Private Healthcare Australia
Better Cover. Better Access. Better Care.

Submission: Senate Community Affairs References Committee

Inquiry into price regulation associated with the Prostheses List Framework

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Contact

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Introduction

On 21 November 2016, the Australia Senate referred the following matter to the Senate Community Affairs References Committee for inquiry and report:

Price regulation associated with the Prostheses List Framework.

Private Healthcare Australia (PHA) is pleased to make a submission to the Committee. We will comment on a number of the terms of reference in order to provide assistance to the Committee. We will also seek to appear before the Committee to expand on the matters raised in this submission or to discuss any other related matter that might be of value to the Committee.

At the outset we wish to say that there are many challenges facing private health insurance in Australia, particularly the fact that health costs are rising at a rate greater than inflation. This is not peculiar to Private Health Insurance, but rather to health care in general, as reflected by health expenditure by Commonwealth and State governments, and in many international health systems.

The Government has embarked on a process of considering reform options to address the cost of private health insurance and we congratulate them for doing so. PHA has both engaged robustly and championed this process, while acknowledging that it may raise matters that we will not necessarily like or that will be to our advantage. We do this as health funds play a vital role in the Australian health care system and we recognise that health fund members cannot keep paying over 6% p.a. more for private health insurance indefinitely. The current situation is clearly unsustainable and without change, price sensitivity modelling shows that in 5-6 years premiums will be unaffordable for at least one-fifth of those currently with private health insurance.

A strong health insurance sector benefits all Australians by easing pressure on public hospitals. Over 13.5 million Australians rely on private heath cover and research shows that over 80% of health fund members are satisfied with their health insurance and want to keep it, with the security of knowing it will be there when they need it.

About Private Healthcare Australia (PHA)

PHA is the Australian private health insurance industry's peak representative body. We represent 19 registered health funds throughout Australia and they in turn represent 96% of people covered by private health insurance. PHA member funds today provide healthcare benefits for over 13.5 million Australians.

Private health insurance is provided through organisations registered under the *Private Health Insurance Act 2007*. The financial performance of the registered health funds is monitored by the Australian Prudential Regulation Authority (APRA), an independent Australian Government body to ensure solvency and capital adequacy requirements are met.

All members of PHA are registered as health benefits organisations with the Commonwealth Government and comply with Government standards and regulations on benefits and solvency.

The role of PHA is:

- To foster and promote the principles, practice, development and philosophy of voluntary health insurance;
- To make representations and submissions where deemed necessary or desirable to the appropriate persons or authorities in respect of any matter affecting the interests of members;
- To provide a medium through which opinions of members may be ascertained or expressed;
- To consult and liaise with relevant national, international and institutional authorities and agencies in Australia and overseas;
- To work closely with departments and agencies of the Government of Australia to be fully informed on policies relating to voluntary health insurance; and
- To encourage the interest and participation of the Australian public in the activities of PHA and its members as appropriate.

Executive Summary

The Prosthesis List (PL) is the mechanism by which the Government regulates which medical devices are paid for by Private Health insurance funds, and the amount that the funds must pay for each item. It involves no Government expenditure or subsidy.

While the PL may or may not have been useful at a point in the past, it has been on 'set and forget' for a long period of time and now is being gamed by providers. It prevents new entrants in to the field; minimises competition; stifles innovation and is the reason that Australians with private health insurance pay substantially more for a medical device than someone in the public system or in a comparable country overseas. In short, it is a disaster for the Australian consumer.

Prostheses prices have risen consistently as a proportion of health insurance premiums for around a decade. Everywhere else in the world prices have dropped rapidly in recent years whereas in Australia they have remained artificially high due to the operation of the PL. Examples of this are provided in the body of this submission.

In short, the operation of the PL is such that it transfers $800 million each year from the pockets of Australian consumers to the balance sheets of private hospital operators and multinational medical device manufacturers. This equates to an additional cost of $150 per year on each private health insurance premium.

The Government has proposed changes to the operation of the PL so that prices paid will be benchmarked against international prices. This is similar to the mechanism that has been working successfully with Australia's Pharmaceutical Benefits Scheme (PBS). We strongly support these changes as we believe them to be in the interest of both transparency and consumers.

This submission details the features and operation of the proposed new system, using international comparisons where appropriate. We share a risk analysis have undertaken regarding the introduction of the new system addressing potential concerns that may be raised by others, and detail is provided on the specifics around transition and introduction of the changes.

We have made detailed comments on Terms of Reference (a)-(g) & (k). We make no comment on (i) & (j).

Responses to the Terms of Reference

a) The operation of the relevant legislative and regulatory instruments.

The current legislation governing private health insurance forces Australians in the private healthcare market to pay some of the highest prices for medical devices of anyone in the world. To understand why this is so, a historical perspective is important.

The regulation of prostheses in Australia has undergone a number of changes over the past two decades and it is these changes that have driven and then entrenched heavily inflated prices. Between 1985 and 2001, The Commonwealth Department of Health set the amount that health insurers were required to reimburse for medical prostheses. In 2001, the industry was partially deregulated; allowing insurers to negotiate benefit levels with providers and suppliers, but with the restriction that no gaps were to be charged to consumers. This change was driven by the insurers and largely opposed by the device manufacturers. How it would play out was unforeseen.

In this new environment, the market power of large, multinational medical device suppliers and brand loyalty by clinicians contributed to rapid benefit inflation that saw average prosthesis benefits skyrocket by approximately 150% in a four year period. This was a significant contributor in turn to premium growth to 7-9 percent per annum. During this same period, growth in the volume of prostheses was slow (see Figure 1).

In reaction to this price spiral, Government intervened in 2005 to set benefits using the Prostheses List, transitioning to a new model in a mostly cost-neutral way, thereby locking in reimbursements at inflated levels. A maximum reimbursement level was also set for each item, re-opening the possibility for providers to charge payment gaps, but this was removed in 2010 as in practice it was not used. Currently, the PL continues to mandate a single minimum reimbursement benefit for each item on the list, benchmarked to groups of comparable items and set relative to the price of the year before.

As a result, today's PL is winning the battle but losing the war: price inflation is under control, but reimbursement levels remain significantly higher than other comparable health systems.

There is one further aspect that is worthy of mention. In recent years, as large hospital operators gain international experience, they are also exposed to otherwise confidential price data as to the level of prostheses prices in other jurisdictions. This enables them to negotiate an international price with the Australian arm of a multinational manufacturer, but 100% of the price saving accrues to the operator, not the Australian consumer. This allows them to game the system, underpinned by the operation of a Government regulated Prostheses List, that mandates that the private health insurer must pay the inflated price. This is largely how the present system operates to deliver substantial rent to manufacturers and hospitals at the expense of consumers and Government. As a result, every year in Australia hundreds of millions of dollars of economic rent is flowing from consumers and Government to device manufacturers and health care providers.

In this environment, funds are unable to use the otherwise wasted resources on innovations such as extension of gap cover schemes, something that is known from research would be positively received by consumers.

In summary, regulatory changes over the past two decades have first created, and then locked in highly inflated prostheses benefit levels in Australia's private health market, resulting in overpricing in the order of $900m per year for privately insured patients, with further unnecessary costs borne by the Department of Veterans Affairs (which also pays benefits set by the PL). Furthermore, the current governance model that regulates the system is flawed and unable to leverage the right price signals to bring costs down.

b) Opportunities for creating a more competitive basis for purchase and reimbursement of prostheses.

Private health insurers have been long concerned at the impact of prostheses reimbursement on their members. They are also mindful that previous attempts to reform the area have sometimes resulted in unintended consequences. In order to positively contribute to the debate rather than simply complain from the sideline, in the past 12 months, Australia's private health insurers have spent a considerable amount of time and money in developing a set of 11 potential reforms for the consideration of policymakers. These proposed reforms attempt to cover the full range of what might be possible in relation to prosthesis payments, based on international case studies; a review of the literature and interviews with experts in the field. They were then evaluated in terms of both impact (i.e., ability to reduce value flowing out of the system while improving or preserving outcomes) and feasibility (i.e., magnitude of reform required and potential downside risks). For the benefit of the committee, further detail on this evaluation is provided at Appendix A.

Two options emerged as the most promising avenues for reform, diverging significantly in scope of impact and change required.

The first avenue is reference pricing, which would enhance the current model with a stronger evidence base of domestic and international benchmarks. Reference pricing may be relatively straightforward to accomplish as it requires little reform; has widespread usage internationally; is familiar to Australians in the operation of our very successful Pharmaceutical Benefits System and

could lower benefits to benchmark levels (i.e., by 45 percent) within two or three years. We discuss this further in our submission.

The second and longer-term opportunity is to integrate prostheses costs into an episode-based payment. Agreeing on a predetermined reimbursement per procedure (e.g. per MBS item) would create stronger incentives for manufacturers to compete on price and improve the sustainability of the overall health system. This proposal would be more controversial, but it reflects the way that health policy is moving in a number of countries.

c) The role and function of the Prostheses List Advisory Committee and its subcommittees.

Currently, the Prostheses List Advisory Committee (PLAC) deals with over 1,200 product submissions a year, mostly from medical device manufacturers applying to introduce a new or upgraded product into the market. While there is a focus on assessing and pricing new entries, many items on the list and their prices remain unchanged for long periods of time. By way of example, close to half of all items on the PL are still priced at the same benefit level in 2016 that they were in 2011. This is at a time when prices internationally are in decline. The Australian system has been in 'set and forget' mode and this is impacting Australian consumers.

In order to add or update an item on the PL, a 'sponsor' (the medical device company who owns the new technology) must submit an application, which is assessed by the PLAC's associated Clinical Advisory Groups (CAGs) to determine suitability of the device for inclusion on the list. Once the initial assessment has been passed, the PLAC will negotiate a set benefit level to charge, based mostly by reference to prices of equivalent products already on the PL. The sponsor then has the right to appeal the set benefit level, triggering a review by external consultants with a clinical background to determine whether the case warrants reopening. This is a highly regulated and proscriptive approach.

Despite the structured nature of the approvals process, the methodology used to review and assign a benefit level to a PL item is limited in four key ways:

1. PLAC does not systematically collect price point data from manufacturers, public hospitals or international benchmarking services. As a result, domestic or international benchmarks are rarely considered, leading to pricing 'in a vacuum'.

2. New entrants have no incentive to compete on price, for two reasons. First, hospitals have no sensitivity to invoice price, so competitors gain no competitive advantage from a lower minimum reimbursement. Secondly, the minimum reimbursement level that the private health insurers have to pay is set at the price offered by manufacturers comprising 25% of the market, so a new product cannot drive down prices until it gains significant market share. The impact can be seen for example, when patents expire: while competitors are quick to list 'me-too' products, they typically do so at the existing minimum reimbursement level, not at the expected 'generic' discount seen with pharmaceuticals and in other systems. To complicate matters, rebates (paid by manufacturers to a hospital) are not included in the calculations, providing a very significant motivation for providers and manufacturers to 'price shield' in contracts (i.e., agree to maintain a high invoice price and negotiate on opaque rebates).

3. Manufacturers regularly do not provide all the data required by PLAC to build a robust view of cost base vs. clinical effectiveness, citing the information as 'commercial in confidence'. This lack of price transparency is unlike the process undertaken in considering reimbursement for pharmaceuticals by the Pharmaceutical Benefits Advisory Committee (PBAC), a process that works well and delivers lower pharmaceutical prices to Australians.

4. Comparative effectiveness is typically calculated using average outcomes, regardless of individual patient needs.

To expand on the second point above, the process of 'price shielding' is the most insidious element in maintaining an artificially expensive system in Australia. Without change, the system gives private providers an incentive to select PL items with the highest possible benefit level, or where benefits differ, to maximise rebates paid, given the cost will be passed on to private health insurers regardless. The private health insurers are then forced by law to be a passive payer of the prices established on the PL, with penalties imposed for non-compliance. A manufacturer looking to sell at a lower price (with a corresponding lower margin and less ability to provide rebates to providers) has few prospective customers, and cannot break into the market.

In reforming the PLAC, we would see a few principles as being reasonable guides.

1. The structure and processes of PLAC decision- making should be fair, efficient and transparent. They need to respond to changing markets and technological innovation in a timely manner.

2. The same clinical assessment process should be applied to incremental changes to currently listed items as to new items for listing.

The points are both critically important. The current system creates unfair advantages for established manufacturers over manufacturers attempting to create a generic version of an existing product. This was not a factor when the PLAC was set up as few generic devices existed.

Today it is a substantial factor and PLAC processes lag behind market realities. The result is that consumers in Australians using private health insurance pay artificially high prices compared to someone using the public system or compared to similar countries.

d) The cost of medical devices and prostheses for privately insured patients versus public hospital patients and patients in other countries.

Both international and domestic weighted price benchmarks and comparisons suggest that the Australian private health system and its members are paying twice as much as they should on average for prostheses, which would equate to approximately $1b per annum in potential savings currently caught up in the system. Appendix B provides further detail on benchmarking sources.

This sizing of the cost of current inefficiencies has been determined by a number of different methods, all of which gives similar results:

1. Domestic benchmarking of prostheses prices published by Western Australia Health for the

cardiac, ophthalmic and orthopaedic categories shows that on average, public sector prices are approximately 45 percent below those set by the PL.

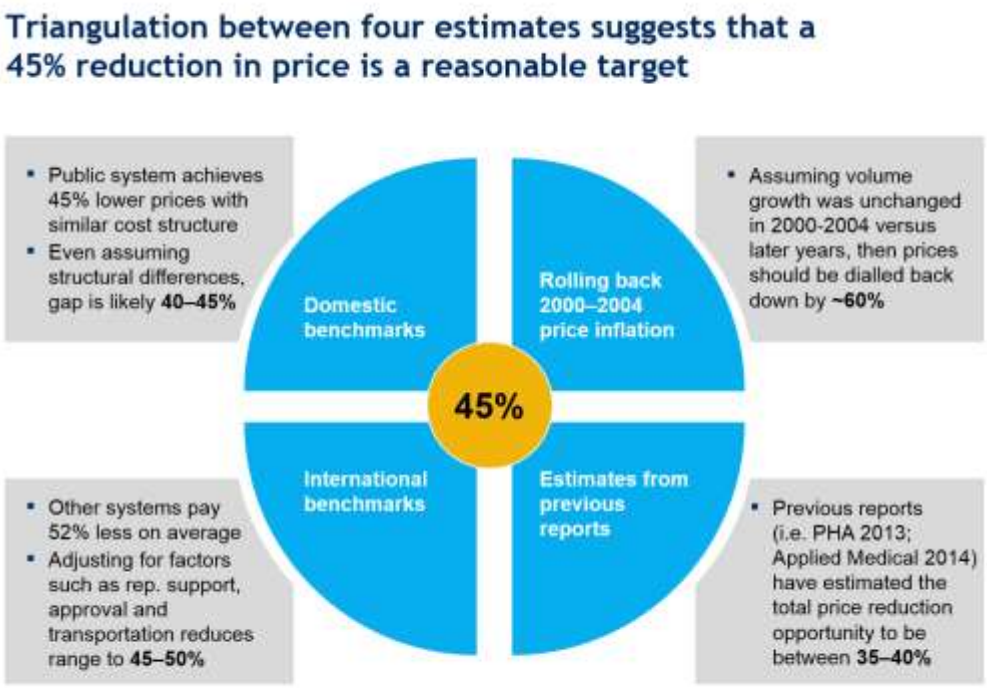
To illustrate this gap, an uncemented Zimmer Trilogy cup (for use in a hip replacement) costs Western Australia Health almost $1,000 less than the listed benefit on the Australian Prostheses List, at $1,939 and $2,900 respectively. This closely matches the hospital-level benchmarking conducted by the Productivity Commission, which found that public prices were 48 percent below those of the private sector,

2. International benchmarking using data from comparable economies such as France, Japan, New Zealand, the United States, Italy, and Spain lends weight to the domestic findings, with prices found to be roughly 50 percent below Prostheses List benefit levels. In France, for example, a Consulta CRT-P model C3TR01 triple- chamber pacemaker costs €4000 (approximately $5,840), compared with a cost of $13,520 on the Australian Prostheses List. These benchmarks come from a range of sources, with France, Japan and Italy publishing public price lists (in a similar way to Australia), and other country comparisons made possible by price point data from suppliers and hospitals.

3. An examination of the rapid price inflation that occurred between 2000 and 2004, when volumes were fairly constant would suggest that prices would need to fall as much as 60% to restore the status quo that existed before unintended policy outcomes took place.

4. Previous estimates have also reached comparable conclusions; Deloitte Access Economics' 2014 report for Applied Medical quantified $592 million waste in the system (implying the potential for a 35 percent price decrease) and a 2013 submission to the National Commission Audit by the PHA estimated a total price reduction opportunity of $700 million (40 percent decrease).

Taking all these estimates together, as shown in the diagram below (taken from a 2015 report commissioned by the industry, *Costing an Arm and a Leg*), would suggest that a 45% reduction in Australian private sector prostheses prices was a reasonable expectation.



e) The impact the current Prostheses List Framework has on the affordability of private health insurance in Australia.

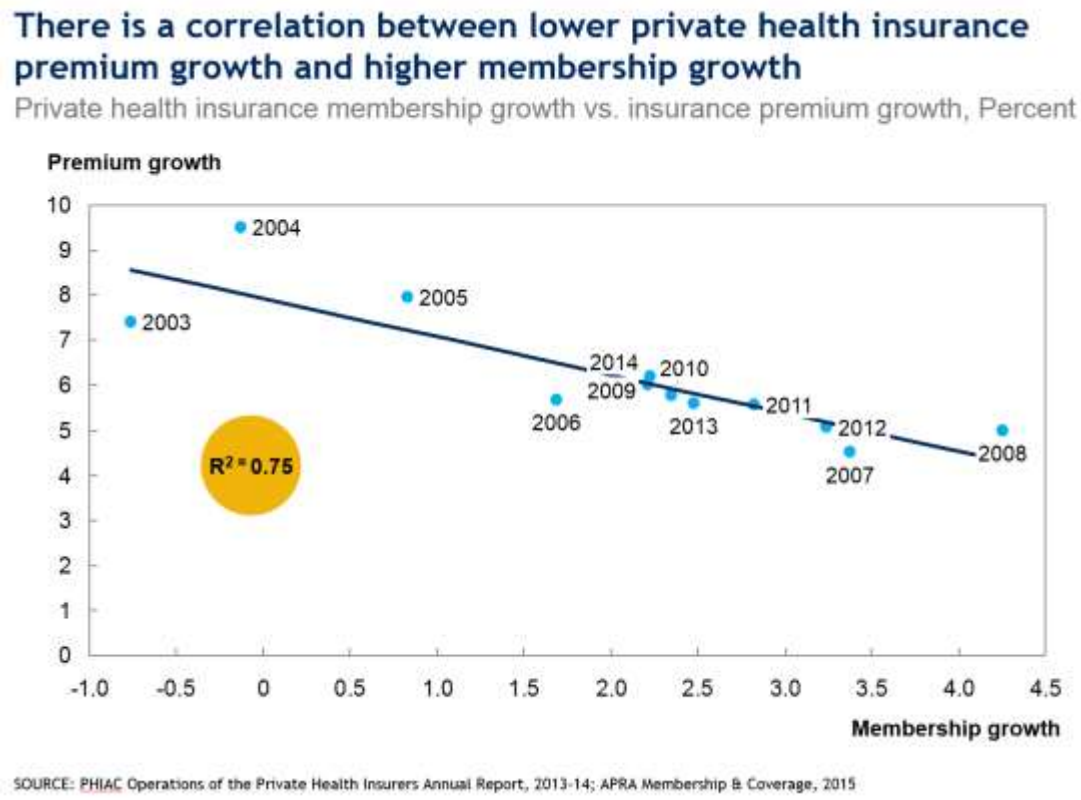
This is the key point facing Australian consumers. The largest single issue facing private health insurance is that of premium increases. In recent years health fund premiums have been increasing at an average of 6.18% pa.

The fastest growing area of health fund costs is that of medical prostheses. The cost of these is 14% of health fund premiums and has more than doubled since 2007. Prostheses benefits paid by insurers increased 9% in 2014/15 and a further 5.6% in 2015/16.

There is urgency to reform of prostheses pricing. Private health insurance is becoming increasingly unaffordable. In the early 1990's, when there was a large reduction in the number of people with private health insurance, there was a commensurate increase in pressure on the public hospital system. In the current challenging financial environment, putting more pressure on the public system makes little sense and will negatively impact Australian patients.

The urgency of action is highlighted by the fact that there is very substantial evidence that Australia is reaching a 'tipping point' where private health insurance will be unaffordable and there exists a very real possibility of a rapid reduction in the numbers of those insured.

The diagram below, taken from PHIAC, illustrates the point about PHI membership and premium price rises.



Affordable premiums in a community rated system such as exists in Australia, requires broad coverage. Without it, those holding onto their insurance tend to be older and sicker, which leads to a 'death spiral' of lower membership numbers, sicker members and high premium increases. This was the situation that existed in 1995/96 prior to the introduction of the 30% rebate.

Australia is not there yet, however it would seem wise to address the issue before a crisis arrives.

f) The benefits of reforming the reference pricing system with Australian and international benchmarks.

Reform of the reference pricing system would adjust reimbursement levels for each clinical category of products to bring them in line with comparable health systems. By defining a basket of common products with domestic and international comparators and accounting for variances in delivery models, exchange rates, etc., a reference pricing system can ensure that all stakeholders receive fair compensation for their value-add with little incremental overhead required.

Reference pricing is a well-accepted system which and is currently used in several countries. For instance, Japan has employed international reference pricing for over a decade. France, Italy, the Czech Republic, Russia and the U.K. are other exemplars of domestic or international reference pricing. In applying this model to prostheses pricing in the Australian health system, the proposed reform would closely resemble similar recent reforms to the Pharmaceutical Benefits Scheme (PBS) where more stringent requirements on price disclosure and international references are expected to yield $3.1 billion in savings by 2018. Many think the actual savings to the system will be much higher.

A concerted effort to introduce reference pricing could yield significant near-term impact; by setting a target of price parity with comparable domestic and international benchmarks, Australia could reduce prostheses expenditure levels by an estimated 45 percent, as described previously. In addition to reflecting external benchmarks, this objective would effectively undo the extreme price inflation of the period 2001-2004, when benefit levels rose by up to 27% every six months.

g) The benefits of any other pricing mechanism arrangements, including but not limited to those adopted by the Pharmaceutical Benefits Scheme, such as:

i. mandatory price disclosure;
ii. value-based pricing; and
iii. reference pricing.

Many countries are grappling with this issue and are dealing with it in a variety of ways. While PHA believes that the Government has chosen the best model for Australia, by way of information, what occurs in Japan might assist the committee.

Japan uses a prostheses list to control prices for complex or innovative prostheses. Prostheses that are considered a commodity, such as sutures or gauze, are included in the cost of the procedure.

Price-setting for a new prosthesis incorporates reference pricing, as a part of a multistage process. At the initial stage, a new prosthesis is categorised as one of two types:

1. Devices that are development or extension of an existing product; or
2. Devices with innovative technologies.

Prostheses that fall into the first category are benchmarked against existing comparable devices, with premiums for added value. The price of the second category is determined through zero-based pricing which breaks down manufacturer costs.

It is only at this stage that international reference pricing is applied. The price generated by the first stage is compared against those of the US, UK, Germany, France and Australia. If the initial price is more than 1.5 times the international average, it will be reduced by up to 25 percent.

Finally, Japan mitigates against the risk that manufacturers will delay or decline to release new products on the market by applying an additional premium to products that launch in Japan within 180 days of their US release.

Japan has successfully utilised international reference pricing alongside other pricing strategies. The result has been to reduce prices every two years (e.g., by 5.6% in 2012) which, unlike Australia, has held prostheses price growth to below the level health inflation.

Other countries have adopted other models. For example, France, Germany, the US and the UK all generally embed prosthesis reimbursement into Diagnosis-Related Group (DRG) episodes. More recently, American bundled payment programs are integrating prostheses payments into an episode of care, negotiated by HMOs, providers and GPOs. Spain includes prostheses costs into hospitals' global budgets. Sweden has instituted a centralised program for value-based reimbursement,

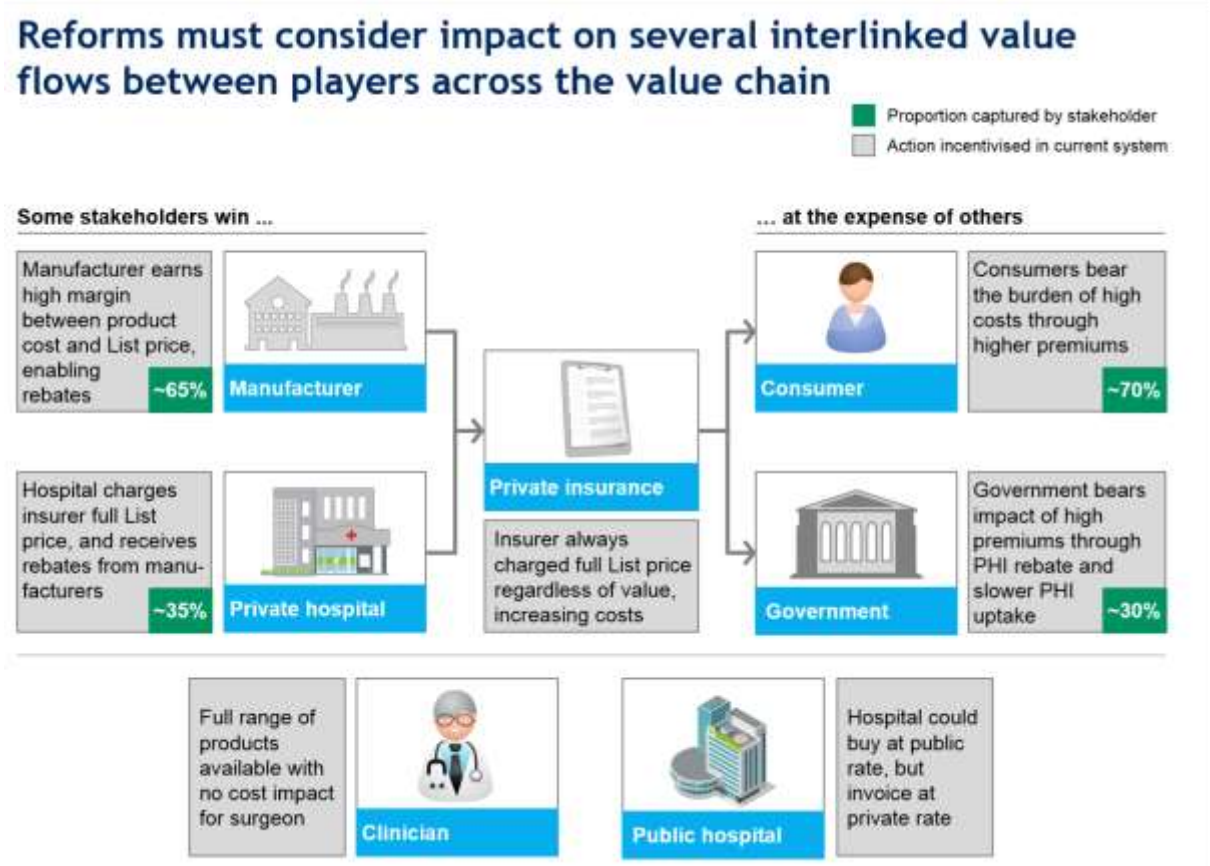
including significant narrowing of reimbursed products and standard follow-up on orthopaedic cases.

All of this reinforces the position that Australia's incredibly heavily regulated system is now working against the interests of consumers and has outlived its useful life. Indeed, while the proposed changes are a substantial advance, many countries are exiting the regulation of this altogether. In the longer term, this too should be the way that Australia goes.

h) Price data and analytics to reveal the extent of, and where costs are being generated within the supply chain, with a particular focus on the device categories of cardiac, Intra Ocular Lens Systems, hips, knees, spine and trauma.

The categories mentioned are the areas where there is the greatest discrepancy between the prices paid by PHI consumers in Australia and public patient or overseas prices. It should be stated that not all prostheses have such a discrepancy and hence we support the Government's focus on these areas as an initial measure. Other areas will work themselves out through the operation of the price disclosure mechanism.

In order to make such an assessment in a fact-based way, it is useful to think about the system in terms of the value flowing from product creation, through to final benefit payment. A simple way of achieving this is to consider who wins and who loses under the present system. We show this by way of a diagram.



As illustrated above, the prostheses value chain can be broken into a number of stakeholders, each of whom add value, and capture value, to varying degrees. They include:

- Manufacturers add significant value via R&D, device production and logistics. However, they are disproportionately profiting by capturing an estimated 65 percent of the markup above benchmark.
- Private hospitals add limited value to the supply chain, primarily sourcing and managing inventory. They are also capturing inappropriate rents equalling approximately 35 percent of the markup above benchmark.
- Insurers add value by covering the benefit of the item via risk pooling and administering funding arrangements. Their profits are negligible, since device costs are passed on to consumers through regulated premium increases.
- Consumers bear the bulk of the cost (approximately 70 percent) through their insurance premiums, but are largely insensitive to the excess payments as they are blended into a single premium payment.
- The Australian Government subsidises almost 30 percent of prostheses costs, regulates the system and covers the healthcare costs of consumers who drop out of private health insurance because premiums become unaffordable.
- Other stakeholders also influence this flow. For example, clinicians often drive product choice, and public hospitals invoice insurers for private patients.

Value is and should be distributed along the chain; however, the system currently tilts that value too heavily towards manufacturers, at the expense of consumers and the Australian Government.

Medical device manufacturer margins are extremely high. In FY15, the top five multinational manufacturers supplying Australian hospitals earned an average gross margin of ~70% on their products internationally, implying that they are earning a substantial markup even on already lucrative international benchmark prostheses prices. In Australia, manufacturers are also capturing at least part of the additional markup from international benchmark prices to Prostheses List reimbursement levels (with the other portion going to private hospitals in the form of rebates), making it likely that they are earning even higher margins on private procedures in Australia.

Private hospital margins are also high: for instance, a large Australian listed private hospital operator recorded EBITDA margins of 25%. By comparison, the average operating margin for American hospitals has ranged between 3.1%-3.4% for the last three years. One contributing factor to those margins is the sharing of the excess value created between international benchmark prices and PL benefits through the practice of rebates for providers provided in exchange for delivery of product volume. While insurers are in theory able to request information on any direct rebates given for particular prostheses and subsequently claim back the value, there are myriad ways of accounting for rebates within a provider/supplier contract that are less overtly tied to particular items and therefore highly unlikely to be picked up and claimed in practice.

The magnitude of the markup split cannot therefore be quantified exactly, however expert and field interviews have led to an approximation of around 35% going to providers (accounting for the wide variability in prevalence of rebates across different categories of prostheses spend), leaving around 65% for manufacturers. Private hospitals therefore have an incentive to always charge the List price to insurers and negotiate rebates connected with spend in other ways, and then to drive increased use of those products that attract the greatest rebate.

Some evidence suggests that Public hospitals also receive a marginal benefit under the current system, when they invoice private patient insurers for the full List amount, but only pay manufacturers public prices. However, this benefit is estimated to be relatively small, as manufacturers typically charge the full Prostheses List price for privately insured patients in public hospitals.

The ultimate burden of a system that drives inflated prostheses spend is borne by consumers and taxpayers.

Consumers bear most of the excessive costs driven by the current system through higher premiums. Given private healthcare insurance premiums are a function of total benefit spend, an excess value of $800 million flowing out of the system equates to approximately 4.5% in premiums for the 11 million Australians who currently hold private health insurance hospital cover, or $150 a year per insurance policy. Or to put it another way, Australian private healthcare consumers are currently subsidising the corporate shareholders of multinational manufacturers and private hospitals.

The Federal Government has also historically paid a heavy price for the inefficiencies of the current system. Since 1999, the Australian Government has offered a rebate of approximately 30 percent to all Australians with private health insurance, to encourage a shift from public to private healthcare. This means that nearly one third of the excess private healthcare spend that has been passed

through to consumers in the form of higher premiums has in fact accrued to public purses. Over time, this additional spend has amounted to a considerable loss to the system: over the past decade, excess government spend on private health insurance rebates due to inflated prostheses costs alone equals $1.7 billion of taxpayer money.

k) Other related matters

We would like to raise two matters here:

1. Potential concerns that might be raised to the proposal and our response to those concerns; and
2. As the success of the reform will be largely determined by design and implementation of the policy, we would like to discuss matters relating to both design and implementation in some detail.

1. Potential concerns.

The proposed reforms will have significant implications for manufacturers, providers, consumers and the Australian Government. As such, these stakeholders should be involved in all phases of the design, and potential unintended consequences must be carefully anticipated. We have undertaken a risk analysis and we share that with the committee. We have divided this into structural and clinical risks.

Structural risks

Three structural risks were identified which could limit the reform's ability to achieve its stated aims:

1. Manufacturer exit;
2. Increasing gap payments; and
3. Price increases for public hospitals.

Manufacturers will feel the greatest margin pressure and may threaten to exit the market. While care must be taken to maintain a viable industry for medical technology players, three facts suggest that the risk of supplier flight is relatively low. First, the proposed reform would not reduce prices below comparable benchmarks. There are no evident reasons why prices should be higher in Australia than in other countries, since transportation costs have been lowered by the shift to Asian production; product representatives assist to a similar degree here as in other systems and Australia's distributor network is also comparable to other markets. Hence, suppliers should still attain the same margins in the private Australian market as elsewhere. Second, a scan of twelve developed countries did not reveal any instances where healthcare reform, including shifting to a reference pricing model for prostheses, spurred a major supplier exit, nor of disruption to supply.

Finally, Australia's exposure to individual suppliers is quite low; with only 1.3% of total prostheses spend being in categories with only one supplier. Thus, manufacturer exit appears to be an acceptably small risk to product supply.

The uncontrolled growth of gap payments is likely to be another alleged adverse consequence of the proposed changes. This is a furphy to maintain the status quo for vested interests. Two points

should be raised. First, most private health insurers and hospitals are in contract. Insurers will not allow such a situation to arise as it is not in the interests of their members. There are multiple suppliers in nearly all PL categories which are TGA approved and should one supplier charge a patient gap, funds would have the option of finding another that did not. This is the way that Therapeutic Group Premiums operate under the PBS and there is no reason to think that it would operate differently here.

In the very unlikely of there being a problem, then the Australian Government may wish to establish protective measures such as requiring manufacturers to agree to no-gap pricing as a condition of listing.

The third area that might be raised as a potential risk is the cross-subsidisation between public and private systems. Manufacturers could claim that the high prices paid by private patients are effectively subsiding low prices in the public system. This is directly contradicted by domestic and international benchmarks, which have demonstrated that Australia's public system has prices in line with a number of other countries. Thus, there is no evidence to suggest that a decline in prices paid in the private sector should entail a commensurate rise in public prices. In fact, public buyers may benefit from the increased transparency afforded by international benchmarks in their negotiations.

Clinical risks

Three clinical risks were identified in our risk analysis:

1. Surgeon throughput may be reduced if manufacturers reduce product representative levels in theatres;
2. Choice of prostheses may be curtailed by providers; and
3. Innovative products could be slower to reach the Australian market.

Manufacturers' product representatives now attend the great majority (perhaps 90%) of orthopaedic surgeries where the company's product is utilised. If lower revenues cause manufacturers to reduce their sales force, surgeons may no longer receive the same degree of support. There are two responses to this. First, interviews with surgeons and international experts indicate that in jurisdictions where prosthesis prices are lower, product representatives still do attend in genuinely necessary cases. Hence, any cutbacks in representative support would likely be most noticeable in 'bread-and-butter' operations, where the surgeon's product knowledge is already expected to be more than adequate. Secondly, if this aspect of the model that has developed in Australia is thought to be absolutely essential (in spite of it not being nearly as frequent in comparable countries) then the model proposed by the government allows for such services to be costed and incorporated into pricing.

Providers may assert that the loss of revenue from manufacturer rebates creates a financial pressure to constrain physician choice. This logic seems flawed, since the PL aims to direct payment through providers, eliminating any incentive to narrow the choice of supplier. Furthermore, many private hospitals are already narrowing choice. For instance, nearly 50% of private providers purchase knees from only one or two manufacturers. If anything, removing the rebates for volume that are a feature of our present system is likely to increase surgeon choice rather than reduce it.

Finally, manufacturers may claim that lower reimbursements will stifle the supply of next- generation technology. While it is important to preserve access to such products, other countries are doing so at substantially lower prices than we achieve in Australia, so this would appear to be of little realistic concern. It is the view of PHI that it is possible to maintain a flow of innovative products without at the same time overpaying for their benefits.

Six key parameters of the proposed reference pricing model

	Recommended solution
Data source	▪ **Combine domestic and international benchmarks** from high-performing, comparable healthcare systems with reliably available data
Calculation methodology	▪ **Set target levels as the best-practice** of product prices in reference health systems, extending to clinically equivalent products where necessary
Integration with current criteria	▪ **Gradually increase weight** of benchmark pricing to create a predictable transition period for business models and industry dynamics
Operating model	▪ **Codify a more transparent price-setting process** for an independent body, including clear points of interaction for each stakeholder with vested interests
Governance structure	▪ **Ensure appropriate involvement** of clinical, policy and industry bodies in each phase of managing prostheses, from overseeing the price-setting reform to evaluating and delisting products
Sequence of roll-out	▪ **Parallel-process** all categories where data is available over three years from May 2016 (as opposed to category-based sequential roll-out)

As these factors are critical for success, we discuss them in some detail.

1. Data sources. To ensure that prostheses benefit benchmarks remain accurate and relevant, the Australian Government could consider adopting a PBS-style approach, wherein manufacturers must provide reference price points from other countries as part of their submission to the TGA or PLAC. The PLAC should define confidence criteria to determine when a benchmark may be used, and assess this independent of industry input. The inclusion of manufacturer catalogue numbers for each item in the Prostheses List would also facilitate cross-referencing.

If a PBS-style approach is unachievable, a secondary method of determining benchmarks would be to identify target systems by evaluating three criteria: their performance in achieving best-in-class benefit levels, their degree of comparability with the Australian health system, and the availability of comprehensive data. An initial assessment suggested that high-potential systems include the Australian public system, the U.K., France, Spain, Japan, large U.S. health systems, and/or Sweden. Appendix C includes a case study illustrating the availability of comparable data for France.

2. Calculation methodology. Several formulae are employed for reference pricing worldwide, typically at the product level. The most common are average, median, or minimum prices from the

benchmark set. It is proposed that reimbursement levels be set to the minimum benchmark price achieved in comparable systems, in order to ensure that consumers are paying efficient prices for prostheses. Where data is not available for a given product, three options exist: either the manufacturer can supply reference prices as described above, or prices of clinically equivalent products can be used, or similar products may be used as a starting point, with the supplier asked to justify any price premium. A mechanism should also be included to adjust for currency fluctuations. The experience of other international reference pricing systems indicates that average exchange rates from the past three years is an appropriate measure.

3. Integration with current pricing levels. To smoothly progress towards full benchmark pricing, it is proposed that the PLAC define both current and target reimbursement levels for each product. A simple step-down mechanism can then be used to define interim reimbursement levels during the transition period. For instance, the first change to reimbursement levels could close half of the gap between current and target reimbursement levels, with the second half closed over the following one to two years. Exceptional cases, such as new products, may be assessed separately, although clear guidelines should be set to ensure that this is limited to less than 5 percent of submissions.

4. Operating model. Under a reference pricing scheme, the PLAC would function with a narrower focus of activities. Its price-setting functions would be simplified to administer reference pricing and rule on exceptional cases.

Further, the PLAC's composition and interaction points with industry could be restructured to ensure that reimbursement levels are set objectively as intended. This would involve a rebalancing of PLAC's membership to ensure equal representation of insurers to the number of manufacturers and providers combined, recognizing that providers are frequently aligned with specific manufacturers. In addition there should be a dominant representation of health economists and clinicians. Manufacturers would be invited to contribute input to the process via three clear steps – first by providing information during the submission, then by presenting to the PLAC prior to price-setting for high-spend products, and finally by choosing whether or not to accept the set benefit level.

The final proposed change would be to strengthen the delisting role of the PLAC. Under the current model, products are rarely delisted and patient outcomes may be compromised by clinicians continuing to use obsolete products. Patent expiration could be another trigger for review of relative clinical effectiveness and reimbursement level-setting.

5. Governance structure. A steering committee of five members (three senior policymakers and representatives from the Medical Technology Association of Australia and Private Healthcare Australia) should be established to review progress 2 months before the release of each Prostheses List. A balanced scorecard of performance metrics should be established to assess progress on average reduction of benefit levels, maintenance of adequate supply, control of gap payments, PLAC backlog, overhead cost of PLAC, and delisting of obsolete products.

6. Sequence of roll out. It is proposed that a 3-year timeline would maximise chances of success. The benchmarking should initially focus on setting the right prices for the 500 prostheses that comprise 75 percent of total expenditure. The set of products with reference prices should be re-evaluated six weeks before the release of each PL to ensure that benchmarks are incorporated as soon as possible.

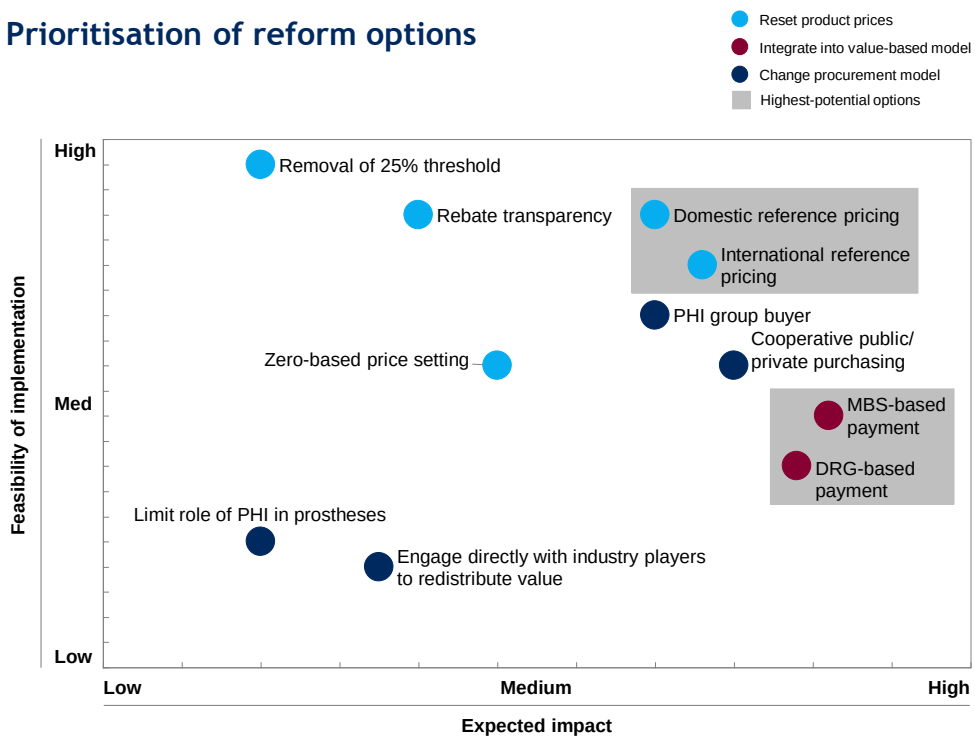
Appendix A: Evaluating reform options

SELECTION AND EVALUATION OF POSSIBLE MODELS FOR REFORM

An international survey of prostheses pricing mechanisms revealed 11 potential options for reform. The relative strengths and weaknesses of each option were evaluated in the context of the Australian market. Each option was assessed against seven criteria along two dimensions: first, it's potential to deliver significant impact (including magnitude, fairness, creation of incremental value, and timing), and second, the ease of implementation (including viability for all stakeholders, operational complexity and downside risk). The results of this exercise are illustrated in Figure 9, below.

These models should not be considered mutually exclusive alternatives. Different models can be complementary, either simultaneously or as part of a gradual timeline for broader reform.
The strengths and limitations of the most promising avenues for reform – reference pricing and value-based pricing – are discussed above. Each of the alternative models for reform is briefly evaluated below.

FIGURE 1



ZERO-BASED PRICING

Zero-based pricing would retain the Prostheses List while re-setting benefit levels based on a close interrogation of manufacturer costs. This mechanism has the potential to significantly reduce prostheses benefit levels, limiting the scope for rebates to providers and excess margins for manufacturers.

However, this model would be difficult to operationalise as it depends on manufacturers to divulge their cost of production. The burden of securing accurate cost data would primarily fall on the PLAC which is already tasked with a significant workload. Furthermore, there is a significant downside risk to this proposal. Manufacturers would have a strong incentive to overstate costs, effectively 'padding' the minimum benefit amount and concealing their actual cost base to maximise profitability.

PRICE TRANSPARENCY

Price transparency requires providers to disclose the actual prices paid for prostheses. Although this model does not address inflated manufacturer margins, hospitals would no longer be able retain excess value in the form of rebates. If hospitals regularly negotiated discounts on Prostheses List benefit levels, the PLAC would be expected to use this disclosed information to gradually reduce minimum benefits.

In practice, providers would be unlikely to reveal the full extent of discounts on minimum benefit amounts. Due to the prevalence of block purchasing arrangements, it would be difficult to identify savings on any particular list item. Furthermore, excess margins to providers may take the form of non-cash incentives such as free consumables and product representative support in the operating room.

REMOVAL OF THE 25 PERCENT MARKET SHARE THRESHOLD

Removing the 25 percent threshold would allow reimbursement levels to reflect the prices of small, low-cost manufacturers. Currently the PLAC uses the prices of manufacturers with a minimum 25 percent market share to determine the minimum insurer reimbursements. This threshold is designed to ensure that benefits are set at a level where the market will be supplied. However, the threshold currently operates to entrench large, incumbent manufacturers and prevent newer, low-cost manufacturers from putting downward pressure on benefit levels.

This measure may be a worthwhile complement, but alone is unlikely to close the gap to benchmark systems. Research and interviews indicate that there are a limited number of manufacturers who are attempting to compete on price. The price impact of low cost manufacturers entering the market would also be moderated by the need to reliably supply the market and ensure equivalent quality.

FORMATION OF COOPERATIVE PURCHASING AGREEMENTS BETWEEN PUBLIC AND PRIVATE HOSPITALS

Allowing public hospitals to purchase on behalf of their private counterparts would allow private patients to share in the discounts negotiated by the public system. Given that prostheses purchased by the public system are approximately 40 percent less expensive than Prostheses List benefit levels, this would offer significant savings to consumers. Additional savings could be driven by the combined bargaining power of the public and private system.

However, this course of action is unlikely to garner the necessary support from the public system. By adding high-price private volumes to low-price public volumes, manufacturers could demand higher average prices than current public levels. One potential path forward would be for motivated public buyers to explore the incremental discounts that manufacturers would be willing to offer for the additional volume of private insurers.

FORMATION OF GPO BY PRIVATE HEALTH INSURERS

The formation of a group purchasing organisation (GPO) by private health insurers would better align incentives by placing purchasing decisions in the hands of payers. This proposal addresses the core structural disadvantage of the current model, which creates little incentive to reduce costs by those who control purchasing decisions (clinicians and hospitals).

There is, however, a sound rationale for the current basic purchasing structure. First, hospitals are better able to respond to the clinical needs of doctors and negotiate appropriate product choice. Product purchasing that is further removed from practitioners may face resistance from doctors. Secondly, there are potential legal complications to this model. PHIs would need to mobilise their combined purchasing power to avoid the rise in benefit levels that occurred in 2001-2004 (where PHIs negotiated individually with large multi-national manufacturers). This would require active collaboration with regulators to ensure that Competition Law is fully respected.

LIMIT ROLE OF PRIVATE HEALTH INSURANCE REIMBURSEMENT IN PROSTHESES

Given that prostheses tend to be less expensive in public hospitals, prostheses spending could be reduced by shifting an increasing share of prosthesis activities to the public system. However this reform would likely have wide-reaching, negative effects on the health system. Lengthy waiting times for elective procedures would only increase, private hospitals would lose a source of revenue, public healthcare expenditure would increase, and private insurance would become less attractive for many consumers.

ENGAGE WITH OTHER INDUSTRY PLAYERS FOR A MORE EQUITABLE DIVISION OF VALUE

Cooperation between private health insurers and manufacturers could reduce excess margins and pass on savings to consumers. For example, manufacturers could agree to pass on a proportion of costs savings to insurers, rather than providing rebates to hospitals.

However, any savings would be limited to excess margins currently flowing to providers. There would be little incentive for manufacturers to voluntarily reduce their own margins. This is only exacerbated by the fact that individual health insurers with no control over product choice would be in a weak bargaining position relative to manufacturers.

Appendix B: Further detail on benchmarking sources

Given the important consequence to the industry and government of any price benchmarks published in this report, every effort was made to take a rigorous and data-driven approach. Further detail is provided below on the sources and methods used for each stage of the benchmarking analysis.

AUSTRALIAN PRIVATE BENEFITS

Prices paid by private health insurers in Australia were drawn from the August 2015 Australian prostheses list, available online at: http://www.health.gov.au/internet/main/publishing.nsf/content/prostheses-list-pdf.htm.

WEIGHTING BY SPEND

In order to arrive at an accurate comparison, each item's minimum benefit was weighted by the overall spend on that item, as measured through aggregated 2014 Australian private health insurer claims data. This process ensured that items could not be deliberately selected to bias the results towards products with extreme price differentials.

DOMESTIC BENCHMARKS

Western Australia Health public hospital procurement data was used as an indicator of prostheses prices in Australian public hospitals. Spend-weighted prices for a basket of 41 prostheses SKUs were compared, to arrive at an average benchmark. Of the 41 SKUs, Prostheses List process were lower for only two SKUs and higher for the other 39 – ranging from being 0.9 to 5.2 times the level of the Western Australia Health price points. As publicly available Western Australia data is limited to particular categories, only cardiac, ophthalmic and orthopaedic prostheses were examined. These three categories represent approximately 34% of overall private health insurance prostheses expenditure. It should be noted that the data is currently limited to Western Australia Health. It is possible that public hospital buying groups in more populous states (e.g. Health Purchasing Victoria) have different - and potentially lower - prices, but information is not yet publically available for these groups.

INTERNATIONAL BENCHMARKS

Prostheses pricing data from the United States, New Zealand, Spain, Japan, France and Italy was used to determine an international benchmark of prostheses prices. A spend-weighted basket of 50 prostheses SKUs from hip, cardiac, and general miscellaneous categories was analysed, representing 42% of total prostheses spend. A rolling 12-month average was used to determine each exchange rate used in the analysis. Of the 50 SKUs, Prostheses List prices were only lower for one SKU and higher for the other 49 – ranging from being 0.8 to 5.3 times the level of international price points. Given the benchmarks across the countries provided a wide range of data points, a weighting was assigned to each based on the number of items making up the sample, the representation of prostheses categories in the sample, and the country's level of comparability with Australia, to arrive at an overall benchmark.

Appendix C: Referencing the French Prostheses List

Case example: Referencing the French Prostheses List

France provides both comparable and accessible data that could be used in international reference pricing. The French system employs a DRG model for financing medical devices, informed by a publically available benchmarked price list called the SPP. The list includes both general items (for commodities), and manufacturer-specific items (for products that are demonstrated to be materially distinct from the closest device in their category). It is available online - searchable by unique code and category - as well as being downloadable in full.

The SPP is divided into four overall sections, of which section 3 is a direct match to the Australian Prostheses List:

Title I: Medical devices for treatments and devices for life care, dietetic food and dressing articles

Title II: External prostheses and orthotics

Title III: Implantable medical devices & human tissue

Title IV: Physical handicap vehicles

Under Title III, items are first categorised by material type (ie. disposable synthetic; disposable derivatives and animal tissue; human tissue; active devices), then divided by area of medical specialty. This categorisation differs slightly from the Australian Prostheses List, which divides directly by area of medical specialty (see Figure 10), but is similar enough to enable relatively straightforward matching of items using the French online category sorting tool, and/or keyword searches. While neither the French nor the Australian list uses a common internationally recognised manufacturer code, once a match is found then the French and Australian unique codes can be linked, to enable continued tracking and comparison.

For any group looking to compare French and Australian item prices, the suggested process to follow would be:

1. Search for each item by manufacturer name and description in the French list. If a particular manufacturer item line is included, use this price.
2. If there is no manufacturer-specific item, search for only the generic description match, and use this price.
3. Once a match has been found, link the unique French code with the unique Australian billing code, to allow for continued tracking and comparison.

It is recommended that the initial matching process outlined above be completed by someone with both French and English skills, and medical knowledge (such as a bilingual physician)

Comparing the French and Australian Prostheses List structure

French List	Australian List
Liste des produits et prestations remboursables	**Prostheses List**
▪ Title III: implantable medical devices & human tissue – Chapter 1: Disposable - synthetic origin ▫ Section 1: Cardiac ▫ Section 2: Ophthalmic ▫ Section 3: Orthopaedic ▫ Section 4: Ear, Nose & Throat ▫ Section 5: Hearing Aids ▫ Section 6: Urogenital ▫ Section 7. – Supporting implants (digestive, cardiac, pleuropulmonary, orthopedic, gynecological, urological, in particular) ▫ Section 8: Plastic and Reconstructive - Breast ▫ Section 9: Plastic and Reconstructive – Liposuccion – Chapter 2 – Disposable - from derivatives or animal tissue – Chapter 3 – Human tissue implants – Chapter 4 – Active implantable devices	▪ Part A – Category 1: Ophthalmic – Category 2: Ear, Nose & Throat – Category 3: General Miscellanous – Category 4: Neurosurgical – Category 5: Urogenital – Category 6: Specialist Orthopaedic – Category 7: Plastic and Reconstructive – Category 8: Cardiac – Category 9: Cardiothoracic – Category 10: Vascular – Category 11: Hip – Category 12: Knee – Category 13: Spinal