanisms between MSAC and PLAC.

Implementation of new benefit setting arrangements

Much can be gained from undertaking a trial of price disclosure (e.g. ask sponsors to voluntarily provide disclosure and rebates to private hospitals for a range of prostheses) and a scoping exercise on the availability of reference prices within Australia (e.g. IHPA ability to collect such data) and internationally. While such trials delay the implementation of long-term benefit setting strategy, they are important ways to both help inform the design of future benefit setting arrangements and would facilitate much more accurate modelling of potential effects.

Both price disclosure and reference pricing, particularly if it involves disclosure of public hospital pricing, will require legislative changes. The price disclosure legislation for pharmaceuticals could provide a framework particularly in the comprehensive definition of what constitutes a rebate. Of the three proposed benefit setting strategies, reference pricing will require the highest level of involvement by PLAC, as benefits will need to be adjusted if evidence can be supplied by sponsors to justify additional benefit on top of reference price. All strategies will require additional resources for the successful implementation. A useful guide is the processes that are already in place for pharmaceutical price disclosure. It is important to note the cost of implementation depends on the number of items covered. We have made proposals on how the list can be rationalised which should be considered when developing future benefit setting arrangements.

The setting of benefits for new prostheses and devices poses its own unique set of challenges, particularly for new classes of devices where it is difficult to ascertain the benefit in relation to existing products on the Prostheses List. A combination of benefit setting arrangements (including tendering when there are multiple products applying for listing within the same class) is likely to be required.

The implementation of any of these strategies will require both careful planning and ongoing monitoring of outcomes. Reforms should facilitate more flexibility in the adjustment of benefits for prostheses and devices, which will help ensure the sustainability of the Prostheses List.
### Table ES1: Comparative analysis of benefit pricing models

<table>
<thead>
<tr>
<th>Benefit Setting Strategy</th>
<th>Price Disclosure</th>
<th>Reference Pricing</th>
<th>Tendering (market based mechanism)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Brief description</strong></td>
<td>Retroactive market based system. Requires all sponsors to participate in ongoing regular disclosure cycles whereby all sales revenue, volume sold and types and value of incentives are disclosed to the Department. Implementation may require significant legislative changes and mandatory participation from all sponsors to reveal ‘true’ price.</td>
<td>A regulatory benefit setting mechanism that base benefits on prices from other markets both internationally and domestically (i.e. state based purchasers for public hospitals). Prices could potentially be obtained from the purchasers or the sponsors (which may be a form of price disclosure). Reference prices may need to be adjusted to reflect additional costs of supply in the Australian private hospital market.</td>
<td>A prospective market mechanism that allows manufacturers to set prices for their products through a tender process. Benefits would need to be set to generate gaps (e.g. co-payments) for higher price devices and potentially rebates for lower price items. Scope for using a tendering arrangement for setting benefits for new classes of devices when more than one sponsor applies for listing.</td>
</tr>
<tr>
<td><strong>Advantages</strong></td>
<td>• Currently already in place for pharmaceuticals. • Allows for ongoing benefit adjustment where traded prices differ from current benefits. • Prices disclosed would be actual trade prices regardless of the level of additional services included.</td>
<td>• Used overseas in many countries for drug pricing and in Japan for devices. • Could be implemented largely within existing PLAC framework. • Facilitates movement in benefits to reflect changes in exchange rates. • Rapid benefit adjustment if large differences between external prices and existing benefits.</td>
<td>• Increases transparency and information flows to patients and surgeons about the cost of devices. • If patients were paid rebates for lower cost devices it would assist them in paying for gaps for other services (e.g. on MBS items). • Could provide a way to set benefits for some new classes of items.</td>
</tr>
<tr>
<td><strong>Risks and barriers</strong></td>
<td>• Limited information on the magnitude and extent of discounting. • Costs of implementation both on sponsors and PLAC are likely to be high. • Cannot be used to set benefits for items with no or limited competition.</td>
<td>• Difficulty in obtaining accurate reference prices. • Cost of assessing variations to reference prices could be considerable for sponsors and PLAC. • Will require adjustment of benefits to reflect additional costs in Australian private market. • Require PLAC to establish evidence-based mechanism to adjust benefits.</td>
<td>• A new approach that has not be tried elsewhere. • Require significant infrastructure change to manage tenders and inform surgeons and patient on choice and price.</td>
</tr>
<tr>
<td><strong>Potential next steps</strong></td>
<td>Undertake a voluntary round of price disclosure (using it to set benefits) to gain information and refine the design of benefit setting mechanism.</td>
<td>Look to obtain international and where possible domestic reference prices and assess the comparability with PLAC items.</td>
<td>Obtaining information on scope for tendering in potential new classes of devices and consult with surgeon and patient groups about acceptability of using tendering for existing items.</td>
</tr>
</tbody>
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1. Background

In Australia the *Private Health Insurance Act 2007* provides that private health insurers pay minimum benefits for appropriately insured policy holders, for hospital treatment cover including prostheses listed in the Prostheses Rules (see Appendix A for a historical overview of the Prostheses Rules and the Australian private health care system). The Prostheses Rules lists more than 11,000 devices and respective minimum benefits to be paid. Listing of each prosthesis occurs following assessment by the Prostheses List Advisory Committee (PLAC).

In early 2016, an Industry Working Group on Private Health Insurance Prostheses Reform (IWG) was established to explore opportunities to reform aspects of the Prostheses List. IWG provided a report that set out a number of areas for improvement and potential change. Among the recommendations to the Minister for an immediate benefit reduction was to apply cuts ranging between 7.5% and 10% across four main high cost categories of the Prostheses List encompassing cardiac, intra-ocular lens systems, hip and knees. The final report detailing the findings and recommendations of IWG is publicly available on the Department of Health website (http://www.health.gov.au/internet/main/publishing.nsf/content/iwg-phi-pros-ref).

In late 2016, the PLAC established a Reform Work Plan that progresses the recommendations of the IWG. One of the early pieces of work for the Committee is defining models that will create a more transparent basis for purchase and reimbursement of prostheses, including consideration of options for new benefit setting mechanisms. This report commissioned by the Department for Health supports this work.

This report proceeds in six sections. First it provides an overview of prostheses regulation and reimbursement strategies outside of Australia. It then examines in detail three proposed benefit setting strategies; price disclosure, reference pricing and tendering. The report then posits ways to rationalise the list and strategies to evaluate new technologies. The report concludes with a set of recommendations for implementation.
2. Prostheses Regulation and Reimbursement Employed Outside Australia

2.1 Differences across systems

Pricing and reimbursement strategies for medical devices vary considerably between countries. The strategies are highly dependent on the structure of the healthcare system, including the source of finance and the nature of health care provision (i.e. the various combinations of private-public finance provision that can co-exist). In a number of instances it is possible to source information on both the listing process and the list price but detailed information on how inclusion and pricing decisions are made are limited (Sorenson & Drummond, 2014), therefore there is a general lack of transparency in this respect.

Table 1 provides an overview of how prostheses are regulated in a number of selected countries. Further details of the French, Taiwanese, German and Canadian systems are given in Appendix B.

2.2 Comparability with Australia’s complementary healthcare system

Among the selected countries, France appears to have a healthcare system most similar to that of Australia where it has universal public health coverage and up to 86% of its population having complementary private health cover (Colombo & Tapay, 2004). For products to be listed in the Liste des Produits ed Prestations Remboursables (LPPR, French equivalent of Prostheses List), applications must be made to the National Commission for the Evaluation of Medical Devices and Health Technologies (CNEDiMTS) which will assess the technical and clinical aspects of the technology and graded against existing technologies (http://www.has-sante.fr/portail/jcms/c_419486/fr/commission-nationale-d-evaluation-des-dispositifs-medicaux-et-des-technologies-de-sante). Submission to the Economic Committee for Health Products (CEPS) justifying the reimbursement price is also required as part of the process. Information required for submission includes a breakdown of manufacturing and distribution costs, sales forecasts, reimbursement status in other EU states and company information. CEPS is responsible for price determination or setting of tariffs for reimbursements and mechanisms used include entering into price-volume agreements with sponsors (http://social-sante.gouv.fr/ministere/acteurs/instances-rattachees/article/ceps-comite-economique-des-produits-de-sante).

By comparison, both Australia and Japan appear to have regulatory systems which do not encourage competition. In Japan, hospitals are reimbursed at the listed reimbursement price and may not have a strong incentive to procure devices at lower prices as reductions in market prices lead to a decrease in reimbursement price thus impact on profit margins (Ide et al, 2007). However prices are reviewed every 2 years through some form of price disclosure of actual purchasing price by medical institutions. Whilst in Australia, there are no price revision mechanisms currently in operation.
<table>
<thead>
<tr>
<th>Country</th>
<th>Australia</th>
<th>United States</th>
<th>United Kingdom</th>
<th>France</th>
<th>Taiwan</th>
<th>Japan</th>
<th>New Zealand</th>
</tr>
</thead>
<tbody>
<tr>
<td>Healthcare system</td>
<td>Publicly funded (with duplicate private insurance)</td>
<td>Mixed (Predominantly private, public programs for specific populations)</td>
<td>Publicly funded</td>
<td>Publicly funded (with complementary private insurance)</td>
<td>Publicly funded (single national payer)</td>
<td>Publicly funded (multiple payer)</td>
<td>Publicly funded</td>
</tr>
<tr>
<td>% Private health insurance coverage</td>
<td>55.8¹</td>
<td>71.9²</td>
<td>10²</td>
<td>86²</td>
<td>64.8⁵</td>
<td>Negligible²</td>
<td>35²</td>
</tr>
<tr>
<td>Procurement process</td>
<td>State executed tendering process (public); Individual hospital purchase (private)</td>
<td>Individual organisations make their own purchases. Practices include selective contracting⁸</td>
<td>Single national approach for purchase and supply of devices (tendering process)³</td>
<td>Public hospitals purchase through tenders</td>
<td>Individual organisations make their own purchases</td>
<td>Individual organisations make their own purchases</td>
<td>National contracting (e.g. volume-based agreements)⁶</td>
</tr>
<tr>
<td>Reimbursement system</td>
<td>DRG (public); Prostheses List – patients face no gaps (private)</td>
<td>DRG</td>
<td>Healthcare Research Groups (HRGs – activity based grouping)</td>
<td>DRG and LPPR (List of Reimbursable Products and Services)⁸</td>
<td>National Health Insurance Pharmaceutical Benefits and Reimbursement Schedule listing required. Partial coverage as patients face gaps “balance billing”</td>
<td>Low-risk devices are reimbursed as part of procedure fee. Medium/High-risk reimbursed at listed price</td>
<td>As listed in the Pharmaceutical Schedule</td>
</tr>
<tr>
<td>Reimbursement price setting</td>
<td>Prostheses List benefit based on functional groups. Adjustments allowed through suffixes</td>
<td>Competitive pricing</td>
<td>Competitive pricing (bundled products and service agreements)</td>
<td>LPPR price – Determined based on manufacturing cost, marketing, training, etc. and negotiations with Ministry of Health⁸</td>
<td>Based on the lowest price in same functional category. Adjustments for innovation and improved function allowed. Reviewed every 4 years – price-volume survey participated by suppliers and medical institutions</td>
<td>Standard price of functional groups determined by weighted average of current market price; adjusted if greater than foreign average prices.⁵ Reviewed every 2 years – actual purchasing price by medical institutions</td>
<td>Competitive pricing from tenders</td>
</tr>
</tbody>
</table>
Source:

3. Benefit Setting Strategies for Existing Items

There are a number of different frameworks for regulatory benefit setting and models for benefit pricing. Below we explore price disclosure, reference pricing and tendering in detail, as these are deemed to most likely to be operationalised given the historical and institutional environment in Australia.

3.1 Price Disclosure

Price disclosure can be termed a retrospective market based system for setting benefits. It has been in operation in Australia for setting benefits for pharmaceuticals for almost a decade. Its implementation required significant legislative change at its introduction and a series of refinements to ensure the system operated as originally intended (Abbott T. Transcript of Press Conference – PBS reform Commonwealth Parliamentary offices, Sydney, 16 November 2006) which was to reduce the benefit paid so they more closely reflect world prices. It is important to note that there are differences in the market for pharmaceutical products and for prostheses and devices in Australia. This section will first outline price disclosure as it has been implemented for the setting of benefits for pharmaceuticals and then discuss ways it could be adapted to set benefits for some items on the Prostheses List.

3.1.1 Operation of price disclosure in setting benefits for pharmaceuticals in Australia

The introduction of price disclosure was to address the problem that Australia paid much more for generic pharmaceuticals than many other countries. The then Minister for Health and Ageing, Tony Abbott, noted at the time of price disclosure introduction:

“the common cholesterol-lowering drug simvastatin, which currently costs the PBS about $300 million a year, we here in Australia pay more than $50 for this drug. In the UK, they pay less than $10 for that drug. Now the difference in price under our system as it currently stands is mostly accruing to pharmacists by way of discounts and so what we are trying to do with these changes is to harvest most of those discounts for the benefit of taxpayers.” (Abbott T. Transcript of Press Conference – PBS reform Commonwealth Parliamentary offices, Sydney, 16 November 2006)

The introduction of price disclosure required considerable legislative change. In particular, the PBS was divided into two separate formularies: F1 which is for single-brand patented medications; and F2 for drugs where multiple brands are available. The introduction of these changes was accompanied by a regulatory price cut to some generics by 25% prior to the commencement of price disclosure.

Initially there were relatively few price reductions as participation was voluntary and the industry was not obliged to reveal actual wholesale prices of most generic drugs. To address this problem, the Department of Health and Ageing and the peak pharmaceutical industry body, Medicines Australia, negotiated changes to price disclosure (Australian Government and Medicines Australia, 2010). This agreement included a provision to reduce the price of
older medications on the PBS, starting with regulated reductions and then benefits were
determined through a policy known as Expanded and Accelerated Price Disclosure, in which
pharmaceutical suppliers were legally obliged to reveal to the Government the actual price at
which they sell their products to pharmacies. This takes into account discounts (a price that is
below the currently determined benefit), rebates, or other types of inducements (discounts on
other products). Future prices are then set using a weighted average of these disclosed prices.

The first round of price disclosure reductions was in April 2012 and the large drops across a
wide range of medications showed that discounting of the wholesale price of generics was
common place in the retail pharmacy sector.

To understand the benefit setting arrangements it is useful to work through a practical
example of how it determined the price of each drug as illustrated in Figure 1. Take the
commonly prescribed cholesterol lowering medication Atorvastatin, in 2014 its retail price
was $30.52 which was paid partly by the patient (concessional patients were required to pay
the first $6 at that time). The rest of the cost is paid by the Government (in the case of
concessional patients which would have amounted to $24.52, which covers pharmacy and
wholesale mark-ups as well as the ex-manufactures price). Sponsors can sell Atorvastatin to
pharmacies for prices below this ex-manufacturers price which generates discounts that
pharmacies can retain.

Figure 1: Make-up of the retail price of Atorvastatin 40mg

[Diagram showing the breakdown of the retail price]

Notes: Based on prices at April 2014 as listed on the Pharmaceutical Benefits Schedule
and information provided as part of the Price Disclosure Reductions for 2014 October

The approved ex-manufacturer price of Atorvastatin (the price the Government expects to
pay to cover the wholesale cost of the drug) was $19.32 in early 2014 (Price disclosure
reductions, 2014). Price disclosure data indicated that the actual average supply price was
$10.45 and so on average each pharmacy dispensing this drug received on average $8.87 in
discounts from manufacturers. These discounts represent an extra source of revenue over and
above dispensing fees and mark-ups for pharmacies.
As indicated above price disclosure works by collecting the actual traded prices from manufacturers and using these to set the future prices of all F2 drugs when discounts exceed a certain level (currently 10%). In the case of Atorvastatin the price was adjusted to reflect the lower ex-manufacturer price, thus reducing the benefit covering the ex-manufacturer price from $19.32 to $10.45.

How successful was price disclosure in reducing the price generic medications to match world prices? Figure 2 below which plots the cost per tablet of a commonly used dose of a statin (Simvastatin) in Australia and England since 2005, which is around the time the drug came off-patent in Australia. In 2006 the ex-manufacturer price of Simvastatin in Australia was over 17 times greater than the comparable price in England. Since that time, price disclosure has narrowed this gap to a point where the Australian price in 2014 is just above the cost in England. It would appear that price disclosure has achieved the objective, but it took almost a decade for the prices to adjust.

**Figure 2:** Comparison of Simvastatin price between England and Australia over time

![Simvastatin Price Comparison](chart.png)

**Notes:** Comparisons based on exchange rate at Feb 2015 $1 Aus = 0.50 pence.

**Data sources:**
Prices calculated from various PBS schedules
([http://www.nhsbsa.nhs.uk/PrescriptionServices/1821.aspx](http://www.nhsbsa.nhs.uk/PrescriptionServices/1821.aspx));

### 3.1.2 Operation of price disclosure for setting benefits of prostheses and devices

There are a substantive number of differences between the operation of price disclosure in setting benefits for pharmaceuticals and the setting of benefits for prostheses. For many generic pharmaceuticals, the wholesale market is highly competitive as there are many
suppliers (for Simvastatin there are 14 companies are currently listed on the PBS) and the pharmacies purchasing the drugs directly benefit from the discounts offered by alternative suppliers. The competition leads to sizeable discounts that have produced large price reductions of over 90% for some generic medications.

The market for prostheses is substantially different; here the market transaction is between sponsors and private hospitals. However, unlike pharmacists, the management of private hospitals does not directly make purchasing decisions regarding the brand of prostheses to be implanted.

Traditionally in the private sector the decision regarding the prostheses is seen as being made by the surgeon, in consultation with the patient. While some private hospitals may have influence on the choice of suppliers, through mechanisms such as providing space to keep inventories on site, this influence is less direct than in the case of pharmaceuticals. It is therefore much harder to forecast the possible impact the introduction of price disclosure will have on the level of benefits for particular items and on the overall expenditure on the Prostheses List. A further complicating matter is the specialisation of both sponsors and private hospitals in particular types of prostheses and so few are in a position to have direct knowledge of more than a segment of the prostheses market. Hence the impact of price disclosure on benefits is subject to a high degree of uncertainty which cannot be reduced without obtaining detailed information on traded prices for a wide range of prostheses and devices in the Australian market place.

In this circumstance, it would be useful to request that sponsors voluntarily disclose data on traded prices before determining if a price disclosure system could be operationalised. This would not only provide information on the level of discounting, but would also allow the costs of implementing such system to be assessed, both by sponsors who would have to file returns disclosing traded prices for a wide range of products and by PLAC who would oversee the calculation of the weighted average traded price that would be used to set future benefits.

3.1.3 Implementation of price disclosure

It is instructive to understand how price disclosure has been implemented for pharmaceuticals before discussing the requirements for its implementation for prostheses.

The current process for setting benefits for F2 medications on the PBS operates with an ongoing regular disclosure cycle which has a six-month data collection period, a six-month processing period followed by a reduction day (Figure 3). With the exception of certain exempted items, all brands of PBS listed pharmaceutical items containing a drug on the F2 formulary are subject to price disclosure.
The collection and submission of information for each brand of pharmaceutical item for price disclosure is the responsibility of the nominated ‘responsible person’. The specific information that is required for each period includes:

- All sales revenue;
- Volume sold;
- Types of incentives provided for the brand in the given period; and
- Value of incentives provided for the brand in the given period.

Data submitted pertains to all sales of the said pharmaceutical item except to public hospitals. The Department has also provided detailed information on the types of incentives to be provided which includes cash or volume discounts, patient support programs, goods in-kind among others. The exact method of extracting and preparing the required data is not explicitly specified by the Department and it is up to the responsible person to ensure the appropriateness of the methodology. Audits may be conducted by the Department where information such as price disclosure data and methodologies may be requested (http://www.pbs.gov.au/industry/pricing/price-disclosure-spd/price-disclosure-operational-guidelines-06-2016.pdf).

Price disclosure data are required to be submitted prior to a specified due date and is done electronically through the Price Disclosure Submission Utility (PDSU) to the Price Disclosure Data Administrator (PDDA). The PDDA is an independent service provider contracted by the Department to provide and manage data services for price disclosure which includes compiling the data and completing preliminary calculations to determine the weighted average of disclosed price (WADP). Penalties will apply in the event of non-compliance by the responsible person. Brands of items containing the same F2 drug with the same mode of administration fall under the same group where WADP is calculated. The Minister (or delegate) finalises the decision on WADP determinations which will inform on the reductions to be made. These reductions will then be announced by the Department and
applied on reduction day. Where there are concerns following the outcomes of each price disclosure cycle, these can be raised following the Price Disclosure Dispute Resolution Administrative Process within five business days after the outcomes are notified.

Similar to the pharmaceuticals, to operationalise price disclosure arrangements for prostheses, implementation would require considerable legislative changes and it is likely to involve several rounds of disclosure to cover items on the Prostheses List and to achieve substantial reductions. However, it should be noted that unlike pharmaceuticals where there is a large variety of brands for the same product, the market for some prostheses is thin (i.e. a market where there are a few buyers and sellers). Hence disclosure arrangements would need to apply at the group level.

A team similar to that managing the Pharmaceutical Price Disclosure would need to be established or an expansion of the current team to manage items of the Prostheses List. Additional support from external consultants or contractors would also be required or be expanded. Ultimately the cost of operationalising such an arrangement would need to be weighed against the potential gains in benefit reductions and the eventual impact on patient’s affordability and access to private health care.

### 3.2 Reference Pricing

Reference pricing, sometimes referred to as external reference pricing or international reference pricing, is where the price(s) of a health technology in one or more countries are used to derive a price for the purposes of setting or negotiating the price of the technology in a given country. As with price disclosure it is a relatively common for pharmaceuticals, but less used for medical devices and prostheses. The one exception to this is Japan, which has had a long history of using reference pricing including using it to price prostheses.

A recent review of external reference pricing in Europe found that 24 of 28 countries studied used reference pricing to some extent for pharmaceuticals (Leopold et al., 2012). Neither the UK nor Sweden use reference pricing, and it is well known that getting a list price in the UK opens the market to manufacturers in many other European countries, so despite the lengthy process to seek reimbursement many manufacturers still pursue approval in England. The methodology employed for reference pricing is discussed below. There are a number of challenges associated with undertaking cross-national comparisons of prices for pharmaceuticals and these are also relevant for medical devices, but there are likely to be additional issues with the application to devices and prostheses which are also discussed.

#### 3.2.1 Reference pricing methodology employed globally

There are at least six different algorithms that can be used to generate reference prices (Richter, 2008). The simplest approach involves using the lowest price from a basket of reference countries. The next easiest (and most common) is to take an average of the price of the technology from a basket of reference countries. It may be that this is limited to a basket of countries with the lowest prices or that the median is used rather than the average in order
to mitigate distributional effects. This estimated price may be further adjusted by applying weights to maintain historical price differentials between the country of interest and the reference basket countries. An alternative weighting approach is to use weights according to sales penetration (as is used in Mexico) or weights to reflect a country’s purchasing power (so weighted by GDP per capita). Innovation weights could also be applied; this happens in Japan.

A key determinant of reference pricing approaches is the basket of reference countries. A recent review found that the basket most often comprised of countries from surrounding geographical areas, i.e. European countries most commonly reference price from other European countries (Lorgelly, 2014). Baskets often composed of five or more countries, although this was much higher in Europe but this is perhaps driven by the existence of prices in these countries. Leopold et al. (2012) analyses of European reference pricing for pharmaceuticals found a relationship between a country’s income per capita and the average rank of the reference country, so high income countries more frequently referenced high income countries in their baskets, while lower income countries refer to other lower wealth countries. It is important to highlight that the wide use of reference pricing can mean that a country is reference pricing from country that is reference pricing and so on.

Japan uses a multi staged approach to price setting for prostheses. The price of innovative technologies is determined through zero-based pricing which breaks down manufacturer costs. This price is then compared to those of the United Kingdom, the United States, Germany, France and Australia. If the initial price is more than 1.3 times the international average (previously 1.5 times), it will be reduced by up to 25 percent. Japan further incentivises innovation by applying an additional premium to products that launch in Japan within 180 days of their US release (Private Healthcare Australia, 2015).

### 3.2.2 Reference pricing in practice in Australia

The first step in implementing reference pricing is to select the reference countries. Given Australia’s social policy and economic environment, it would be unwise to use the prices of countries in the Asia-Pacific, except perhaps that of New Zealand. It would be necessary to select countries that are similar in terms of the income level and the level of development, this should ensure that many of the same prostheses and devices are available within the healthcare system, such that prices would be available. Countries of interest might include: Austria, Belgium, Canada, Denmark, Finland, France, Germany, Ireland, Italy, Japan, the Netherlands, New Zealand, Norway, Spain, Sweden, Switzerland, the UK and the US. It is important to note that these countries may already undertake reference pricing, such that the inclusion of them may exacerbate prices, somewhat of a circular pricing formula, which will ultimately result in a global price (Seiter, 2010).

Reference pricing would normally involve some type of weighted average of past exchange rates (e.g. a moving average of past five years) and be undertaken periodically (e.g. every two years). However, a potential benefit for sponsors of international reference pricing is that benefits could be adjusted either upwards or downwards based on changes in the exchange rate as and when a periodically review is undertaken. The removal of the need to absorb
exchange rate risk should facilitate some reduction in the benefit across the board, but would mean benefits would be subject to exchange rate movements.

An alternative specific to the Australian complementary health system is that state hospital prices could be used, that is internal (or domestic) reference pricing, or even a combination of domestic and international prices.

The next step in implementing reference pricing is to gain access an external set of prices on prostheses and devices that covers the items on the Prostheses List. It will be necessary to understand exactly what this price covers (for instance, does the quoted price include freight and any associated support). As the previous section highlights international information on prostheses and devices is less common than for pharmaceuticals where it is available both publically (NHS Drug Tariff) and from commercial firms such IMS.

A previous review (Lorgelly, 2014) was able to source prices for drug eluting stents and knee femoral components from the US, France, and Belgium, but not all countries provided prices for all technologies. The source of these prices came from publicly available documents in Belgium, France and the US. They are therefore the published ‘list’ price. The availability of public prices for all of the products or groups on the Prostheses List is unknown internationally and it would involve considerable transaction costs for the Australian Government. Importantly the prices paid for use of devices in public hospitals are not available publicly. Prices are normally set by tenders and are usually commercial-in-confidence with limited exceptions.

One method to obtain reference prices would be to require sponsors to disclose supply prices for public sector domestically (which would be an extension of the price disclosure arrangement outlined above) or of the products’ international prices. If this approach was adopted it would be important to capture any additional inducements (such as rebates) that were associated with the sale of the product. Another potential source of domestic public sector prices is Independent Hospital Pricing Authority (IHPA) data collection which includes device and prostheses costs for the purposes of deriving DRG cost weights.

Critical for implementation would be the need for PLAC to ensure that benefit takes into account of any differences in the use of the product in Australian private hospital setting. In our consultation with sponsors many potential reasons were highlighted to justify a variation on the benefit from either a domestic or international reference price. Potential factors include:

- Costs of freight;
- Cost of maintaining large inventories in relation to the volume of devices supplied;
- Technical assistance provided at the time of implantation;
- Ongoing support for the device.

If a reference pricing system was implemented to set the benefit level it should take into account these factors and whether they are consistent with benefit setting policies of PLAC. The cost of these factors would be covered at least to some extent in the domestic public
price and international prices and any additional cost would need to be justified through evidence from the sponsor.

Hence a reference pricing approach could involve a two-stage procedure (Figure 4). First the sponsors are notified of the reference price that is used to set benefits in the absence of evidence of the need for adjustment. Sponsors could then provide a case for such adjustments based on evidence of what extra services are provided over the market from which the reference price is obtained. To assist sponsors and to ensure comparability and transparency, PLAC could provide reference costs for factors such as freight that would be used in calculations by sponsors for variations to reference price. The submission should be assessed by Clinical Advisory Groups (CAGs) to determine if the additional technical support is clinically appropriate and the cost calculation that form the basis of the submission would be reviewed by PLAC’s Health Economics Sub-Committee (HESC) before making a final benefit determination.

**Figure 4: Two-stage reference pricing approach**

As determined by PLAC through reference pricing - Base price to set benefits.

If no adjustments proposed, this is then set as benefit on Prostheses List.

Sponsor to justify adjustments, if necessary.

These will be submitted for assessment by:
(i) CAG (establish clinical need)
(ii) HESC (cost considerations)

Revised benefit on Prostheses List.

Once a set of relative benefits has been established it may be possible to reduce administrative requirements, by estimating a ratio of the relative benefits set by PLAC over the reference prices. This ratio could be applied in future rounds (i.e. a percentage added to take into account the different conditions that exist in the private hospital market) unless sponsors can provide evidence for the need for a separate variation).
3.3 Tendering - Market based benefit setting

The final approach to benefit setting would be to allow sponsors to set their own prices through some form of tendering process such as that routinely used by State based purchasing authorities such as Health Purchasing Victoria. Tenders are one of the most frequently used approaches for national public hospital purchasing and are used in countries such as the UK, Spain and Italy where the healthcare systems are predominantly publicly funded, nationalised systems. While there is a wide range of arrangements that could be put in place, it is unlikely that this would involve preferred supplier arrangements for private hospitals as these limit patient and surgeon choice of the type of prostheses and device. Tendering arrangements by themselves do not promote competition and so several conditions would be required for market forces to operate:

- There would have to be more than one supplier for a class of products and all items within that class would have to be judged to deliver clinically equivalent outcomes;
- Benefits would need to be set at a level which would generate price signals to patients in the form of gaps or out-of-pocket payment which would arise when the price of a product exceeded the benefit;
- There would also be scope to reward patients for choosing prostheses or devices which were priced below the benefit for the class with a rebate that could be used to cover other out-of-pocket costs;
- Patients would need to be informed of the prostheses or devices within a class deemed clinically equivalent and the gap-payments or rebates associated with devices within the class.

As Figure 5 illustrates the method of benefit setting will determine the price signals that patients will face. For example as demonstrated in Case 1 below, if benefits are set at the lowest supplier’s price (Supplier F), then a patient will face gap payments for a large number of devices within the class. Alternatively, if the benefits are set at the highest price (Supplier A) to ensure no gaps (which is the current situation – Case 2) then there is no incentive for sponsors who could offer lower price devices to accept a reduced benefit. Instead the difference between the price and benefit (which economists call producer surplus) is shared between the sponsor and private hospitals via rebates. The final scenario (Case 3) is to set the benefit based on the minimum level of volume supplied (e.g. it could be set at the median price). Here patients would face co-payments for devices that costs more than the benefit and potentially they would have incentives to choose lower cost devices which are priced below the level of the benefit for that class of product.
Figure 5: Potential scenarios through market based benefit setting

<table>
<thead>
<tr>
<th>Case 1: Benefit at the lowest price</th>
<th>Implications</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>The benefit would be set based on the lowest price of devices received within the category.</td>
</tr>
<tr>
<td></td>
<td>All other devices would require the patient to pay a gap or co-payment.</td>
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<table>
<thead>
<tr>
<th>Case 2: Setting benefits at the highest price</th>
<th></th>
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<tbody>
<tr>
<td></td>
<td>The benefit is set at level that is equal to the highest price within the category.</td>
</tr>
<tr>
<td></td>
<td>There is no mechanism for patients or private health insurers to pay prices below this benefit. Rebates for lower priced devices could be given to private hospitals.</td>
</tr>
<tr>
<td></td>
<td>This is the current situation operating for benefit setting for most items on PLAC.</td>
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<table>
<thead>
<tr>
<th>Case 3: Benefits based on a minimum level of volume</th>
<th></th>
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<tbody>
<tr>
<td></td>
<td>The benefit would be set based on volume (e.g. the median price based on volumes used in the Australian market).</td>
</tr>
<tr>
<td></td>
<td>Here higher priced devices would have gaps and potentially prices below benefit could attract rebates for the patient. Or possibly rebates to the hospital to encourage use of the product.</td>
</tr>
</tbody>
</table>

An effective tendering scheme would require careful design to ensure incentives for competition, while maintaining patient choice and access to a range of prostheses.
3.3.1 Tendering system in Australia

While tendering arrangement are widely employed to set prices in the public sector by State based purchasing authorities, most of the conditions required for such an arrangement do not currently operate in Australian private market for devices and prostheses. Hence the adoption of such an approach would require significant changes for both private health insurers and surgeons as it requires the patient to make more device centric decisions. For example, patients would need to be informed of the co-payments (and potentially rebates) for each device and be provided with information concerning which surgeons implant the no-gap devices. Such an approach would require careful consideration and stakeholder consultation as it represents a significant departure from the current process in the choice of device (i.e. a decision made by the patient on advice from the surgeon).

One possible role for tendering in Australia is in determining the benefits for new classes of products when more than one sponsor is applying for listing at the same time. In these circumstances one could organise a tender to set the initial benefit. Instead of adopting sole supply arrangements (which has been used by PHARMAC in New Zealand for insulin pumps) it would be possible to favour earlier access for the sponsor that is prepared to accept the lowest Prostheses List benefit. Sponsors that proposed higher benefits would have to wait a period before they could be listed (e.g. six months). Such a process could engender significant competition if sponsors deemed it to be advantageous to be the first product on the Prostheses List.

For such a strategy to work effectively, PLAC would have to consider the listing of classes of new products and invite all sponsors with products that are expected to be available before an expected listing date to apply for listing at the same time. As we outline in section 5.1 there is a significant lag in obtaining an MSAC approval for the associated MBS item of around 21 months which presents an opportunity to implement a tender process if more than one product is available at the time the MSAC item is approved. The MSAC could also provide a maximum guide price (based on cost-effectiveness threshold) for these products. Sponsors could indicate that they are willing to accept a lower benefit than that proposed through the MSAC process. The advantage of employing tenders for setting benefits in new classes of products is that the benefit could be set at the sponsors proposed price and so there would be no gap.

More generally the role for tendering is limited if it is the objective of PLAC to continue with no, or few gaps, for existing products. While it is possible to point to market places for consumers to make purchasing decisions regarding private health insurance products, it is hard to identify such a market operating for devices and so this option would require the greatest level of change among all of the benefit setting alternatives considered in this report.
3.4 Funding based on outcomes

There are some items on the Prostheses List that receive a greater benefit because they are deemed to produce results that are clinically superior to other devices within the same grouping, for the indicated uses. This has primarily involved use of orthopaedic prostheses where performance is based on Australian registry data. It only relates to well established devices, in that it requires a minimum of 10 years follow-up and a minimum level of performance (greater than 95% survivorship). These prostheses after the evidence is assessed by both CAGs and PLAC are denoted by a superior clinical performance suffix which means they are paid an additional benefit. Currently this only applies to a limited range of items where registry data are available.

Such arrangements of linking benefits to long-term outcomes is not a common feature of other types of health care products (e.g. no premium is paid for older generations of pharmaceuticals if they are shown to be as effective as newer more expensive products). The basis for adopting such an arrangement is that it is a way of linking benefits to evidence regarding patient outcomes, which maybe important when the long-term performance of devices cannot be prospectively assessed. Given the nature of evidence collected from registries such benefit setting arrangements can only be used for well-established products.

If the concept of rewarding superior performance is accepted as a basis for setting benefits, it is difficult to see why products with inferior clinical performance (e.g. those with lower survivorship) should not be penalised by setting a lower benefit. One way to implement such a scheme would be to use relative performance, i.e. denote those prostheses in the top 20% in terms of survivorship as superior and those in the bottom 20% with inferior performance. Those with superior performance could receive an additional benefit that is equal to the reduction in benefit of those with inferior clinical performance. An advantage of implementing such a system is that it could be cost neutral in regard to overall expenditure and provide a signal regarding devices that have a higher failure rate but have not reached the threshold for removal from the market. For devices and prostheses whose performance is not tracked by registries it may be possible to adjust benefits through a review process when new evidence emerges on the effectiveness, or cost-effectiveness after it has been listed.
4. Rationalisation of the Prostheses List

The total number of items on the Prostheses List is at 11,146 (as of February 2017). While these items meet the criteria for listing, it is important to recognise that the size of the list will have an impact on the cost of implementing and administering any new benefit setting arrangements. All of the proposed benefit setting arrangements will involve costs to all key stakeholders (for example, price disclosure requires manufacturers to report any form of discount provided for each item on the list). One way to reduce these costs would be through a rationalisation of the size of the list, or through regulatory arrangements that linked the benefit paid across different items on the list.

4.1 Removing lower cost items from the list

The lowest minimum benefit for an item on the list is $7 and close to a quarter of the items on the list have a benefit of $250 or less (Figure 6). These items include insulin infusion sets, ligating clips, ventilation tubes, orthopaedic fixation screws and plates and neurosurgical or gastronomy catheters. These items meet the listing criteria and are considered as separate items on the list. Multiple quantities of these items are likely to be used in a single operation and at a hospital level they will be used in high volumes over the course of a year.

Figure 6: Distribution of items in Prostheses List by benefits

In such circumstances, it is potentially more efficient to make payments based on expected rather than actual use, as this would facilitate a single payment, rather than each item having to be separately accounted for after each operation. Such a principle underlies the DRG payment system which uses a cost-weight that is based on an expected rather than actual cost. Using such a mechanism for payment would require removal of low benefit-high volume items and incorporating these into a DRG cost weight (or as part of a theatre band fee if day
surgery). For insurers that are not currently using DRG cost weights to pay for services it may be possible to quantify the contribution of these items separately to allow these insurers to make a single payment per separation based on the DRG (e.g. a fractional DRG weight that reflects the cost of items that are removed from the list).

It is important to note that there are potentially risks associated with this approach including perverse incentive for sponsors that are near the lower threshold to raise their prices to be included in the list. However, it is also possible that some sponsors who have higher priced devices would prefer to offer bulk purchases, as opposed to the current arrangements which involve purchase for each individual device sold. Hence further consultation with all relevant stakeholders would be required before implementing such an approach, but a payment mechanism that is based on expected rather than realised costs could an efficient way to pay for a range of items on the list.

PLAC should also assess whether any items on the list are already paid via other mechanisms. According to the report by the Private Healthcare Australia (2015), it was noted that some of these items which are commonly used in surgical procedures are in fact already included in the theatre fees or hospital payments, so PLAC should investigate if there is double reimbursements or payments for some of these items.

### 4.2 Low-volume items

Some items which have been superseded by more recent prostheses or devices remain on the list as this enables benefits to be paid when items need to be replaced or adjusted. It is difficult to use any of the benefits setting arrangements proposed in the sections above as there is likely to be very little competition and they are difficult to implement regulatory process such as reference pricing. Either these items could be excluded from any benefit setting arrangements, or they could be systemically reviewed to link the benefit paid for these items to comparable higher volume items that are used on the list.

Both these options would lessen the administrative and regulatory burden of PLAC to manage these items as well as to individually assess benefits set via any future benefit setting revisions.
5. Health Technology Assessment for New Technologies

The evaluation of new prostheses not currently funded or with demonstrated superior effectiveness warrants special consideration. This evaluation is likely to require an assessment of effectiveness and cost-effectiveness to establish an initial benefit particularly when there is only one (or a limited number of sponsors).

The Medical Services Advisory Committee (MSAC) has an independent role in evaluating new medical services for public funding on the basis of safety, clinical effectiveness, cost effectiveness and total cost (http://www.msac.gov.au/). Its principal role is to advise the Australian Minister for Health on new medical technologies and procedures and decisions about public funding. The majority of MSAC assessments are for funding of new technologies but the evaluation of amendments and reviews of existing services are also considered by MSAC.

MSAC considers a broader range of professional services associated with devices than meet the criteria for prostheses. The TGA (https://www.tga.gov.au/what-medical-device) definition of device is used as follows but MSAC does not place restrictions on the types of technologies it assesses:

Medical devices:
- are used on humans;
- have therapeutic benefits;
- generally have a physical or mechanical effect on the body or are used to monitor functions of the body.

The main distinctions between the definition of device and prostheses are that devices do not need to be implanted and do not need to replace a bodily function.

5.1 Historical interaction between MSAC and PLAC

There is considerable overlap in the types of technologies considered by the MSAC and PLAC. We reviewed MSAC decisions and assessments performed since 2010 to understand the extent to which prostheses are involved in the MSAC assessment. Since 2010, a total of 127 applications have been received by MSAC that have led to funding decisions (a number more are still under consideration). These applications relate to 106 distinct technologies. Of these technologies 58 (55%) were related to devices and 16 (15%) were related to prostheses, 28% of devices were also prostheses. This indicates that MSAC is receiving a considerable number of applications that relate to prostheses as well as devices.

The role of MSAC in evaluating a submission for a prostheses or device is in setting the MBS item fee which relates to the professional services delivered. Professional services can be
rendered to non-admitted patients (by general practitioners, practice nurses, specialists, etc.), or as part of an episode of hospital treatment (other than public patients), or as part of a privately insured episode of hospital-substitute treatment (Medicare Benefits Schedule Book Category 3, 2016). The MSAC considers the cost of the device or prostheses in evaluating cost-effectiveness and setting the professional services fee, but it is not directly involved in setting the benefits for devices itself.

There is some level of communication between MSAC and PLAC. MSAC will occasionally refer an application or specific information to PLAC. For example, with Application 1347.1 for Transcatheter occlusion of the left atrial appendage for patients with non-valvular arterial fibrillation, MSAC supported the application for a proposed item number to perform the procedure (Fee $912.30) but communicated to PLAC the following:

“MSAC noted that costs to private health funds and patients for purchase of the device and hospital admission were likely to be five times greater than MBS costs. MSAC expressed concern about the high cost of the device (redacted) and suggested that the Prostheses List Advisory Committee (PLAC) be advised of MSAC’s concerns with the use of these devices.” (Public summary document Application No. 1347.1 [p.4], 2016).

It is not uncommon, as in the example above, that the cost of the device will be much higher than the cost of the professional services listed on the MBS. If the proposed cost of the device or prostheses leads to a MSAC application that is considered cost-effective there may be no reference to PLAC in the Public Summary Document and MSAC decision. Furthermore, the exact cost of the device or prostheses may not be disclosed but rather may be part of a bundled package of care including support, training and costs to insurer and patient. For example, with Application 1150 Insertion of colonic stents for the management of malignant large bowel obstructions a recommendation was made by MSAC to support public funding for the insertion of stents (proposed fee $640) on the basis of effectiveness and cost-effectiveness with no mention of PLAC (Public summary document Application No. 1150, 2012).

There is however one example where MSAC specifically recommended negotiation of a reduced benefit for the prostheses in order to satisfy requirements of cost-effectiveness. MSAC support was conditional on a reduced Prostheses List price. This example was Application 1361.2 for Transcatheter Aortic Valve Implantation via Transfemoral Delivery. Details of the considerations made are as follows:

“Further, as much of the incremental cost in the model was driven by the cost of the prosthesis, MSAC advised that negotiation of a reduced benefit for the relevant prostheses when considered for the Prosthesis List would address this concern.” (Public summary document Application No. 1361.2 [p.4], 2016).

“Overall, MSAC supported public funding for TAVI provided that it is cost neutral per patient compared with SAVR. MSAC advised that the proposed MBS fee for the TAVI procedure be decreased by 25%, and that the benefit for the TAVI prosthesis
in the Prosthesis List reflect the cost-minimisation basis outlined above.” (Public summary document Application No. 1361.2 [p.6], 2016).

MSAC therefore has some ability to suggest a lower prostheses price in order to support a listing of a proposed MBS item if this also relates to the cost-effectiveness of the MBS item as was demonstrated above.

There is no formal link between information on a listing with MSAC and PLAC. It can be difficult to determine if a prostheses relating to a MBS item went on to have a listing on the Prostheses List. Clearer information links between the two processes would be beneficial. This would aid MSAC to clearly identify existing Prosthesis Listings, but also would inform policy makers, clinicians and other interested stakeholders.

When assessing MSAC decisions since 2010, we found that a similar proportion of overall technologies (47%) and devices (47%) received a positive recommendation for public funding from MSAC (noting that the final decision rests with the Health Minister). A larger proportion of prostheses (69%) received a position recommendation for funding noting that numbers considered are smaller which may limit analysis (Table 2). We could hypothesise that MSAC provides a good mechanism that allows for funding of medical services associated with prostheses and that in the majority of cases assessed led to a positive funding recommendation.

**Table 2:** Assessment of all health technologies with MSAC decisions since 2010

<table>
<thead>
<tr>
<th></th>
<th>Recommended by MSAC for public funding</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>All health technologies</td>
<td>50 (47%)</td>
<td>56 (53%)</td>
</tr>
<tr>
<td>Devices</td>
<td>27 (47%)</td>
<td>31 (53%)</td>
</tr>
<tr>
<td>Prostheses</td>
<td>11 (69%)</td>
<td>5 (31%)</td>
</tr>
</tbody>
</table>

We also assessed the length of time between application or PICO Advisory Sub-Committee (PASC) meeting and MSAC meeting in order to assess current MSAC timeliness in reaching funding recommendation. There were 97 applications for which this information was available. Length of time was obviously longer for submissions requiring a resubmission. There was no difference on average between consideration of all technologies, devices or prostheses. The average length of time between PASC and MSAC meetings was 21 months (SD, 11) regardless of whether it was device, prostheses, or other technologies.

Another indicator of timeliness is the proportion of applications requiring resubmissions. Device applications (16%) were no more likely to be resubmissions than all technologies applications (16%) considered, but prostheses (31%) were approximately twice as likely to be a resubmission- albeit based on small numbers.

In summary MSAC has been considering a large proportion of devices and prostheses over the last 6 years. Devices are equally as likely to other technologies to receive a positive
funding recommendation and prostheses are more likely to be supported (based on small numbers). MSAC is equally as efficient at considering devices and prostheses. Devices are no more likely to lead to a resubmission than other types of health technologies. MSAC appears to be an appropriate mechanism for the consideration of medical services associated with devices and prostheses and is well placed to assess suitability for public funding. It is therefore worth considering an expanded role for MSAC in setting a benefit for devices and prostheses. There are at least two occasions (Applications 1347.1 and 1361.2) where MSAC played a role in either recommending PLAC consider price or denying MBS funding unless PLAC benefit was set to be cost neutral relative to a comparator. These cases demonstrate some potential for MSAC to play an increasing role in setting benefits of devices and prostheses and the value of further consideration of this role.

5.2 Integration of PLAC and MSAC

It would be useful to integrate the PLAC and MSAC processes in the evaluation of new prostheses and devices and in providing guidance for the setting of initial benefits for new classes of products. It is important to recognise the methodological strengths of MSAC in evaluating new technologies and assessing cost-effectiveness. To avoid duplicating processes, PLAC could consider formalising a role for MSAC in assisting with setting benefits for new prostheses on the basis of cost-effectiveness information already submitted and assessed. PLAC could leverage on MSAC’s current role and the processes MSAC use to initiate the collection of new evidence to support ongoing funding arrangements. This will help streamline the process in assisting with reviews of benefit when new evidence emerges regarding the clinical effectiveness of the product. To operationalise such a process, there needs to be a formalised working relationship between MSAC and PLAC with clear processes and communication mechanisms. PLAC will continue to maintain its role in determining eligibility of prostheses for considerations to be listed and would need to consider a plan for setting benefits for new prostheses and devices that do not require a new MBS item for the medical services fee.

Consistency in MSAC and PLAC processes will be advantageous in that it would allow cost-effectiveness to be taken into consideration when setting benefits for new items. PLAC could consider making demonstrated cost-effectiveness the criteria for listing as it would take into account both the effectiveness (as assessed by CAGs and MSAC) as well as the costs of implantation, a component of which is the price of the prostheses and device. If cost-effectiveness becomes the listing criteria it is important to note that a price of a device may exceed a threshold where it is considered to be cost-effective. In the case of pharmaceuticals and medical procedures that cannot demonstrate cost-effectiveness, they either have to lower their price (which often involves a period of negotiation), or are not listed. In this way PLAC would move to a process that involves both consideration of the costs and the benefits simultaneously when determining whether to list a new device. Where there is more than one product for a new class of device, tendering arrangements (as outlined in section 3.3.1) could help set benefits by introducing an element of competition among sponsors for preferred access on the Prostheses List (e.g. PLAC agree to exclusively list the lower priced product for a defined period), before allowing other product within the same class access.
6. Implementation of New Benefit Setting Arrangements

Our review finds that internationally other countries employ a wide variety of price setting arrangements to set Government subsidies for prostheses and devices. It is hard to find evidence that one benefit setting arrangement is superior to another and much depends on the way they are implemented. Multiple benefit setting arrangements can be employed in a complementary way. For example, it would be possible to undertake a one-off round of international reference pricing to adjust benefits where there are large differences between Australian and overseas prices and then implement a system of price disclosure on an ongoing basis. Use of multiple approaches adds to the cost of implementation, but could bring about more rapid benefit adjustment.

Three major objectives need to be considered when deciding on a strategy for implementation:

- The potential level for savings that can result from benefit adjustment if the current benefits for some prostheses and devices are shown to be too high;
- Impact on sponsors of the changes and potential disruption from the withdrawal of items;
- The development of a flexible system for ongoing benefit adjustment.

One way to obtain more information to refine the development of new benefits setting arrangements is to undertake a trial in which information is collected, but not used for benefit setting. As we have suggested above, this approach could be applied to both price disclosure and to reference pricing. Given that both these options are likely to require legislative change additional information to assess likely effects would seem to be a sensible approach. It would also be possible to look at trialling tendering to establish the benefit for new classes of products where more than one device is available at the time of listing. While such trials delay the implementation of long-term benefit setting strategy, they are important ways to both help inform the design of future benefit setting arrangements and would facilitate much more accurate modelling of potential effects.

Table 3 summarises key aspects of the implementation of each of the benefit setting approaches.

Price disclosure will require substantial legislative changes which could be based on the same framework as those already in place for pharmaceuticals. Importantly the existing legislation protects the confidentiality of the information disclosed by the sponsor. Only the aggregated weighted average price is publically available. A substantial upgrade to information systems will be required in order to manage and analyse the data that is submitted. In the case of pharmaceuticals this is managed through an independent service provider called the Price Disclose Service Utility (see section 3.1.3). The information on disclosed prices requires analysis to determine a weighted average price, which in the case of pharmaceuticals is undertaken by the department and an independent contractor to cross-check the calculated
prices which would have resource implications. PLAC would play no direct role in the setting of benefits for items subject to price disclosure. It would review the impact on stakeholders and the implications for overall prostheses expenditure. This would be particularly important in the initial rounds as the experience from pharmaceutical disclosure suggests additional refinements may be required to bring about an effective price setting mechanism.

**Table 3:** Key aspects of the implementation of each of the benefit setting approaches.

<table>
<thead>
<tr>
<th>Policy</th>
<th>Price Disclosure</th>
<th>Reference Pricing</th>
<th>Tendering</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Steps required to implement</strong></td>
<td>Given limited understanding of discounts, an initial trial of voluntary disclosure would be beneficial.</td>
<td>Conduct a reference price scoping exercise both domestically and internationally to understand the availability of pricing data.</td>
<td>Look to trial when there are new classes of products with more than one device available at time of listing.</td>
</tr>
<tr>
<td><strong>Legislative changes</strong></td>
<td>Legislative framework to require sponsors for mandatory disclosure of prices. Analysis of disclosed data required to estimate a weighted average price for ongoing benefit setting.</td>
<td>Legislation is likely to be required if reference prices for the public sector are to be obtained from companies through mandatory disclosure of public prices.</td>
<td>May require legislative changes.</td>
</tr>
<tr>
<td><strong>Likely resources</strong></td>
<td>Similar to pharmaceutical price disclosure, which involves a team in the Department of Health and an independent service provider contracted by the Department.</td>
<td>A team in the Department of Health and an possibly an independent service provider contracted by the Department.</td>
<td>A team in the Department of Health and an independent service provider contracted by the Department. Only needed for establishing new classes of products.</td>
</tr>
<tr>
<td><strong>Role of PLAC</strong></td>
<td>Need to liaise with relevant team in charge of price disclosure. Evaluate impact on stakeholder and sector.</td>
<td>Role of PLAC (CAGs and HESC) to not only consider listing of devices but also reviewing ‘adjustments’ - need and costs for additional services.</td>
<td>A team as an extension to PLAC to manage the tenders would be required.</td>
</tr>
</tbody>
</table>

A key decision which would be informed by a scoping exercise is the determination of the external prices that would form the basis of a reference price. If reference pricing involves Australian public sector prices these will need to be obtained, either through an agreement with IHPA to supply these data, or a system of mandatory price disclosure of public sector
prices. Both of these options may require legislative changes. The challenge with international reference pricing is to obtain reliable pricing data. Currently few countries make this available, so again a scoping exercise would help inform the feasibility of this approach. In addition to obtaining price information it is important to obtain information on whether this is for the device alone, or it covers any additional services (e.g. technical support). Reference pricing will require a high level of involvement by PLAC, as benefits will need to be adjusted if evidence can be supplied by sponsors to justify adjustments to the benefit on top of reference price. This could either be undertaken on either an item or class basis and would require substantial resource particularly in the initial round of price setting.

A method to reduce the resource requirements in future reference pricing rounds would be to establish fixed increments for adjustments to the reference price based on percentage difference. One way to base this increment would be for PLAC to undertake an initial round to calculate adjustments based on evidence-based submission from sponsors from sponsors (e.g. cost of additional technical support) and then use the adjustments to determine proportional mark-up for subsequent rounds. For example, if the PLAC benefit in the initial round based on submission of sponsors required an adjustment of 20% difference over the reference price. The same percentage adjustment could be used in future rounds of reference pricing to adjust the external price to reflect costs in the private hospital sector in Australia. Such an approach would obviate the need for PLAC to be involved in an ongoing adjustment process. Another approach would be for PLAC to set the benefit for the price of the device alone and then allow hospitals and private insurers to negotiate additional services that are required, although the relative bargaining power of the parties would need to be carefully assessed, potentially on a trial basis for a selected number of items.

The setting of benefits for new prostheses and devices poses its own unique set of challenges, particularly for new classes of devices where it is difficult to ascertain the benefit in relation to existing products on the Prostheses List. There are three options for setting benefits of new devices:

- Obtaining international reference prices, which may require legislation to mandate disclosure by the sponsor;
- Working with MSAC in a streamlined process to set benefits which are based on the benefit in relations to the assessment of cost-effectiveness;
- Tendering when more than one product within the same class is applying for listing.

A combination of these strategies may be required in order to appropriately determine benefits of new devices.

The implementation of any of these strategies will require both careful planning and ongoing monitoring of outcomes. Reforms should facilitate more flexibility in the adjustment of benefits for prostheses and devices, which will help ensure the sustainability of the Prostheses List.
References


Appendix A: The History of Prostheses and Medical Device Reimbursement in Australia

Rationale for a Prostheses List

The Prostheses List was introduced in 1985 as part of initiative by the Commonwealth Government to resolve the dispute by surgeons in New South Wales on their fees, rights and prostheses choice. The Prostheses List sets out the types of prostheses and devices which private health insurers must fund as part of the policies offered to their members. A fundamental aim of the list is to ensure choice and adequate coverage of prostheses and devices for patients with private health insurance that need surgically implanted prostheses, human tissues or other medical devices.

While some aspects of the Prostheses List are unique, the development of government regulations regarding products offered by private health insurers occurs in other countries. For example, the Dutch Government regulates competition between private health insurers for a prescribed package of benefits (Wynand, van de Ven and Schut, 2008). Providing a system for “weights and measures” has long been held to be a rationale for Government intervention in a private market (Mill, 1848). The economic rationale for the Government regulating what private insurers are required to cover rests on facilitating a consumer’s ability to purchase insurance products by ensuring it covers a minimum level of benefits.

For prostheses and devices to be covered by Australian private health insurers, they must meet a series of criteria set out in Box 1.

Box 1: Definition of prostheses as defined by the Prostheses List Advisory Committee (PLAC)

<table>
<thead>
<tr>
<th>A prosthesis should:</th>
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<tbody>
<tr>
<td>(a) be surgically implanted in the patient and be purposely designed in order to</td>
</tr>
<tr>
<td>(i) replace an anatomical body part; or</td>
</tr>
<tr>
<td>(ii) combat a pathological process; or</td>
</tr>
<tr>
<td>(iii) modulate a physiological process;</td>
</tr>
<tr>
<td>or</td>
</tr>
<tr>
<td>(b) be essential to and specifically designed as an integral single-use aid for implanting a</td>
</tr>
<tr>
<td>product, described in (a) (i), (ii) or (iii) above, which is only suitable for use with the</td>
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<tr>
<td>patient in whom that product is implanted</td>
</tr>
<tr>
<td>or</td>
</tr>
<tr>
<td>(c) be critical to the continuing function of the surgically implanted product to achieve (i),</td>
</tr>
<tr>
<td>(ii) or (iii) above and which is only suitable for use by the patient in whom that product</td>
</tr>
<tr>
<td>is implanted; and</td>
</tr>
<tr>
<td>The product has been compared to alternative products on the Prostheses List or alternative</td>
</tr>
<tr>
<td>treatments and</td>
</tr>
<tr>
<td>(i) assessed as being, at least, of similar clinical effectiveness; and</td>
</tr>
<tr>
<td>(ii) the cost of the product is relative to its clinical effectiveness.</td>
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</table>

Source: Prostheses List: Guide to listing and setting benefits for prostheses, February 2017
Several stakeholders (primarily sponsors of products) provided written submissions for this report (Appendix C) that the criteria (Box 1) apply to exclude some innovative technologies that could improve patient outcomes or deliver operational efficiencies. While making specific recommendations to redefine the listing criteria is beyond the scope of this report, it is hard to come up with an economic rationale as to why such technologies are not assessed by the Prostheses List Advisory Committee (PLAC), or through a parallel process.

While there are important healthcare system differences, expert bodies that are charged with advising Governments internationally tend to take a much broader and holistic approach to the assessment of new medical technologies than has been adopted in Australia. For example, the National Institute for Health and Care Excellence (NICE) in the England and Wales provides guidelines on wide range of new technologies including items that are covered by the Prostheses List (insulin pumps - https://www.nice.org.uk/guidance/dg21) as well as items not covered (catheter radiofrequency ablation). Similarly, the Pharmaceutical Management Agency (PHARMAC) in New Zealand has recently had its remit broadened to include devices and prostheses (https://www.pharmac.govt.nz/medicines/hospital-devices/).

Such an approach would require PLAC in combination with MSAC to undertake a more rigorous evaluation process and ensure that benefits were set at a level that ensures new items are cost-effective. If such a change was adopted it would also be necessary to determine if technologies being listed are not funded elsewhere in the system (e.g. though procedure banding or diagnosis-related group (DRG) or cost weights) to avoid the problem of insurers paying twice for the same item.

**Historical background**

The regulatory conditions for determining benefits have changed over time. As Figure A1 illustrates, the major change in benefits occurred following the de-regulation of benefit setting arrangements in the early 2000s. During this period the average benefit paid per item increased rapidly. Between 2003 and 2005, reforms to prostheses listing arrangements were introduced and implemented. This included the re-regulation of benefit setting, the inclusion of evidenced-based assessment into the listing process and applying a centralised benefit setting arrangements for all prostheses on the list. During this time, the Prostheses and Devices Committee (PDC) was established to advise the Minister on listing and benefits of the Prostheses List under the advisement of Clinical Advisory Groups (CAGs), Panel of Clinical Experts (PoCE) and Benefits Negotiating Group.

In response to the recommendations of the Review of Health Technology Assessment in Australia (HTA Review) in 2009, PLAC was established in place of PDC with a broader and more balanced membership. Following the recommendations from the HTA Review, prostheses were categorised into clinically relevant groups by CAGs and PoCE and single benefits were applied to all products included in each group.
Figure A1: Total benefit paid and benefit paid per item for each quarter from 1997 to 2016 (Real 2016 dollars are adjusted using the CPI from the ABS)

Timeline of regulation changes

<table>
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<tr>
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<th></th>
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<tbody>
<tr>
<td>De-regulation; Insurers negotiate benefitting no gaps allowed</td>
<td>Re-regulation; new arrangements to include evidenced-based assessment; Prostheses Devices Committee (PDC) established; at least one no gap prostheses</td>
<td>Following HTA Review (2009) recommendations; PLAC established; abolish negotiation of benefits for Individual listing; categorisation of prostheses into clinically relevant groups and group benefits established</td>
<td>IWG established and developed a report with areas for improvement and change, PL Advisory Committee draws up Reform Work Plan.</td>
</tr>
</tbody>
</table>

Source: Statistical Trends in Membership and Benefits Data Tables and APRA Prostheses PHI Quarterly Statistics and supportive materials provided by the Prostheses Reform team.
During the last decade benefits for many items have been frozen at historic levels and so after taking into account inflation, the average benefit has been declining over time. Despite this total spending continues to increase. Between 2011 and 2015, the total annual benefit paid has increased by 35% and now totals around $2 billion per year. Notably this growth came at time when the average benefit paid per item was declining and hence the increase in recent expenditure appears primarily due to a rise in the volume of items used, rather than an increase in the average benefits. It would be useful to further explore the reasons for this growth to determine whether the increased use of devices and prostheses on the list is in accordance with established clinical need. In the case of pharmaceuticals, the volumes of major items on the Pharmaceutical Benefit Scheme (PBS) are monitored through the Drug Utilisation Sub Committee (DUSC) and this has led to several major reviews, particularly when new evidence emerges regarding the efficacy of a class of drugs. The comparable issue in pharmaceuticals is what is often termed “leakage” which is when medications are used for indications or patient groups beyond that foreseen at the time of listing on PBS (DUSC Public release document, October 2014).

One way to reduce the growth in expenditure that results from expanded use of products is through price-volume agreements. When making submissions for listing drugs on the Pharmaceutical Benefits Advisory Committee (PBAC), sponsors must provide an estimation of predicted extent of use in terms of volume. Exceeding these volumes can trigger automatic reductions in the benefit paid, which provides a way of sharing the risk associated with listing when future demand for a drug is uncertain. Currently there is no mechanism within PLAC for either a function equivalent to DUSC, or for price-volume agreements.

By total expenditure, cardiac, hip and knee represent the top three categories although their respective volumes were smaller than the other categories. Figure A2 shows a representation of mean annual spend across four recent years against volume for majority of the prostheses categories in the Prostheses List.

**Figure A2:** Distribution of mean annual benefit by volume, 2012-2016
Broader private health insurance policy direction in Australia

The Australian Government has boosted private insurance uptake and population coverage through various policy changes over the years (Frech et al., 2003). A major motivation for these changes was to encourage greater use of private healthcare services which is hoped to help alleviate the pressure on the public sector. Between 2015 and 2016, the Australian Government spent over $6 billion on private health insurance rebates (http://www.health.gov.au/internet/main/publishing.nsf/Content/phmac-terms-of-reference).

In 2015, a public consultation focusing on the value of private health insurance and its long term sustainability showed that consumers were most concerned about the cost of private health insurance. This is in line with the annual increases of 5.7% annually observed in private health insurance premiums since 2010 (http://www.health.gov.au/internet/main/publishing.nsf/Content/privatehealth-average-premium-round). Among the other issues raised as a result of the consultation were the expense, affordability and lack of value for money of private health insurance. Additionally as part of the consultation, prostheses reform was made a priority area to alleviate pressure on private health insurance premiums. This has brought about the establishment of IWG mentioned earlier.

In September 2016, the Private Health Ministerial Advisory Committee was established and was tasked with examining various aspects of private health insurance and to bring about broader reforms encompassing consumer information, regulation affecting affordability and transparency to name a few. Among its aims was to ease the pressure on premium rises, to maximise gains from the large investment through rebates as well as to look into the sustainability and improvement in private health insurance participation through ensuring affordability and value of money for consumers (http://www.health.gov.au/internet/main/publishing.nsf/Content/phmac-terms-of-reference).

Transparency within the Australian healthcare system

The Department of Health openly publishes data on the volume and benefit paid for each of the Medical Benefits Scheme (MBS) services as well as PBS items. In the case of the PBS it also publishes annually the total funds that flow to the top 20 pharmaceutical companies from benefits for items on the schedule. It publishes data on volume by item rather than brand, or supplier (see Table A1).
Table A1: Extent of transparency of publicly available data

<table>
<thead>
<tr>
<th>Publicly available data</th>
<th>PBS</th>
<th>MBS</th>
<th>PLAC</th>
</tr>
</thead>
<tbody>
<tr>
<td>List of items/services covered</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Benefit amount for each item/service</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Volume: Item/Service</td>
<td>✓</td>
<td>✓</td>
<td>x</td>
</tr>
<tr>
<td>Available by year, State and patient category</td>
<td></td>
<td></td>
<td>Only by group categories</td>
</tr>
<tr>
<td>Total benefits to sponsor</td>
<td>✓</td>
<td>x</td>
<td>x</td>
</tr>
<tr>
<td>Available by year</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

In contrast there is no public information on volumes at the item level. The lack of published information on volumes significantly impedes the monitoring of trends in use as well as the associated flow of funds, for example it is not possible to examine the likely impact of a change in benefits on overall expenditure. There is significant precedent for publishing this type of information as the AIHW routinely reports information on separations from private hospitals ([http://www.aihw.gov.au/haag10-11/admitted-patient-care-same-day-acute/](http://www.aihw.gov.au/haag10-11/admitted-patient-care-same-day-acute/)) and detailed statistics on private health insurance policies is routinely published by Private Health Insurance Administration Council and more recently Australian Prudential Regulation Authority (APRA).

**Conceptual bases of item benefits**

A number of submissions from stakeholders highlighted the multi-dimensional nature of the benefit, it is intended to cover not only the device costs but other factors such as technical support at the implantation stage, freight, providing loan kits, and after care support including any necessary adjustments.

Conceptually the current Prostheses List benefit represents a bundled benefit in that it is intended to capture all of these costs (Figure A3). Through our consultations and review of written submissions the additional services are said to be necessary in optimising patient experience and ensuring better outcomes.
There is however a lack of transparency on how these additional services are costed and the degree of variation among sponsors in the level and type of additional services provided. Such factors add to the complexity comparisons between costs in private and public markets within Australia and with list prices overseas.

It has been claimed in submissions that these extended services such as professional training, product support in the form of theatre assistance, patient management and support are additional services provided uniquely to the private sector. Within the public sector, such services are usually provided by salaried hospital staff hence funded and absorbed within the hospital budget itself. Market barrier entries such as lag time between product launch and private market entry have also been cited by sponsors as a justification for higher benefits, although such factors are not normally taken into account when setting benefits for other health care products (e.g. pharmaceuticals listed on the PBS).

Aside from the support and additional services provided in the private market by sponsors, the differences in prostheses prices paid between the private and public sector can also be explained by the use of a competitive mechanism (tenders) in procuring devices by State purchasing authorities on behalf of public hospitals and the ability of public hospitals to dictate the range or specific devices to be used. It was also noted from our consultations and submissions received that sponsors are perceived to offer favourable terms to public teaching hospitals to encourage the training of young doctors on their products hence establishing their foundations in preferences, skills and knowledge particularly in speciality areas.

As such it is important to understand the composition and price differences between prostheses provided in the public and private sectors, particularly when implementing any future benefit setting strategies. Importantly additional services provided by sponsors should be assessed clinical (which could be a role for CAGs) thus determine that the benefits can be justified in terms of input costs (e.g. wages of support staff).
Market components and stakeholders

The private market for prostheses and medical devices in Australia involves a complex interplay between several stakeholders as shown in Figure A4. The relationship between each of the stakeholders and the impact of benefit adjustments on each party should be examined closely and assessed when considering future benefit setting strategies.

Patient

Patients purchase private health insurance with an expectation that if they require a medical intervention which involves implantation of specific medical devices or prostheses they are covered (i.e. the insurer will cover some, or all of its cost). The decision over choice of device is made between the patient and the surgeon. Currently as all devices on the Prostheses List have no gaps neither the patient’s nor the surgeon’s decision is based on the price of the device.

Surgeon

In consultation with the patient the surgeon chooses the device based on a variety of factors including known clinical effectiveness. Sponsors and surgeons may also develop relationships such as industry-provided support for training and continuing education. There has been a move by both Medicines Australia and the MTAA to adopt a code of conduct to govern the financial support provided by industry to medical professionals. In the case of pharmaceuticals this has included routine disclosure of health care practitioner payments since October 2015. These are publically available for pharmaceuticals from Medicines Australia website (https://medicinesaustralia.com.au/code-of-conduct/transparency-reporting/payments-to-healthcare-professionals/member-company-reports/).

Private Hospitals (and public hospitals taking private patients)

The private hospitals can have an indirect influence on the accessibility to particularly brands of a device by providing sponsors with space for inventories of medical devices and prostheses. They appear to have very little capacity to directly influence the surgeon and patient choices regarding the device. Private hospitals can receive rebates or discounts, which occur when the amount charged for a device is below the Prostheses List benefit.

Private Health Insurance

Insurance funders are mandated to cover the cost of the medical devices and services rendered to the privately insured patient under the Private Health Insurance arrangements. Reimbursements to the private hospital for any medical device listed in the Prostheses List should at least be at the benefit that is listed. As the insurers do not directly choose or procure the medical devices or prostheses, they are not able to monitor the actual cost of the device or able to dictate their choice on which devices to cover and level of coverage. Hence in the
current environment, health insurers do not have significant bargaining power to negotiate with sponsors.

**Sponsor/Supplier**

Unlike pharmaceuticals where the sale of a medication is relatively straightforward, in the medical device or prostheses industry, the sponsor is not just a supplier of the device or equipment but is also largely involved in the education, training and guiding surgical staff on the use of the supplied product. This adds to the value of the services provided as described in Section 1.5 above. As prostheses prices are set at a Prostheses List minimum benefit to which private insurers are legally bounded to cover and no gaps are chargeable to patients by the private hospitals, the sponsors have little incentive to compete on price.

**Australian Government**

The role of the Government and PLAC as regulatory bodies and their strategic objectives have been described in the previous sections. The flow-on effect of any reforms implemented will no doubt have an impact on all stakeholders with the potential to change the current market mechanism. Some of the key considerations include enhancing value of private health insurance such as ensuring savings from price reductions are passed onto patients as reduced premium increases, maintaining the freedom for choice, supporting an innovative and viable medical device industry, long-term sustainability of the insurance industry and increased transparency of financial flows within the system. Ultimately reforms should be implemented without causing disruption to the provision of appropriate care to patients.

**Figure A4:** Key stakeholders involved in the private healthcare market for prostheses and devices
Appendix B: Regulation and Reimbursement of Prostheses Internationally

France

Market Access

A CE mark ensures that medical devices are in accordance with European directives and represents the first mandatory step to market access in France, whether the device is funded directly by Health Insurance through its enlistment on a positive list or funded indirectly through DRG tariffs.

Reimbursement and Coverage

The Commission Nationale d’Evaluation des Dispositifs Médicaux et des Technologies de Santé (CNEDiMTS) – part of Haute Autorité de Santé (HAS) – provides scientific opinion concerning the usefulness, interest and good use of medical devices and other non-drug healthcare products.

DRG funding

A DRG funding scheme in both the public and private sectors was implemented in France in 2004. Therefore, most devices are included in the DRG tariff funded by the Health Insurance. In those instances hospitals are purchasers in the context of public tender regulation and there is no health technology assessment at national level. It is the role of COMEDIMS (Comité des Médicaments et des Dispositifs Médicaux Stériles), a subcommittee of the Hospital Medical Committee in every hospital or group of hospitals undertake an assessment for enlisting on the hospital formulary and decide on purchasing. Hospitals are increasingly grouped in procurement organizations to obtain lower prices and have been encouraged to do so by the Ministry of Health.

Some innovative and/or costly devices are not included in DRG funding and reimbursed separately from a specific budget. In that case, prices are regulated by the government and procurement by hospital is managed by negotiations which may result in discounted prices. This funding is generally temporary and ends when the device is included in a new DRG or the tariff of an existing DRG is updated.

Positive Reimbursement List

To receive reimbursement from the Mandatory Health Insurance a medical device that is used in ambulatory care or is too expensive to be funded with DRGs tariffs is submitted for listing on a positive list, the LPPR (Liste des Produits et Prestations Remboursables). (http://www.has-sante.fr/portail/jcms/c_412130/la-commission-nationale-devaluation-des-dispositifs-medicaux-et-des-technologies-de-sante)

This list has 4 chapters (4 “titles”):
- Title I: medical devices for treatments and devices for life care, dietetic food and dressing articles
- Title II: external prostheses and orthoses
- Title III: implantable medical devices
- Title IV: physical handicap vehicles

To be listed in the LPPR, two different pathways exist:

1. **Listing under “generic line”** (ligne générique) is the general rule (i.e. hip prosthesis, ceramic) to which a tariff for reimbursement is attached. Generic lines describe a class of products, their intended use, and their technical characteristics without mentioning any trade name.

   A medical device conforming with the LPPR generic line description, does not go through an assessment by the CNEDiMTs; the manufacturer only needs to label its product with the corresponding LPPR code. The device will therefore be reimbursed by Mandatory Health Insurance at the existing tariff. The only requirement for the manufacturer is to declare it to the Health Products Safety Agency (AFSSAPS) to ensure proper post marketing surveillance (materiovigilance) of the device.

   Note that all existing generic lines are required to be reviewed by CNEDiMTs over a period of ten years. Each year there is a preset reassessment programme which is known through a ministerial order. A reappraisal will then be mandatory every five years. This will allow to ensure that the description (indication and/or technical description) corresponds to the changing environment of medical devices.

2. **Listing under the medical device own trade name.** Trade name listing is necessary or recommended when the device is: a) innovative and presents some characteristics that makes it different from the existing generic description, b) presumed to impact Health care expenditure or c) requires a specific follow-up for safety issues.

   A two steps process is to be followed in this instance, after the manufacturer has submitted a dossier in line with the recommended format:

   1. Technical assessment by CNEDiMTS: to assess
      - Whether a trade name listing is appropriate, given the innovative characteristics of the device
      - Whether the expected service that should be delivered by the new device is sufficient to grant reimbursement (yes or no), based on its impact on disease or handicap, its safety profile, its interest for public health; eventually technical specifications or restrictions for utilisation by only qualified hospital departments or specialists will be determined;
      - What is the added value for the patient graded as major (grade I), important (grade II), moderate (grade III) minor (grade IV) or absent (grade V) versus existing strategies, whether they are other MDs or pharmaceuticals or medical procedures; the assessment will be based mainly on clinical evidence, possibly completed by expert opinions;
- The number of patients who might benefit the device, based on epidemiological data.

The CNEDiMTS’ appraisal is published on the HAS website. If the opinion is positive a negotiation with the CEPS will proceed.

2. Tariffs fixing: after negotiating with the manufacturer, the Economic Committee for Health Care Products (CEPS: Comité Economique des Produits de Santé”) will set a tariff for reimbursement by the MHI (the price can be higher, but the reimbursement rate will apply to this tariff) or a price (the manufacturer is not allowed to sell the medical device above the fixed price, to which the reimbursement rate will be applied). Price or tariffs fixing will take into account the ASR (a higher grade will facilitate a high premium over existing strategies) and the costs for development and production. Eventually, reimbursement will be submitted to commitments by the manufacturer to set up a registry or produce further clinical evidence.

When many devices presenting similarities are listed with trademarks, the CEPS may consider creating a new generic description and set a common tariff.

Figure B1: French Pricing & Reimbursement (PR) process for medical devices

Reimbursement of a device through a medical procedure

When the medical device is delivered to the patient only within a medical procedure that is not already coded for reimbursement, the enlistment of the new procedure is mandatory in order to obtain MD reimbursement in ambulatory or hospital setting. As of September 2011, medical procedure that are used in hospital and not associated with a new code are not submitted to HTA. However, a draft bill is discussed in Parliament that plans to make HTA mandatory also for those medical devices.
Figure B2: The French market access pathway for medical device

More details are available at the ISPOR roadmap here:
https://www.ispor.org/HTARoadMaps/FranceMD.asp
Taiwan

*Market Access*

Taiwan regulates both medical devices and pharmaceuticals under the same legislation. According to the Pharmaceutical Affairs Act Article 13, medical devices mean apparatuses, appliances, instruments and their accessories, fittings, and parts, which are used to diagnose, treat, relieve or prevent human diseases or may have an effect on the structure and function of human bodies.

The regulatory framework for a medical device in Taiwan covers product classification, quality system and GMP manufacturing, registration of products, labeling control, commercial advertisement control, control of clinical investigation, adverse event reporting, and sales and distribution control.

*Reimbursement and Coverage*

The reimbursements of the new medical devices are determined by the Bureau of National Health Insurance (BNHI). There are two reimbursement types for medical devices established by the BNHI: a fee-for-service (FFS) schedule and, Taiwan-Diagnosis Related Groups (Tw-DRGs).

During the NHI system's early years, Taiwan's health care providers were reimbursed based on a "fee-for-service" system. Under the fee-for-service system, patients only pay a small amount of copayment to the medical facility, and the medical facility receives the reimbursement from the BNHI for all the services they provided.

In 2010, the BNHI launched the Tw-DRGs payment system for certain inpatient diagnosed groups, in which hospitals are reimbursed as a package for the entire treatment of a particular episode for a patient. However, unlike all other countries, Taiwan is simultaneously and continually setting reimbursement prices for individual medical devices used in the DRGs procedures.

Since 2011, the amended and promulgated “Second Generation” National Health Insurance Act legitimized the Balance Billing program for expensive medical devices. Under the Balance Billing program, the NHI system also covers a number of newly developed and more advanced products that provide better health benefits. For patients who choose to use more expensive medical devices, the NHI system covers the standard fee it would pay for similar conventional medical devices, while patients cover the additional cost.

The new medical device submission process requires manufacturers to complete a New Product Application form after they have received the marketing approval granted by the TFDA. The submission form and guidance notes on how to complete it are provided on the BNHI website. The Medical Device Experts Committee consists of BNHI officers, physicians, and economists. The Committee has regular meetings to discuss new medical device cases submitted by the providers. The Committee is responsible to make two recommendations to the BNHI regarding new medical device reimbursement: listing or not,
and any restrictions on coverage. Once a product has been added to the reimbursement list by the BNHI, its reimbursement price will be determined by the Medical Device Division in BNHI, and it can be used at any healthcare of the facilities in Taiwan. The application result will be announced to the applicants by the BNHI.

When assigning a reimbursement price for a new product, the BNHI will compare the new product with similar products currently on the market. Generally, the BNHI will request that an applicant provide a list of published reimbursement prices from other developed countries. If reimbursement prices are not available, then the actual market prices for these countries should be provided. The applicant also has the option to refuse the reimbursement price via an appeal.

**Pricing Principles - three possible outcomes:**

1. **Applicant receives the desired reimbursement price for their product**
   In this case, the medical device company will most likely meet their desired profitability in their product’s market. Once a product is listed for reimbursement, it cannot switch to the self-paid (non-reimbursed) market.

2. **Applicant does not receive the desired reimbursement price for their product**
   For this outcome, the company may not have reasonable profit margins since the distributors may have to pay the discount to the hospitals. The additional expenses incurred by the distributors could also impact their ability to promote the product efficiently.

3. **Applicant chooses to sell the product as “Out of Pocket”**
   The “Out of Pocket” healthcare market for better quality products is becoming more popular in hospitals as it does not affect the hospital’s Global Budget. Nevertheless, the company will still need to apply for reimbursement, as required by the BNHI and hospitals, even if an “Out of Pocket” product is desired.

**Price-Volume Survey (PVS)**

Periodically (usually every other year), the BNHI puts both drugs and medical devices through an exercise known as the Price-Volume Survey (PVS). The objective is to ensure that reimbursement rates reflect the real prices that hospitals are paying the vendors.

More details are available at the ISPOR roadmap here: [https://www.ispor.org/HTARoadMaps/TaiwanMDD.asp](https://www.ispor.org/HTARoadMaps/TaiwanMDD.asp)
**Germany**

*Market Access*

The CE mark is required for a new technology before it can be marketed and reimbursed. Specific diagnostic and procedure codes are used for prospective (hospital) or retrospective (ambulant) reimbursement. However, coding does not directly and automatically lead to reimbursement.

There is a time lag between the availability of a new procedure and the correct coding. The update of the G-DRG by the Institute for the Hospital Remuneration System (InEK) is done yearly based on the data from the previous 2 years. Hospitals can apply individually for using a new procedure under the NUB process (eue Untersuchungs- und Behandlungsmethoden - see below). The adequate uptake and correct coding of a new technology by the hospitals that participate in InEK’s calculation system is surveyed by InEK. The reimbursement for NUBs is negotiated with the Social Health Insurance (SHI).

In addition to the CE mark, ambulatory care procedures need a listing in the EBM (“Uniform Value Scale” catalogue) and to be reimbursed by the SHI. Private physicians can only charge for services listed in the EBM, which is edited and administrated by DIMDI (German Institute of Medical Documentation and Information).

*Reimbursement and Coverage*

All medical devices and diagnostics are subject to contracts (Hospitals, Medical Doctors, and Health Insurers). These contracts differ between hospitals and ambulant services.

All applications for reimbursement of CE-certified medical devices and care products must be submitted to the SHI umbrella organization. Applicants must provide information supporting product functional suitability, safety, quality, and – subject to requirement – medical or nursing care benefits. The SHI informs applicants of the application decision in writing.
**Broad Mechanisms of Hospital Funding**

Hospital Funding in Germany is regulated by the “Hospital Financing Act” which establishes a dual funding mechanism for German hospitals. Under the Act, each state is responsible for covering large investment costs and the procurement of assets with a long economic life (more than three years). These types of investments need to be negotiated and agreed between the state and the hospital in question. Inpatient hospital activity is the responsibility of each patient’s SHI (or private insurer) and this covers facility maintenance costs (unless the facility is going to be completely replaced in which case the state would be liable for that), labour costs and disposable costs. The principle mechanism of inpatient activity reimbursement to hospitals by the SHIs (or private insurers) is a highly evolved Prospective Payment System (PPS) called the German DRG or G-DRG.

The G-DRG builds on the September 2004 Version 5.1 of the Australian “Australian Refined Diagnosis Related Group” AR-DRG system, but has since evolved far from its originator and is now a completely separate hospital financing mechanism. Different to other healthcare systems around the world, the G-DRG does not aim to incentivise, or disincentivise hospital activity; instead it aspires to accurately reimburse all activity types in a budget-neutral way for the hospital.
The G-DRG system is maintained by the InEK. InEK is responsible for the collection and processing of hospital costing data, the updating of the funding units associated with each funding code and the updating of the funding codes themselves. The institute is also responsible for certifying the logic system of various grouper software available to German hospitals. However, InEK does maintain neither the diagnostic, nor the procedural codes employed by G-DRG, which are responsibilities of the DIMDI.

Procedure codes (arguably one of the most important pillars of successful market access in Germany) in the G-DRG come from the OPS (Operationen- und ProzedurenSchlüssel) system which is also maintained by the DIMDI and also updated on an annual basis. In contrast with ICD-10-GM, OPS is unique to Germany.

As with every PPS system, the reimbursement of newly introduced technologies depends on the availability of specific diagnostic and procedure codes, as well as the adequate uptake and correct coding of this new technology by the hospitals that participate in InEK’s calculation system. InEK is updating G-DRG on an annual basis, using however data from the previous two years. This may contribute to a time lag for successfully funding a new technology or creating new funding codes for it. Furthermore, as explained, correct coding of a new technology will not necessarily lead to sufficient reimbursement immediately. Therefore, German hospitals (who are constantly under pressure to contain expenditure and improve efficiency) may have a counter-incentive against potentially useful and cost-effective or cost-efficient technologies because of the certainly negative initial budget impact. In addition, diagnostics and medical devices for hospital use often are part of the procedure (flat rate per case) and therefore do not necessarily lead to a new coding. This creates even more disincentive to introduce a new additional procedure (e.g. diagnostic) since it most probably decreases the margin.

Quick Pathway to Access for Innovative Products – The NUB Application

Recognising the need for a mechanism allowing innovation within the G-DRG system, the InEK has created an “on-top” funding process for innovative products. This process, known as NUB (Neue Untersuchungs- und Behandlungsmethoden). Application can be filed by hospitals only for technologies that have just been introduced in Germany. Every hospital will need to apply separately (electronic application at InEK) and the “on-top” payment (if the application is approved) will be available only to the hospitals that applied for it and not to every hospital in Germany. Approved applications are subsequently monitored by InEK and should the new technology be adequately used; correctly coded; and, exhibit a cost profile of sufficient difference, the InEK may integrate it permanently to the G-DRG. It should be noted that InEK makes no decision on the actual amount of the “on-top” payment. That will need to be directly negotiated between the successful hospital applicants and the SHIs. The NUB pathway has the potential to accelerate market access for new technologies but requires significant effort from its users.

Despite the introduction of the G-DRG system, hospitals in Germany are not free to increase activity beyond pre-defined limits. Through G-DRG based calculations, German hospitals are
still under a system of “global budget”. Therefore, all new technologies are essentially attempting to capture a share of a budget that remains largely stable throughout the years. Successful market access will be based either on increases of this activity caps or on more efficient inpatient activity that will allow space for new procedures within current limits.

**Ambulatory Sector**

The majority of ambulatory services are provided by private practitioners in the community. These physicians are paid by their regional association who is in turn paid by the SHIs. Payments by the SHIs to physician associations are usually based on a “per physician member” or a “per insured person” basis and while private insurers predominantly pay on a fee for service basis. The physician associations are responsible for distributing these payments to their members in accordance with the “Uniform Value Scale” catalogue, also known as EBM (Einheitlicher Bemessungsmassstab). The EBM system constitutes a mix of services delivered, number of patients served, and fixed budget distribution system. Physicians are only able to invoice services that appear on the EBM. The EBM is maintained by the Ambulatory Care Committee which is a part of the Federal Joint Committee.

In general, new diagnostic and therapeutic procedures can only be reimbursed by the SHI if they are ‘necessary, appropriate, and economic’. The decision on acceptance of new procedures for coverage by the SHI has to be ratified by the Federal Joint Commission (Gemeinsamer Bundesausschuss, G-BA). New technologies aspiring to be used in the ambulatory sector will need to be listed on the EBM, a process which requires physician support and may involve a Health Technology Assessment (HTA) by the Institute for Quality and Efficiency in Healthcare (Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen) or IQWiG. It should be noted that the actual payment amount of an EBM-listed procedure is the responsibility of the Valuation Committee which is separate from the Ambulatory Care Committee.

Ambulatory care procedures will need to be approved by the Ambulatory Care Committee and the Federal Joint Committee if they are to become listed on the EBM and offered to German patients through private physicians. This may involve an HTA by IQWiG which closely resembles the process used for the evaluation of pharmaceutical products. The IQWiG methodology has been recently updated. To date, no medical devices or diagnostics have been subjected to such an HTA.

More details are available at the ISPOR roadmap here: https://www.ispor.org/HTARoadMaps/GermanyMD.asp
Canada

Market Access

Medical devices for human use in Canada are regulated by the Medical Devices Bureau (MDB) of Health Canada’s Therapeutic Products Directorate (TPD) under the authority of Medical Device Regulations, in accordance with federal legislation, the Food and Drugs Act.

Medical devices are regulated according to a risk-based classification system, generally according to the degree of invasiveness. Under this classification scheme, Class I devices represent low-risk items, while Class II – IV represent higher-risk devices. Factors also considered are risk to patients from failure, duration of contact, and whether the device emits or controls (e.g., software) the emission of ionizing radiation. In vitro diagnostic tests are also regulated under this system, and generally are considered Class II devices. However, they may also fall into higher-risk classes according to the degree to which accuracy of test results may affect human health.

Manufacturers of Class I devices must apply for a Medical Device Establishment License (MDEL). Manufacturers of Class II, III, or IV medical devices must apply for a Medical Device License (MDL). All distributors and importers must apply for a MDEL. Information requirements vary according to the product Class. The application is then reviewed according to requirements of the Medical Devices Regulations. If a negative decision is reached, companies have an opportunity to appeal or provide further information. Positive reviews result in an issued license. The timing of the review depends on the medical device class with Class II, III, and IV license applications having a 15-, 75-, and 90-day target to complete, respectively. A recent Federal Auditor’s report reveals these targets are only met roughly 50% of the time (6). Evidence of effectiveness from clinical studies are only required for Class IV products.

Manufacturers of Class II, III, & IV medical devices are required to implement a quality system compliant with ISO 13485:2003 (Health Canada does not require ISO 13485 for Class I). The ISO 13485 quality system must be audited by a Registrar accredited under the Canadian Medical Device Conformity Assessment Scheme (CMDCAS). (http://www.hc-sc.gc.ca/dhp-mps/md-im/qualsys/index-eng.php) To remain active, a medical device license must be renewed yearly through payment of an annual fee to Health Canada.

Reimbursement and Coverage

Decisions to reimburse medical devices in Canada are highly de-centralized. The vast majority of decisions are made by hospitals, who typically receive global funding for providing services. In most provinces, budgets are allocated to hospitals through a geographic or operational health region or authority, and bound by provincial legislation. In this scheme, hospitals are separate legal not-for-profit entities that administrate service through their centres and associated facilities.

The use of Health Technology Assessments (HTA) within hospitals and health regions across Canada varies widely. For example, there are no hospital-based HTA units in Saskatchewan.
or Newfoundland, whereas provincial legislation in Quebec requires all teaching hospitals have an HTA body. Typically, decisions to fund a new technology are made by hospital administrators without a formal HTA process to support decision making. Hospitals may seek advice or a formal assessment from the province.

In the four most populated provinces (British Columbia, Alberta, Ontario, and Quebec – where approximately 86% of Canadians live) province-wide HTA processes have been developed for new or existing technology. Decisions to participate or adhere to recommendations from province-wide review by hospitals and administrators may still be voluntary depending on the province. Typically, technologies with substantial budgetary pressure or clinical uncertainty will be identified for review or recommendation. There are no national recommendatory processes for medical devices or technologies in Canada. The Canadian Agency for Drugs and Technologies in Health (CADTH) acts as an information resource to all provinces except Ontario and Quebec, who do not pay for this service, giving decision makers information to inform individual decisions on request. They also provide information to federal programs.

Once reimbursement decisions are made, shared delivery or group purchasing arrangements for health technologies may be implemented. Intending to leverage buying power, group purchasing arrangements are increasingly common among hospitals, regions, and provinces. Since 2009, three provinces: Alberta, British Columbia, and New Brunswick have signed contracts with privately owned Group Purchasing Organizations (GPOs) for services to supplement shared purchasing activities. The GPO facilitates by consolidating back office functions that include procurement, information technology, and financial functions on a regional or provincial level. Similar organizations, Shared Service Organizations (SSOs), provide pooled services and are organized within hospital groups.

Regional or National consensus by physicians through existing professional networks can be a strong influence on decisions to reimburse technology. In almost all cases, specialty physicians (e.g., surgeons, interventional cardiologists, emergency doctors) are not paid or affected by hospital budgets, but rather by provinces through a provincial fee-for-service arrangement. Some specialties are more typically salaried (e.g., pathologists) although alternative funding arrangements for other physician specialists are seeing a slow rise.

More details are available at the ISPOR roadmap here: https://www.ispor.org/HTARoadMaps/CanadaMDD.asp
Appendix C: Consultations

Since the commencement of this work late October, a number of key stakeholders from various organisations have been approached by the research team to gain an insight in the processes in medical devices procurement and supply and better understand each stakeholder’s interest. Input was sought from a diverse group as listed below.

<table>
<thead>
<tr>
<th>Date</th>
<th>Stakeholder type</th>
<th>Organisation</th>
</tr>
</thead>
<tbody>
<tr>
<td>21(^{st}) November 2016</td>
<td>State purchasing authority</td>
<td>Health Purchasing Victoria</td>
</tr>
<tr>
<td>23(^{rd}) November 2016</td>
<td>Commonwealth Government</td>
<td>Department of Health, Canberra with representatives from: Private Health Insurance Branch, Pharmaceutical Price Disclosure, Office of Hearing Services, Private Health Insurance Reform and Emeritus Professor Lloyd Sansom</td>
</tr>
<tr>
<td>28(^{th}) November 2016</td>
<td>Purchasing authority</td>
<td>PHARMAC, New Zealand</td>
</tr>
<tr>
<td>29(^{th}) November 2016</td>
<td>State purchasing authority</td>
<td>NSW Health Government</td>
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<tr>
<td></td>
<td>Sponsor/supplier</td>
<td>Biotronic Australia</td>
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<tr>
<td>30(^{th}) November 2016</td>
<td>Private health insurer</td>
<td>Medibank</td>
</tr>
<tr>
<td>1(^{st}) December 2016</td>
<td>Sponsor/supplier</td>
<td>Medtronic</td>
</tr>
<tr>
<td>19(^{th}) December 2016</td>
<td>Private hospital</td>
<td>Uniting Care Health</td>
</tr>
<tr>
<td>21(^{st}) December 2016</td>
<td>Private hospital</td>
<td>Pulse Health</td>
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<td></td>
<td>Government agency</td>
<td>Independent Hospital Pricing Authority (IHPCA)</td>
</tr>
<tr>
<td>22(^{nd}) December 2016</td>
<td>Sponsor/supplier (Peak body)</td>
<td>MTAA with representatives from Johnson and Johnson, Boston Scientific, St Jude Medical and Stryker</td>
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<tr>
<td></td>
<td>Private hospital</td>
<td>Healthscope</td>
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<tr>
<td>9(^{th}) January 2017</td>
<td>Sponsor/supplier</td>
<td>Stryker</td>
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<tr>
<td></td>
<td>Sponsor/supplier</td>
<td>Johnson and Johnson</td>
</tr>
<tr>
<td></td>
<td>Sponsor/supplier</td>
<td>Boston Scientific</td>
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Additionally, stakeholders and interested parties were given the opportunity to contribute to the consultation process through written submissions. A list of those who have contributed to the process are as listed.

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<thead>
<tr>
<th><strong>Private hospitals</strong></th>
<th><strong>Sponsors/suppliers</strong></th>
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</thead>
<tbody>
<tr>
<td>Catholic Health Australia</td>
<td>Medical Technology Association of Australia</td>
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<tr>
<td>Day Hospitals Australia</td>
<td>Australian Medical Manufacturers and Distributors Association</td>
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<td>Australian Private Hospital Association</td>
<td>Stryker</td>
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<td>Carl Zeiss Pty Ltd</td>
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<td>Surgical Devices Pty Ltd</td>
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<td>St Jude Medical</td>
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<td>LifeHealthcare</td>
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<td>Cochlear</td>
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<td>Medistar</td>
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<td>Global Orthopaedic Technology</td>
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<td>Johnson and Johnson</td>
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<td>AusBiotech</td>
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<td>Spiran Care</td>
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<td>Vestech</td>
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<td>Boston Scientific</td>
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<td>Biotronik</td>
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<td>Applied Medical Resources Corporation</td>
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<tr>
<th><strong>Private health insurers</strong></th>
<th><strong>Medical professionals</strong></th>
</tr>
</thead>
<tbody>
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<td>Bupa Australia &amp; New Zealand</td>
<td>Australian Orthopaedic Association</td>
</tr>
<tr>
<td>Australian Health Services Alliance and hirmaa</td>
<td>Anthony Wilson</td>
</tr>
<tr>
<td></td>
<td>Australian Medical Association</td>
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<td></td>
<td>David Gill</td>
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<td></td>
<td>David A.F. Morgan</td>
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