

Australia's Surgical Surcharge: How Australians are paying too much for medical devices through the Prescribed List of Medical Devices

June 2023



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#### **Executive summary**

Australia pays some of the highest prices in the world for medical devices through the Prescribed List of Medical Devices (PL).

Australia's spending on medical devices through the PL since 2006 has grown three times faster than inflation.

Prices of medical devices on the PL are much higher in Australia compared to an aggregate of eight peer countries, including the United Kingdom, New Zealand, and France.

Australia pays 70 per cent more through the PL than New Zealand for a hip replacement stem, for example, and 30 per cent more for a drug eluting stent.

Australia pays 2.4 to 4.7 times more than peers abroad for a selection of frequently-used devices.

The cost for a selection of 46 frequently-used devices is 2.4 times as much in Australia compared to the average of these eight overseas markets. Compared to the lowest prices from these markets, prices on Australia's PL are 4.7 times higher.

Germany pays the least for these 46 devices: just 22% of what Australia does through the PL.

These high prices persist despite the fact that the medical device market is mature with a diverse range of suppliers. Instead, the PL's lack of downward price adjustment mechanisms and other settings to boost competition mean that costs have grown substantially. This additional expense has important implications for Australian consumers and taxpayers.

Even if the current reforms are implemented as promised, Australia will still pay twice as much for medical devices compared to the average of eight peer countries.

The previous federal government agreed a set of price adjustments with medical device manufacturers in 2022 that would reduce prices by 13%. But this would still leave Australia with a total device cost base twice that of the average of eight peer countries.

This agreement was made without advice from the Department of Health, who wrote after the fact that it "predominantly benefitted industry rather than providing a negotiated balance of benefits to industry and the Australian community".

Consumers foot the bill. The total cost of medical devices on the PL is an estimated \$967 million higher than in similar countries per year. Higher costs further burden consumers, who are managing difficult cost-of-living pressures.

\$619 million of these additional costs are paid by consumers through their private health insurance premiums, \$77 million paid by consumers through self-insurance, and \$271 million paid by the federal government through the Private Health Insurance Rebate, veterans' care, and workers' compensation.

The government must also fund the administration of the PL, despite the fact that this centrally-managed system does not result in lower costs and isolates prices from the downward pressure of market forces. This is estimated at approximately \$14 million per year.

Rising costs that contribute to premium growth leads to lower participation in private health insurance, especially when cost-of-living pressures are high. In turn, lower insurance participation mean that a larger share of Australians must rely on the public system.

Higher premiums also reduce consumer spending and are an additional drag on other sectors of the economy.

There is an opportunity to further reform the pricing framework of medical devices in Australia to lower prices and boost patient outcomes by embracing a more open and competitive system.

An ageing population will mean demand for medical devices will keep growing. Ensuring prices are sustainable in the long term while prioritising patient outcomes is a critical challenge facing Australian healthcare.

Aligning prices to those abroad is unlikely to impact supply or require co-payments. Countries such as Germany, Sweden, and Austria pay a quarter of Australia's prices and still enjoy plentiful supply, without charging patients co-payments.

Australia's relatively small market size and distant geography should not be a barrier to lower prices. New Zealand's prices are 1.7 times lower.

There are greater opportunities to better align price signals with clinical effectiveness through a reformed PL. As an example, our hip and knee replacement revision rates through the PL are 3 percentage points higher compared to in the United Kingdom, New Zealand, and Sweden.

Australia can do better.

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3 Higher costs are borne by consumers and taxpayers

Further reform of the Prescribed List for Medical Devices can reduce prices and put patients first



## Australia pays more for medical devices than our peers abroad through the Prescribed List of Medical Devices (PL)

### Medical devices in Australia cost significantly more than in other countries

The total cost of medical devices through the PL has grown three times faster than inflation trends over the past 15 years.

Such expensive costs are driven by growing utilisation and the inflated prices that Australia pays on the PL. Common medical devices such as pacemakers, drug eluting stents and hip replacement stems cost approximately 20 to 70 per cent more in Australia compared to eight peer countries with similar health markets.

For example, Australia is paying three times as much as France for a common hip replacement component and almost 30 per cent more than New Zealand for a drug eluting stent.

A study comparing the price of 46 commonly used medical devices on the PL found that they are 2.4 to 4.7 times more expensive compared to international peers. Controlling for population size and utilisation, Germany pays a quarter of what we pay. While the global prices of many devices have fallen significantly as technologies have matured and production scaled and diversified, prices on the PL have remained expensive.

### Centrally-managed prices through the PL have not produced globally competitive outcomes

Prices set on the PL are negotiated between the federal government and medical device manufacturers, without the input of payors such as private insurers and public payors such as the Department of Veterans' Affairs. The broader health sector are also not involved in setting prices. Even the federal Department of Health was not included in discussions in 2022 where the Minister of Health agreed a Memorandum of Understanding with manufacturers. The department has since said that the agreement is not to the benefit of Australians (see Section 3).

The PL has isolated device prices from market forces: its high prices are unreflective of supply. The medical device sector is globally diversified and mature, with prices in other markets being much cheaper because of the falling cost of these well established technologies.

The PL also does not encourage competition to drive prices down. Reference pricing means device sponsors are not incentivised to introduce lower prices below the minimum benefit amount.

#### Other peer markets overseas secure value for money through competitive tendering and bundling payments by episode, type of procedure or outcome

Four markets – Germany, Austria, Sweden and Italy – allow prices to be negotiated by third-party procurement agencies who are incentivised to drive prices down. In these markets, prices have fallen much more than in Australia for commonly used and established devices.

France and New Zealand (PHARMAC) set nationalised list prices but use their national scale purchasing power to negotiate competitive prices with suppliers. Similarly, NHS Supply Chain in the UK negotiates competitive pricing and allows NHS trusts to negotiate further with suppliers based on their needs and volumes.

All of these markets secure value for money by using competitive tendering and bundling. Australia's PL is an anomaly in this landscape, with no competitive pricing mechanisms and no bundling of payments.

## The Prescribed List of Medical Devices (PL) sets the price for medical devices for private health insurers and other healthcare payers, including the Department of Veterans Affairs

The purpose of the Prescribed List of Medical Devices (PL) is to...



- Regulate the prices of medical devices to control costs and ensure access to affordable healthcare for all Australians
- The PL sets minimum benefits for each approved medical device listed that must be paid by private health insurers (PHI), the Department of Veterans' Affairs (DVA) and other compensation insurers such as Comcare, icare, and the Transport Accident Commission (TAC)
  - The PL lists ~11,000 devices in ~1,700 price groups
  - The PL is updated 3 times per year
- The PL was introduced in 2005 to control prices after a period of rapid price inflation in medical devices
- However, since then, prices on the PL have been held high, affecting premiums and diverting funds from other areas of health

Common examples of PL medical devices include:



- Hip replacement components
- **Knee** replacement components
- Shoulder replacement components
- Pacemakers

- Drug eluting stents
- Interocular lenses

### Medical devices benefits paid by private health insurers have grown 3x faster than inflation

The total cost of medical device benefits paid by private health insurers in Australia rose by 144% from \$0.9 billion to \$2.2 billion over the past 15 years. This has been in part caused by growing utilisation and in part by prices being 'locked' at elevated levels in 2005 after a period of rapid price inflation.

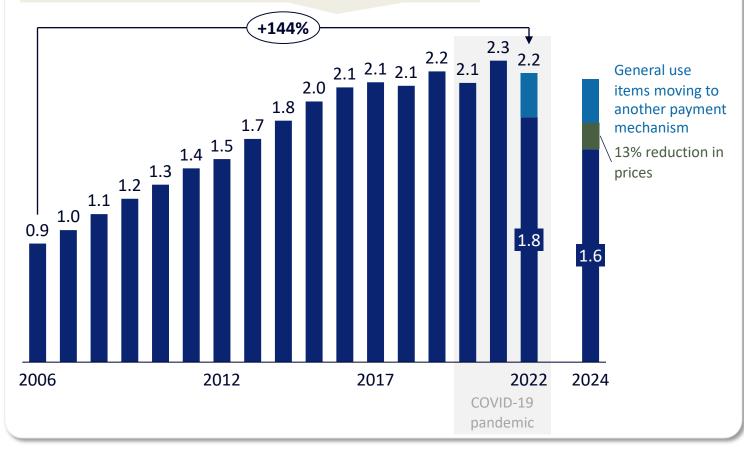
From 2005 to 2016, the benefit amounts set by government did not substantially go down for the majority of medical devices. As utilisation grew, this caused the total cost of the PL benefits to expand by an average compound annual growth rate of 5.7% per year to \$2.2 billion in 2022.

Price adjustments introduced for 2024 are expected to reduce prices by 13%, and shift general use items off the PL to another mechanism of private health insurance reimbursement.

#### Exhibit 1: Medical device benefits paid by private health insurers in Australia annually

\$AU billions, nominal

During this period, inflation rose by 48.2%, meaning the increase in medical device benefits paid was ~3 times the rise in inflation



Note: Inflation estimate based on RBA data up to April 2023. 2024 reflects the removal of \$328m in general use items off the list and a 13% reduction in prices on the rest of the list. Price reduction discussed further in Section 2. For the expected 2024 cost, utilisation has been held constant using latest available data in order to compare price changes.

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Sources: APRA Dec 2022; Federal Department of Health & Aged Care 2023; Reserve Bank Australia 2023; Mandala analysis.

# The costs of common medical devices on the Prescribed List are 2.4 to 4.7 times higher in Australia compared to peers

A comparison of medical device prices between Australia and peer countries for a sample of 46 commonly used devices, representing about 14% of the PL by value, show that Australia pays more for medical devices compared to 8 peer countries.

Based on February 2022 PL prices, the cost for these 46 devices is approximately \$286 million. Had Australians relying on the PL paid prices equivalent to the cheapest in eight peer countries (see exhibit), the total cost would have just been \$61 million: 4.7 times less than what PL prices cost. This would represent a saving of \$225 million dollars for these 46 devices alone in 2022.

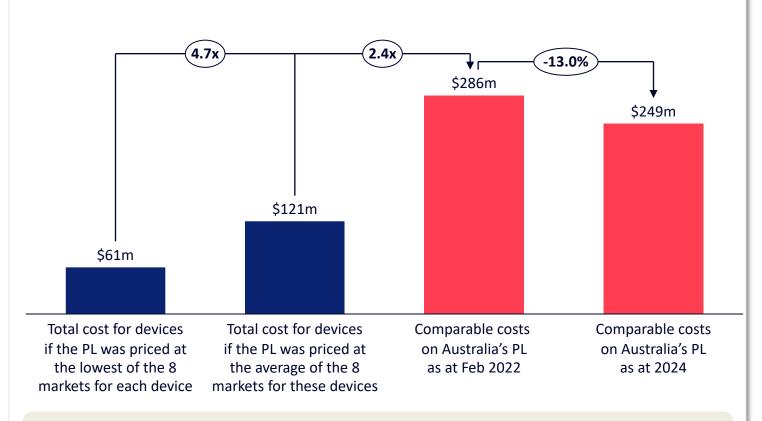
Compared to average prices in these eight countries, the PL is 2.4 times more costly.

Modest price reductions that are planned to be phased-in between 2022 and 2024 will reduce prices by about 13%.

The 46 devices used for comparison here include joint replacements, drug eluting stents, pacemakers, neurostimulators and two high-volume general and miscellaneous items (gels used in surgery).

#### Exhibit 2: Utilisation-matched costs of 46 PL devices compared to 8 peer countries

\$AU millions, February 2022



Benchmark countries: UK, NZ, Germany, France, Sweden, Italy, Austria and South Africa. These eight countries are similarly developed and have markets comparable to Australia's private health system.

Note: This chart compares costs across 46 devices spanning hips, drug eluting stents, pacemakers and neurostimulators. The total Australian spend on these 46 devices was \$286m per annum (p.a.). Utilisation was matched to Australia's HCP1 utilisation in 2020-21.

Sources: Evaluate 2022; Department of Health 2023; Mandala analysis.

# Countries including Germany and Sweden pay a quarter of the price of the Prescribed List for common devices

Based on the aforementioned selection of 46 commonly used medical devices, Germany's equivalent cost for those devices was just 22% – just over a fifth – of Australia's PL in February 2022, controlling for volumes used.

Sweden's equivalent cost was 25% and France's was 46%. New Zealand's and the United Kingdom's costs were closer to the PL's cost but were still just 60% and 71% of the PL's cost, respectively.

The PL's cost for these items in 2024 are expected to be 13% lower than in February 2022 but this will still be substantially higher than peer countries. Given that prices in other markets may also reduce, the very large gap between the PL and other international markets may persist.

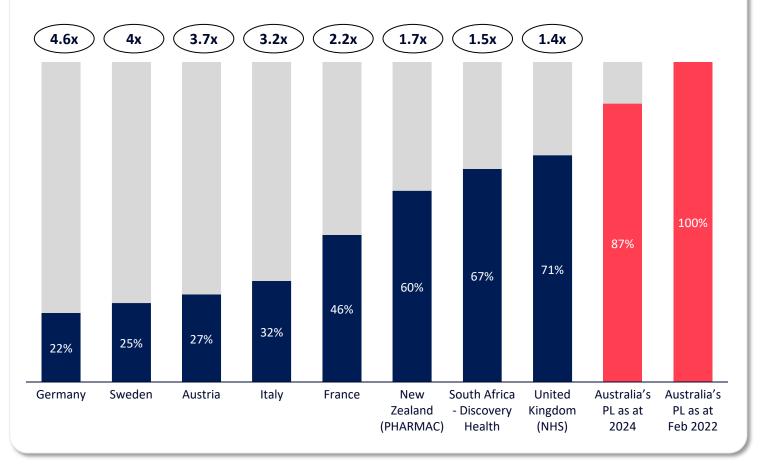
These peer countries include markets with similar geographic distances, similar sizes and with similar incomes to Australia.

#### Exhibit 3: Utilisation-matched cost of 46 common devices compared to 8 peer markets

% of Australia's February 2022 PL cost

Sources: Evaluate 2022; Department of Health 2023, Mandala analysis.

#### Premium that Australia's PL set compared to Feb 2022



Note: Information is not available for every device code in every market, for example, pacemakers are not listed on PHARMAC in NZ. This comparison is based on a selection of up to 46 medical devices and their prices and Australian utilisation in 2020-21, including pacemakers, hips and drug eluting stents, costing the PL between AUD \$129-286 million p.a.

# Common devices such as drug eluting stents and hip replacements cost 20-70% more than the UK, NZ & France

Even after price reductions between 2022 and 2024, the PL's prices will remain higher than the UK, France and New Zealand for common individual devices such as drug-eluting stents and hip replacements.

The expected 2024 price of drug eluting stents are approximately 30% higher than in New Zealand and 20% higher than in France.

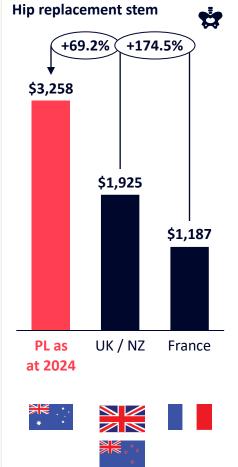
For two common devices used in hip replacements – stems and cementless HA cups – 2024 PL prices will be approximately 70% higher than in the UK and New Zealand.

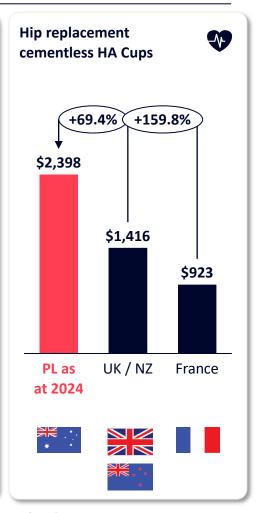
In the case of hip stems, the 2024 PL prices are 175% more than that paid by the French in 2022. For cementless HA cups, 2024 PL price are 160% more than French prices in 2022.

#### Exhibit 4: Price comparison of three high-use medical devices between Australia and peers

\$AU price per medical devices, 2024 estimate for PL and February 2022 for other markets







Note: High-use devices based on HCP1 utilisation in 2020-21. Devices shown are the Medtronic Resolute Onyx MI189, S&N Polarstem SM122 and the S&N Reflection/R3 SN286.

Sources: Evaluate 2022; Department of Health 2023; Mandala analysis.

# The Prescribed List's price for a drug eluting stent has historically been much higher than the UK's, Germany's, and France's

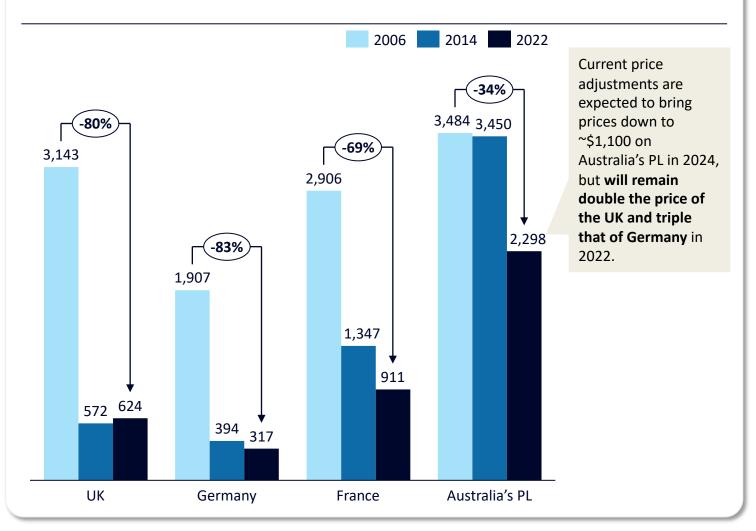
Prices for medical devices can reduce over time as manufacturing processes scale and become more efficient and as new producers enter the market.

In 2006, the price for a cardiac drug eluting stent cost over \$3,000 in the UK, nearly \$2,000 in Germany, and nearly \$3,000 in France. By 2014, these prices had dropped substantially in the UK and Germany to \$572 and \$394 per stent. In France, this was at \$1,347.

The PL's prices have persisted at much higher levels. Prices for a stent were above \$3,400 in 2006 and 2014 and were still over \$2,200 in 2022. Current price adjustments agreed to by the previous government will reduce this to \$1,100 by 2024 but this would still be triple the 2022 German price.

#### Exhibit 5: Case study of drug eluting stents (cardiac) - price evolution from 2006 onwards

\$AU per stent, nominal terms, 2006, 2014, 2022



Note: Device compared is listed on the PL under the grouping 08.12.01.01 Coronary stents Drug Eluting - General Purpose.

Sources: Wenzl and Mossialos 2018; Evaluate 2022; OFX 2023; Australian Prostheses List Feb 2006 & 2014, Mar 2022; Mandala analysis.

### Higher prices do not reflect limited supply; in fact, there is ample supply and multiple suppliers for most devices

Trade data shows that the global supply of devices is relatively unconcentrated and that Australia unnecessarily sources its supply from a more concentrated set of countries.

Globally, 80% of global supply comes from 8 countries, whereas 80% of Australia's supply comes from just 5 countries.

Globally, the US is the largest source of medical devices and contributes approximately a quarter (24%) of total exports, followed by Ireland (15%), the Netherlands (14%) and Germany (8%).

Australia's largest sources of medical devices are currently the US (41%), followed by Ireland (18%), and Switzerland (10%).

Australia is unnecessarily sourcing its supply from a more concentrated set of countries.

#### Exhibit 6: Sources of global supply and Australian supply of medical devices

% of exports to global and Australian market

80% of exports to a particular ma					
porter to world	Share of exports	Exporter to Australia	Share of exports		
USA	24%	USA	41%		
Ireland	15%	Ireland	18%		
Netherlands	14%	Switzerland	10%		
Germany	8%	Germany	7%		
Switzerland	7%	Singapore	5%		
Belgium	6%	United Kingdom	4%		
Singapore	5%	Mexico	2%		
United Kingdon	n 4%	Italy	2%		
France	4%	Belgium	2%		
Costa Rica	3%	France	1%		
	102/	0.1	60/		

Others

Sources: CEPII Trade Flow 2021; Mandala analysis.

Others

### The existing funding model for the Prescribed List uses standalone item pricing, rather than bundled or outcomes-based payments

There are three typical models used to price medical devices:

- Standalone pricing model: Under this model, payments are made per device. This is the model of the PL and NZ's public system. However, under the PL, there are no price adjustments made to align to international benchmarks or cost effectiveness data. New Zealand is currently negotiating national contracts for devices, including market share agreements for competitive pricing on products. This is similar to practices of Australian states in our public system.
- **Bundled payments:** Instead of assigning prices for individual devices, prices can be based on the type of procedure or treatment (referred to as a DRG, diagnostic related group) where healthcare providers receive an amount based on an 'episode of care'. Such a structure incentivises cost reduction. The UK, France, and the US have systems that bundle prices in this way.
- Outcomes-based reimbursement: define rules within applicable categories to incentivise high value care and reduction in system level costs (e.g., provider coverage for revisions). For example, in Sweden health providers must assume financial costs that are related to the primary surgery two years post-operation. Their OrthoChoice model also withholds 3% of provider reimbursement pending achievement of outcomes, such as patient pain assessment.

#### Exhibit 7: Six approaches and models to price and fund medical devices

	Standalone item pricing			Bundled payment	Outcomes- based reimbursement	
	1	2	3	4	5	6
Pricing approach	Existing PL model	Re-priced PL model	Buyer-led market pricing	Episodic DRG- based bundled prosthesis pricing	Episodic DRG- based pricing for entire episode of care	Outcomes- based reimbursement
Description	Maintenance of existing PL pricing mechanism, with minimum prices adjusted based on intermittent industry agreements	Pricing of prostheses relative to benchmark price based on international benchmarks and/or technology assessment on evidence of effectiveness (e.g., in reducing revisions)	Pricing based on negotiations directly between payors and device manufacturers, with or without caps on gap charges for prostheses	Mapping of prostheses to the most appropriate DRG, and providing bundled payments for the DRG within which providers will need to optimise prostheses costs	Integrated bundled payment for entire episode of care, of which prostheses form one component, allowing benefit to be captured for prostheses which reduce overall cost of care	For applicable categories, defining rules to incentivise high value care and reduction in system level costs (e.g., provider coverage for revisions)

Note: DRG refers to diagnostic-related group, e.g., hip replacement, minor complexity. Buyer-led pricing typically enacted through groups or organisations, who by aggregating purchasing value, can negotiate discounts with manufacturers, distributors and other vendors

### Compared to peer countries, Australia's PL sets nonbundled and non-competitive prices for medical devices

Other international markets ensure efficient prices and overall costs for medical devices through bundling and competitive tendering or negotiation.

Bundling of payments by episode of care encourages both efficient allocation of spending and suppliers to lower prices to compete. This helps healthcare markets overseas use market forces to reduce medical device costs compared to Australia's PL.

Incentives may be set on top of the allocated payment for a bundle in order to incentivise the selection of evidence-backed devices. Provisions can also be made to ensure flexibility as required for patients who may require special devices due to their circumstances.

Competitive pricing is also secured through tendering or negotiation.

System	Is there bundling of medical device payments?		Are prices subject to competition?				
Description	_	sets a total reimbursement price e of procedure or treatment.	includ	s can be subject to competition through various mechanisms, ding direct negotiation or competitive tendering by rnments, hospitals or procurement groups.			
Australia's PL – private	X •	No	X	<ul><li>No competitive tendering or negotiation</li><li>No benchmarking with international prices</li></ul>			
NZ – public	<b>X</b> •	No	$\checkmark$	Prices negotiated via national contracts			
NZ – private	•	By prostheses (an allowance of the prostheses is set within the bundled price negotiated by insurers and healthcare providers)	X	<ul> <li>Prices negotiated by hospitals, although their individual purchasing power is smaller than the national scale.</li> </ul>			
Australian – public	•	By episode-of-care	<b>(</b>	<ul> <li>Prices negotiated by states, although their individual purchasing power is smaller than the PL's scale.</li> </ul>			
UK (NHS)	•	By episode-of-care	$\checkmark$	Prices negotiated by hospitals/NHS/procurement groups			
France	•	By episode-of-care	$\checkmark$	Prices informed by negotiations by government			
USA – Medicare CJR	<ul><li>.</li></ul>	By episode-of-care		<ul> <li>Bundled payment model based on historical costs (over 3 years), hospital location, patient need &amp; an outcome incentive for quality of care (e.g., reduced revisions)</li> </ul>			
Sweden	•	Combination of models, including outcomes-based OrthoChoice model		Centralised tenders and contracts negotiated by a leading procurement contract negotiation group			
Germany	<ul><li>•</li></ul>	By episode-of-care		Centralised contracts negotiated by contract negotiation group based on actual cost, effectiveness & pt benefit			

Exhibit 8: Australia's approach to pricing medical devices is an anomaly internationally

Note: USA Medicare CJR refers to their "Care for Joint Replacement" model. Pt benefit means patient benefit.

Sources: Private Healthcare Australia 2020: Evaluate 2022: Centers for Medicare & Medicaid Services 2023: French National

Sources: Private Healthcare Australia 2020; Evaluate 2022; Centers for Medicare & Medicaid Services 2023; French National Authority for Health (HAS) 2023; Mandala analysis.

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- Australia pays more for medical devices than our peers abroad through the Prescribed List of Medical Devices (PL)
- Existing 2022-24 reforms will leave us a long way from international price benchmarks

3 Higher costs are borne by consumers and taxpayers

Further reform of the Prescribed List for Medical Devices can reduce prices and put patients first



## Price adjustments agreed to between the previous government and manufacturers will take place between 2022 and 2024 but PL prices will remain extremely high compared to international peers

Prior adjustments to the PL (referred to as the Prostheses List until 2023) plan to reduce price gaps between the PL and prices paid by public hospitals

On 14 March 2022, the then Minister for Health entered an MoU with the Medical Technology Association of Australia (MTAA) to reduce prices in a phased approach between 2022 and 2024.<sup>1</sup>

Under that agreement, the price adjustments will reduce PL prices that are more than 7% above the value of public hospital prices:

- 1 July 2022 a 40% reduction of the gap
- 1 July 2023 a 20% of the gap
- 1 July 2024 a 20% of the gap

This agreement maintains a discrepancy of +7-20% where the PL costs more than public prices. <sup>1,2</sup> The basis for this has not been explained publicly.

The agreement was made without departmental advice.<sup>3</sup> The Department of Health has since written of the MoU that it:

"predominantly benefitted industry rather than providing a negotiated balance of benefits to industry and the Australian community"<sup>3</sup> Price reductions agreed to in 2022 still mean that Australia will still be paying some of the highest prices in the world for medical devices

In 2019, the Independent Health and Aged Care Pricing Authority (IHPA) estimated a 130% price difference observed in 2017-18 between the PL and public hospital medical device prices.<sup>4</sup> Our analysis of costs for prostheses for the same type of surgery shows prices were 46% lower in the public sector than in the private sector.<sup>5</sup>

The 2022 agreement made by the former government and the MTAA promised savings from reforms of \$800-900m.<sup>1</sup>

However, our analysis shows the current set of adjustments will only deliver a 13% price difference.<sup>6</sup>

The methodology informing the price reduction has not used the lowest available public price, and relies partially informed by figures provided by device companies.<sup>7</sup>

The ACCC noted that the MoU's floor on prostheses benefit reductions is likely to have some distortionary impacts on prices. Specifically, the floor will maintain benefits at inflated levels.<sup>8</sup>

There are substantial savings if PL prices were to reduce further to match other suitable benchmarks

Current reforms have assigned price reductions based on an estimated average public price against the same device billing codes in the private sector, relying on data from both state governments and device companies.

Prices could also have been calculated based on alternative benchmarks. For example:

Prices could also have been calculated based on the average public price per procedure for a given DRG

Prices could also have been calculated based on the average prices of peer markets

Prices could also have been calculated based on the lowest prices of international peer markets

# Current price adjustments will see prices remain well above international benchmarks

Price adjustments agreed to by the previous government, taking place between 2022 and 2024, are estimated to reduce the total cost of the PL by 13%.

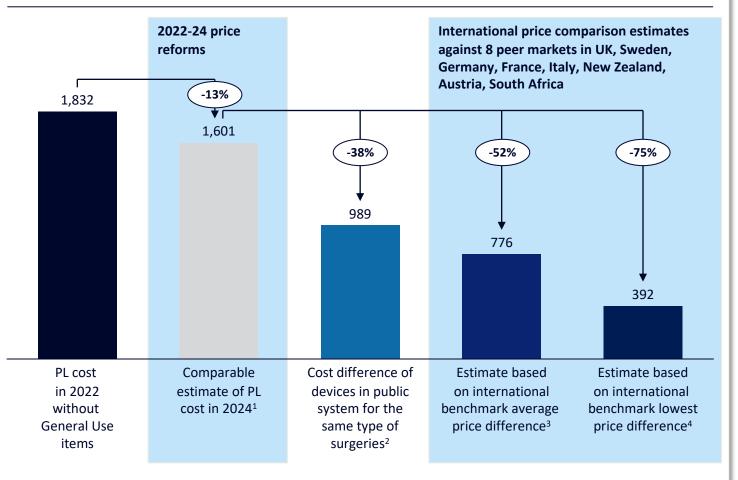
The reason the 13% reduction is small when compared to the price difference observable per same type of surgery between the public and private sectors is due to a number of factors. These include the methodology for determining the public benchmark price, the caveat to the reductions that left prices at least 7-20% higher than this benchmark prices, and the shape of utilisation in the private sector where efficiencies are not promoted via bundling.

Larger cost savings – of 38% – would be possible if prices were benchmarked to public hospitals' diagnostic related group codes.

Even larger savings are possible if prices are matched to those paid by Australia's overseas peers. Were the PL to contain prices equivalent to the average of prices in 8 peer markets, total cost may roughly halve. Costs can reduce by 75% if PL prices were set at the lowest prices in those 8 markets.

### Exhibit 9: Modelled PL cost burden on private health insurance if medical devices prices were reduced to meet benchmarks

\$AU millions, 2022



Note: The international benchmarks likely represent a ceiling potential reduction as they rely on price difference data for a sample equivalent to 14% of the PL with known discrepancies in pricing internationally. \$238m in general use items are excluded due to their removal from the PL on 1 July 2023. Cost differences for the same type of surgeries are calculated based on the weighted total of diagnostic related group codes prostheses costs in the private and public sector (2019-20 data)<sup>2</sup>.

# Demand for surgeries involving medical devices has been growing at 5% every year for the past decade

As demand for medical devices grow, the total cost of the PL will rise accordingly, especially if prices in Australia remain globally expensive.

Over the past ten years, the number of surgeries requiring medical devices has grown by 5% annually.

This has led to 60% in the overall growth of prostheses-requiring surgeries from 561,000 in FY11 to 905,000 in FY21.

Aside from a drop in FY20 due to the COVID-19 pandemic, growth has ranged between 3-9% per annum pre-pandemic.

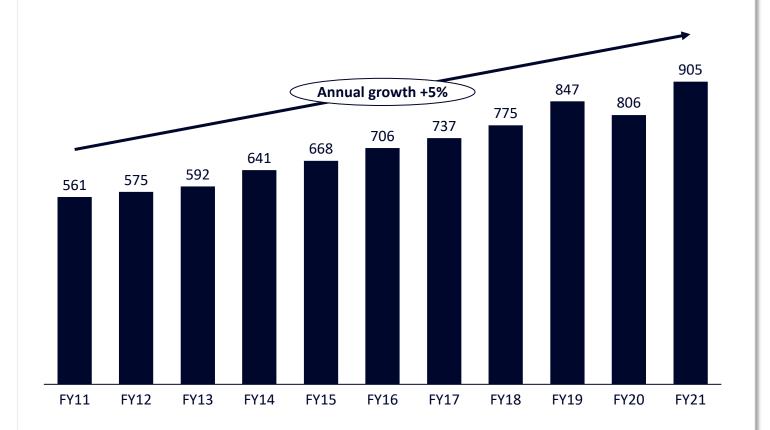
In FY21, the top diagnostic-related groups by volume were:

- Lens Interventions (145,855 interventions) such as those used for cataract surgeries
- Knee Replacements of minor complexity (35,742 replacements)

Both these procedures are expected to grow in volume as the Australian population ages.

#### Exhibit 10: Number of private hospital surgeries with a medical device (prostheses) charge

Thousands of surgeries by financial year, Australia



Note: FY means financial year. Surgeries is defined as one separation from hospital per diagnostic-related group (DRG) code. Sources: Private Hospital Data Bureau (PHDB) 2022; Mandala analysis.

# Demand for surgeries will keep growing as the population ages

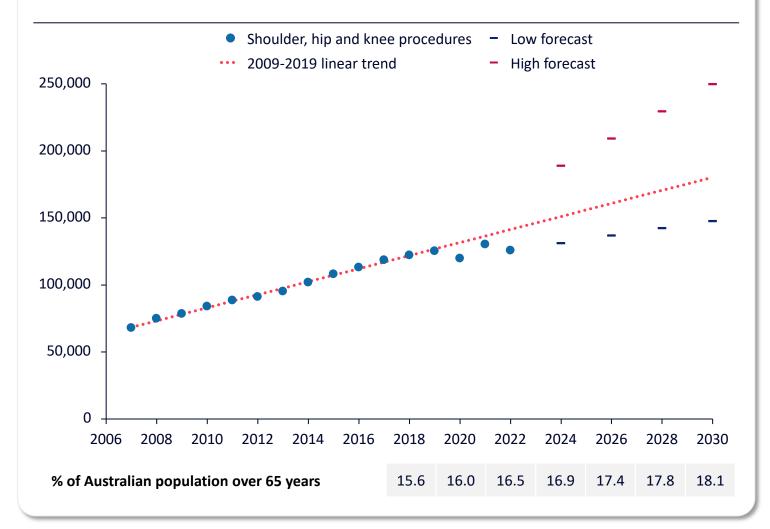
Australia's ageing population will increase demand for medical devices such as hip, knee and shoulder replacement procedures overtime.

These demographic factors are compounded by rising obesity rates associated with higher rates of joint replacement procedures.

Lowering prices of common medical devices, such as joint replacements, will help suppress overall healthcare costs.



Number p.a., Australia



Note: Forecasts use data from Ackerman et al. 2019 using age- and sex-specific TKR and THR procedure rates against demographic projections. The high forecast models growth in procedure rates while the conservative model holds these constant at 2013 level. Ackerman, Soh and Steiger 2022 found efficient approximation of predicted figures. See appendix for more detail. Sources: Australian Orthopaedic Association National Joint Replacement Registry 2023; Ackerman et al. 2019, 'The projected burden of primary total knee and hip replacement for osteoarthritis in Australia to the year 2030'; BMC Musculoskelet Disord; 20(1):90, ABS Population Projections 2018 – moderate (series B); Mandala analysis.

# As premiums rise, consumers cut back on private health insurance coverage and other parts of the economy

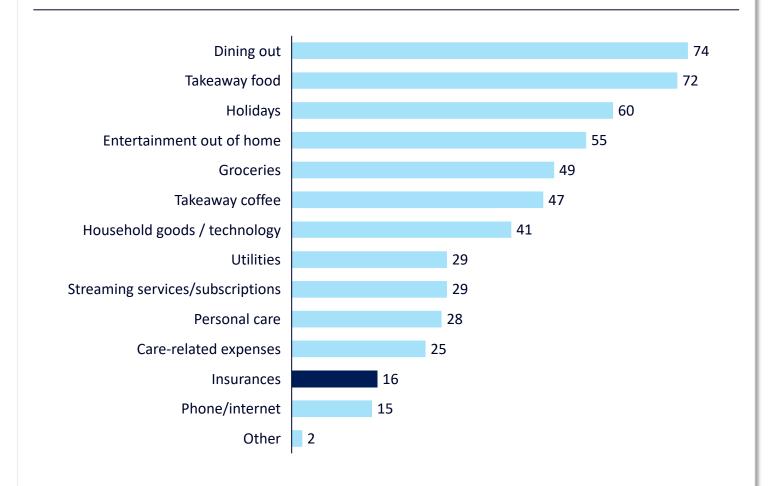
High prices of medical devices contributes to growth of private health insurance premiums, which in turn inhibits spend on other sectors across the economy.

The current inflationary environment adds further pressure on consumers. A survey of consumers conducted in the first quarter of 2023 showed that 16% - 1 in 6 respondents – have reduced spending on insurance.

Consumers who give up private health insurance necessarily rely wholly on the public system, adding strain on public healthcare providers.

Exhibit 12: Where people have already cut back spending as the cost of living increases

% of survey respondents, 2023



Sources: Nature, as reported by Wootton and McCubbing in the Australian Financial Review 2023.

- Australia pays more for medical devices than our peers abroad through the Prescribed List of Medical Devices (PL)
- 2 Existing 2022-24 reforms will leave us a long way from international price benchmarks

3 Higher costs are borne by consumers and taxpayers

Further reform of the Prescribed List for Medical Devices can reduce prices and put patients first



# Australian consumers and taxpayers are paying \$967m more than in peer countries for medical devices on the Prescribed List

Should the PL in 2024 use average prices from the eight previously mentioned peer markets, its cost would be approximately \$911 million. However, the actual expected prices in 2024 mean that the PL is expected to cost an estimated \$1.89 billion.

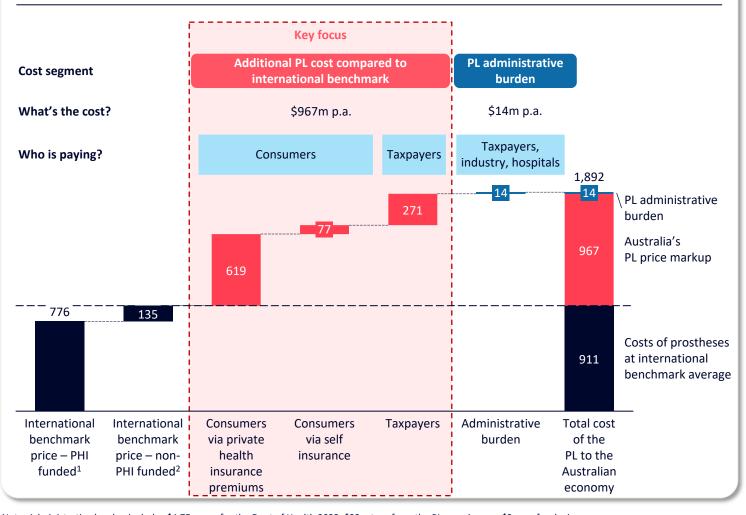
This is a difference of about \$981 million: \$14 million is estimated to be the administrative costs and \$967 million due to the price markups compared to international benchmarks.

In detail of the additional \$981 million that Australia would pay in 2024:

- \$619 million would be borne by consumers in the form of higher private health insurance premiums;
- \$77 million from consumers and companies paying directly;
- \$271 million from taxpayers via the private health insurance rebate, and payments by the Department of Veterans' Affairs, workers' compensation schemes, and the Department of Defence. Of this \$271 million, an estimated \$206 million is attributed to the federal government's PHI rebate; and
- An estimated further \$14 million would be incurred through administrative costs of the PL.

Exhibit 13: PL costs based on 2024 PL prices compared to international benchmark average

\$AU million p.a., 2024 estimate



Note: Administrative burden includes \$4.75m p.a. for the Dept of Health 2023, \$22m to reform the PL over 4 years, \$2m pa for device company applications, and \$1.5m in conservative time costs for 657 private hospitals to update the PL in their systems and for surgeons to understand changes 3 times per year.

# Of the estimated \$271 million additional costs in 2024 attributable to taxpayers, \$41 million is through Defence and Veterans' Affairs

The additional costs that is attributable to taxpayers worth \$271 million – due to the PL's higher costs (compared to an international benchmark) – are further attributable to the following sources:

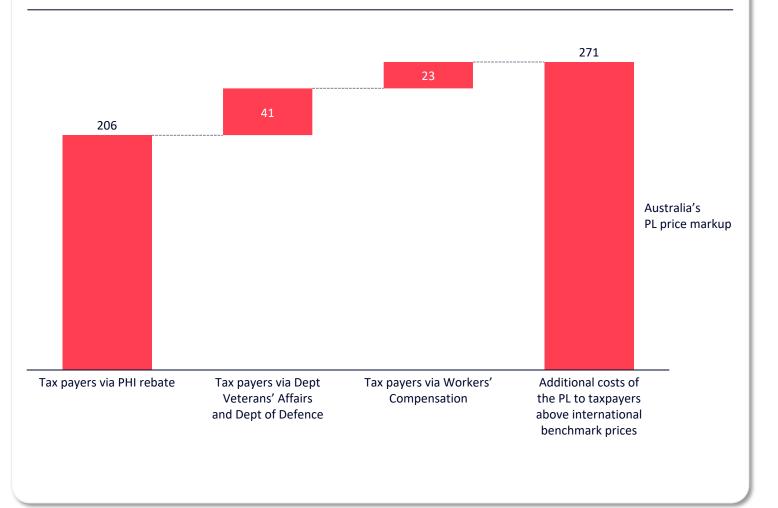
- \$206 million through the private health insurance rebate;
- \$41 million through Defence and Veterans' Affairs; and
- \$23 million through Workers' Compensation schemes

The spend for 2024 has been forecast maintaining current utilisation rates to show the impact post reductions to PL prices in 2024. Taxpayers are estimated to pay for 25% of private health insurance (PHI) prostheses benefits via the federal government PHI rebate.

Estimates for Defence, Veterans' Affairs and Workers' Compensation prostheses expenditure was constructed from Private Health Data Bureau data on private hospital charges by patient funding source.

#### Exhibit 14: Breakdown of the Prescribed List price markup cost to taxpayers

\$AU million p.a., 2024 estimate



Note: The total estimated prostheses spend for each was \$5.8m for Defence, \$74.7m for Veterans' Affairs and \$45m via workers compensation. The average prostheses spend across all funder types was 16% of total private hospital spend, which was applied to the total private hospital spend by funder (e.g. DVA) estimated from number of separations and average hospital charge per separation. Sources: APRA 2022; PHA 2020; PHDB Preliminary Annual Report 2021-22; Mandala analysis.

# The high cost of the Prescribed List sees a large value transfer from Australia to device companies overseas

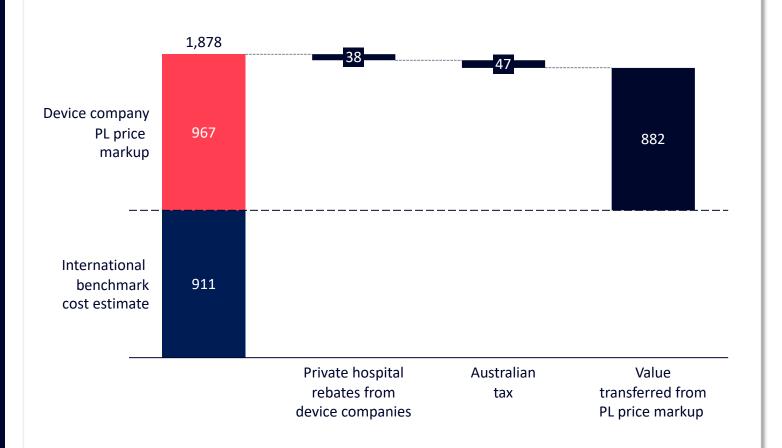
Due to the PL's higher costs, compared to an international benchmark, Australia pays an additional \$967 million for its medical devices bought in private hospitals.

\$882 million of this is directed to device manufacturers, most of whom are based abroad.

Comparatively small amounts are directed to private hospitals in the form of rebates and paid as tax at \$38 million and \$47 million, respectively.

#### **Exhibit 15: Value transfer to device manufacturers**

\$AU millions p.a., 2024



Note: Hospital rebates are estimated at 2% and Australian tax paid on total income at 2.5% per PHA reports.

Sources: PHA 2020; PHA 2023; Mandala analysis

- Through the Prescribed List of Medical Devices (PL), Australians pay some of the highest costs in the world for medical devices
- Existing 2022-24 reforms will leave us a long way from international price benchmarks

3 Higher costs are borne by consumers and taxpayers

Further reform of the Prescribed List for Medical Devices can reduce prices and put patients first



## Reforming the PL unlocks significant opportunities...



Introducing greater market-based competition to the PL can help align prices to those paid by others overseas



There are other barriers in the PL that **inhibit competition** and **keep prices high**, such as poor reference pricing, which means increased competition cannot lower prices to consumers



Reform can help strengthen incentives to deliver **better patient outcomes**, such as setting financial incentives for high-performing devices with low revision rates



Reform can help new entrants compete, as current arrangements can incentivise providers to preference incumbents over new entrants through brand-specific rebate schemes and other sponsorships

#### ...and the risks from reform are minimal



The medical device market is mature: many devices are based on **long-established technologies** and sold by a variety suppliers across the world



Australia's relatively distant geography and small market have been used to justify expensive prices, but countries that are similarly located such as **New Zealand pay less for their medical devices**, despite having an even smaller market size than Australia and a more remote location



The international markets that pay lower prices than Australia have **not had to impose co-payments on their patients**. This should give Australians confidence that reform can unlock genuinely lower prices rather than merely shifting costs to patients



Reform to the PL can be accompanied to **better support Australia capture a larger share of the medical technology value chain,** capitalizing on a strong skills pipeline and a globally competitive research environment

### Under the Prescribed List, there is more frequent use of devices with higher revision rates

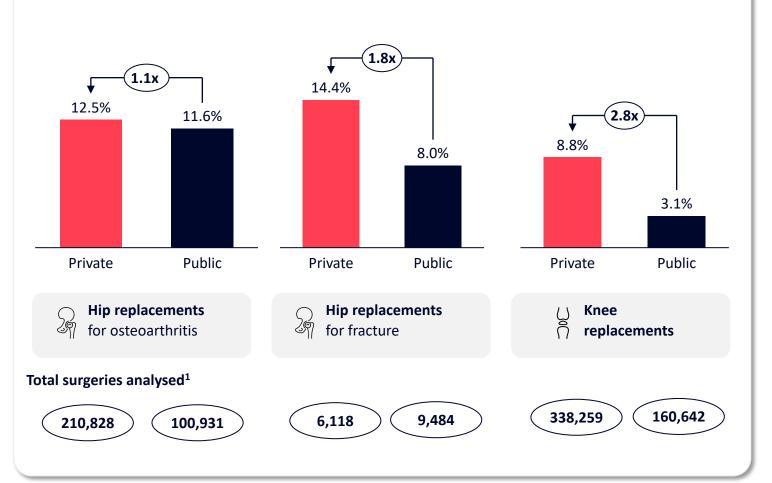
Australia has one of the best and oldest registries of joint replacements in the world, since 1999. Through the registry, medical devices with higher-than-average rates of revision (HTARR) are identified. These devices have 10% higher revisions than similar devices.

A study of the use of HTARR devices in private and public settings for hip and knee replacements in Australia, spanning 13 years from 2003-16, found HTARR devices were used 1.6x more often in private settings (Harris et al. 2019). This can be broken down to 1.1x more use for hip replacements for osteoarthritis in private settings, 1.8x more use for hip replacements for fractures, and 2.8x more for knee replacements.

The study found that choice of device was the main reason behind the higher rate of revision surgery seen in private hospitals.

#### Exhibit 16: Use of medical devices with higher-than-average rates of revision (HTARR)

% HTARR medical devices used by setting, 2003-2016, Australia



<sup>1.</sup> Total elective surgeries included in analysis (2003-2016) include 555,205 private surgeries and 271,057 public surgeries. Sources: Harris et al 2019, "Outcomes of hip and knee replacement surgery in private and public hospitals in Australia," ANZ Journal of Surgery, 89:1; Mandala analysis.

# Revision rates for hip & knee replacements relying on the PL are up to 3 ppts higher than in Sweden, UK, and NZ

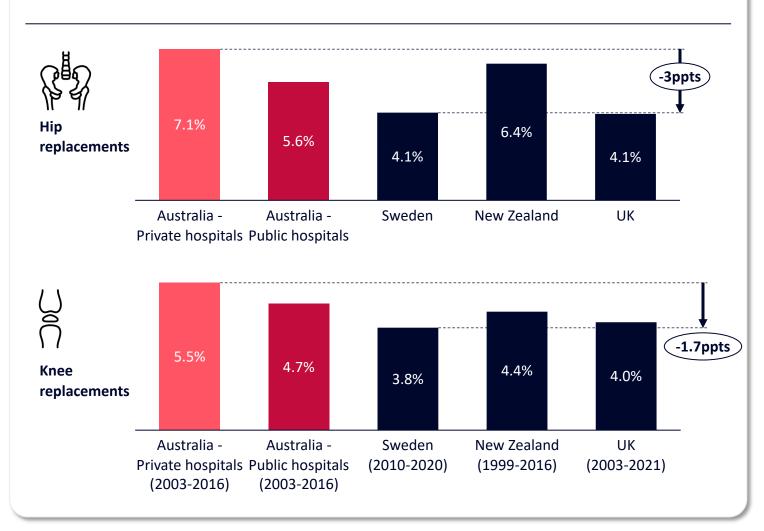
Australia's private health system, which procures through the PL, has higher revision rates for hip and knee replacements compared to Australian public hospitals which procure separately from the PL. A revision is a subsequent surgery where an inserted prosthesis is replaced, adjusted, removed, or somehow compensated for because of poor clinical outcomes.

Revision rates are also lower in Sweden, New Zealand, and the United Kingdom compared to Australia's private hospitals.

Patients who receive revision surgery are at 5-6x risk of further revision surgeries, with cost per revision conservatively estimated to cost \$25,000² and putting patients out of action for a longer period than their initial surgery, during which they may need to use a walker and go through extensive physio-therapy.

#### Exhibit 18: 10-year revision rates for total hip replacements and total knee replacements

% of surgeries



Sources: Harris et al <u>2019</u>; Kandala et al <u>2015</u>; Swedish Knee Arthroplasty Register, Annual Report <u>2020</u>; Stone at al <u>2022</u>; Mandala analysis. See appendix for detailed references.

<sup>1.</sup> Ong et al  $\underline{2010}$  and Deere et al  $\underline{2021}$ .

<sup>2.</sup> Stryker 2022.

# The medical device market is mature – most device types have been around for a long time

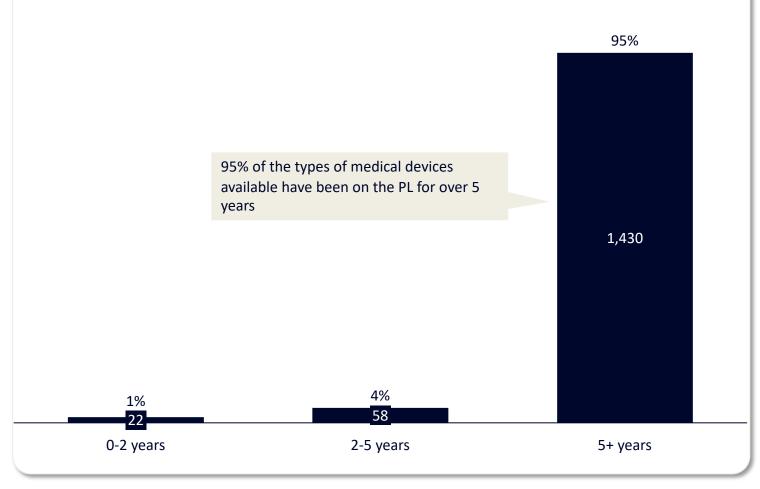
The medical device market is mature and stable. 95% of medical device sub-groups and any relevant suffixes (which detail a similar or interchangeable type of product) have been listed on the PL for five or more years since 2023.

Each device type represents a group of similar or interchangeable products that will attract the same PL benefit.

For new or novel products where there is no existing comparator on the PL, and hence no applicable group, a more detailed Health Technology Assessment (HTA) is undertaken to determine clinical and cost-effectiveness and the corresponding PL benefit.



Number and share of medical devices by time listed on the PL, 2023



Note: "Medical device types" available analysed at the Product Sub-Group and suffix level.

Sources: Prescribed List of Medical Devices (formerly known as Prostheses Lists) March 2023, March 2021 and February 2018, Mandala analysis.

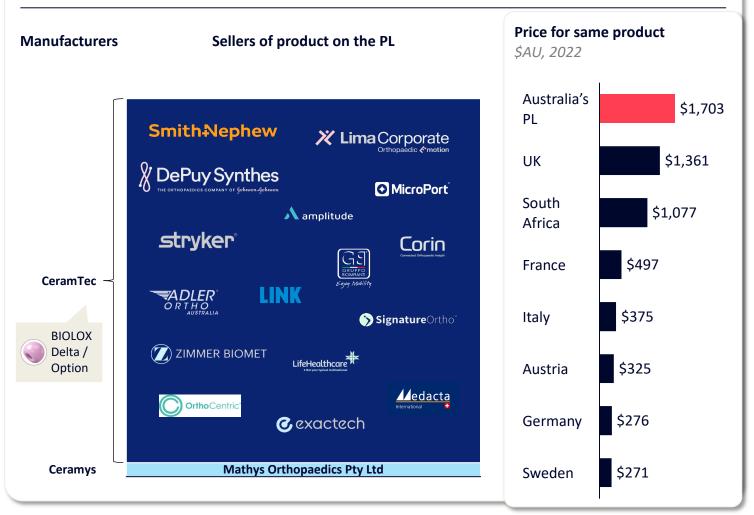
### There are multiple sellers of the same device in Australia who benefit from a high PL price compared to other markets

Many different companies import and sell medical devices to the Australian market. A ceramic head used in hip replacements, BIOLOX, manufactured by CeramTec in Germany is imported and sold by 26 different companies into Australia.

This ceramic head is sold for \$1,703 each in Australia, compared to about \$270 each in Germany and Sweden.

#### Exhibit 20: Conventional ceramic femoral heads for hip replacement on the PL

Relative market share of sellers and manufacturers



For examples see Exactech, Stryker, Johnson&Johnson, Smith and Nephew, Zimmer Biomet, Cross-checking of Australian Register of Therapeutic Goods codes listed on the PL with details on the ARTG register, for the Product Sub-Group Hip 11.02.01 - Conventional Femoral Heads, ≤32mm 11.02.01.05 - Ceramic Mix (27 items without sleeve) per March 2023.

# In 2022, prices on the PL were 67% higher than those in New Zealand for 25 common devices

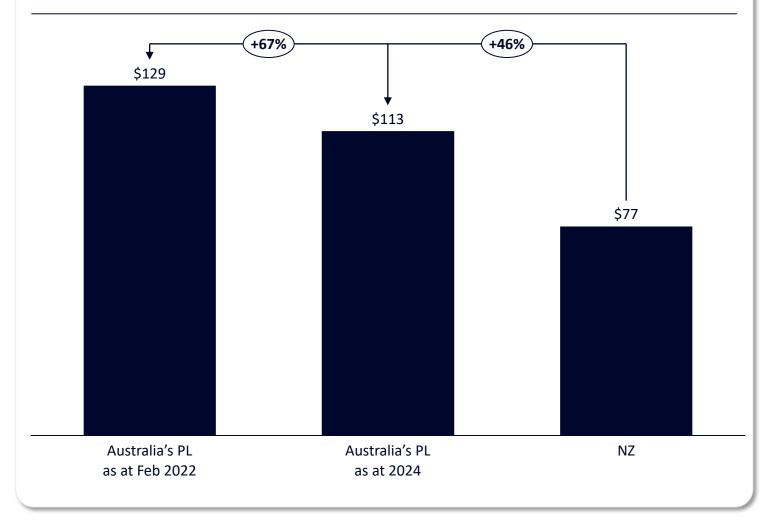
Australia's relatively distant geography and small market size have been used to justify expensive prices, but countries that are similarly distant from international manufacturers such as New Zealand pay less for their medical devices, despite having an even smaller market size than Australia.

In 2022, prices on the PL were 67% higher than those in New Zealand for 25 common devices, including drug eluting stents and hip replacement joints.

Given an overall expected price reduction of 13% by 2024 through adjustments to the list, Australia's PL will still be up to 46% more expensive than New Zealand for this selection of devices.

#### Exhibit 21: Utilisation-matched comparison of 25 billing code prices in Australia and New Zealand

\$AU millions, equivalent utilisation, February 2022 unless stated



Note: 25 billing codes compared include hip replacements, drug eluting stents, and lenses. PHARMAC pricing data was available for 25 of the 46 manufacturer product codes selected for the review as ophthalmic lenses, pacemakers and neuromodulators are not listed by PHARMAC.

Sources: Evaluate 2022, Mandala analysis.

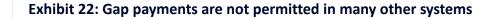
# Peers have low prices without introducing gap payments or co-payments

Gap payments for medical devices are currently very rare in Australia. A mere 0.04% of medical devices paid for by private health insurers through the PL in 2022 had a gap permitted charge.

Countries that enjoy lower prices for medical devices compared to the PL have not had to resort to charging patients gap payments.

For example, the UK and NZ uses similar list-based systems to the PL. Their prices are much lower than the PL's but they have not required gap payments from patients.

Continental European prices, such as those from France, Austria, Sweden, and Germany, also do not charge gap payments and have much lower prices than the PL.



Country	Are there gap payments permitted?	How much do they pay compared to Australia's PL? <sup>1</sup>
Australia's PL – private		100%
UK (NHS) – public	X	71%
NZ public – PHARMAC	X	60%
France – universal National Health Insurance System	X	46%
Austria	X	27%
Sweden	X	25%
Germany	X	22%

Sources: PHA 2020; Evaluate 2022; Mandala analysis

<sup>1.</sup> Based on pre-reform prices in March 2022.

# Strong research capabilities and skills pipelines form a potential foundation for Australia to capture more of the medical device value chain

Australia has the potential to capture more of the value chain in the production of medical devices.

Australia has a strong medical research ecosystem in the form of large, stable basic research funding through the NHMRC and dedicated medical research institutes. Dedicated innovation hubs and medical technology accelerators help attract philanthropic and private funding, industry investment, as well as leading talent from overseas and locally.

These institutions have also helped foster a strong skills pipeline.

A more open and competitive system for healthcare providers to procure medical devices that has a lower cost base frees up capital and funding that can in part be re-directed to Australian healthcare and Australia's local medical technology sector.

Exhibit 23: Australia has two global competitive advantages in medical technology

#### Strong medical research ecosystem

#### Skill system that produces a pipeline of talent



**\$6.8 billion** in direct **medical research** funding over 4 years



**340,000** Australians have an **Engineering university qualification** 



**R&D Tax Incentive** to unlock business pursuit of R&D activities



**30** medtech accelerators, **1,342** medtech, biotech and pharmaceutical companies, including **152** ASX-listed firms



**\$206 million Patent Box** to reduce taxes on Australian medical and biotech patents



70 independent medical research institutes in Australia

#### Six dedicated innovation hubs



Sources: Austrade 2022; Australia's Chief Scientist 2020; Mandala analysis.



### Appendix

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## Data sources: This study used a range of publicly available data on medical device costs to insurers, private hospitals, and public hospitals in combination with specific reports on medical device pricing



Australian Prudential Regulation Authority (APRA) Data

 Publicly available statistics on Private Health Insurance published quarterly on membership & coverage, and prostheses statistics



Prescribed List of Medical Devices (PL) Data

- Publicly available information from primary sources including the PL:
  - Historical PL lists and price information
  - Advice on the Prostheses List adjusted benefits amounts



**Private Hospital Data Bureau** 

Private Hospital Data
 Bureau ('PHDB') annual
 reports covering hospital
 and prostheses charges,
 including by type of
 surgery (diagnostic-related
 group) and by patient
 funding source



Independent Hospital Pricing Authority

Independent Hospital Pricing Authority (IHPA) data on public hospital and prosthese charges, including by type of surgery (diagnostic-related group), including the National hospital Cost Data Collection Report for the Public Sector



**Key reports** 

- Evaluate (2022) Price comparison of the Australian Private Prostheses List with 8 international markets. (Unpublished)
- Australian Orthopaedic Association National Joint Replacement Registry (AOANJRR) annual reports
- Australia Bureau of Statistics (2018)
   Population Projections category 3222.0.

#### Methodology: International comparison of revision rates for hip and knee replacements

The 10-year revision rate calculates the percentage **likelihood that a patient undergoes revision surgery within 10 years** after the primary arthroplasty. It does this by finding the midpoint of the distribution of when revision is required from the time of primary surgery. This metric typically informs the benchmark rates used by authorities to determine the success of different brands and types of prostheses.

Country		10 year revision rate	Years	Source	
Hip replacem	ent				
Private hospitals Australia		7.1%	2003-2016	Harris et al (2019), ANZ Journal of Surgery, 'Outcomes of hip and knee replacement surgery in private and public hospitals in Australia'	
Australia	Public hospitals	5.6%	2003-2016	Harris (as above).	
UK (England and Wales)		5.0%	2003-2012	Kandala et al (2015), 'Setting benchmark revision rates for total hip replacement: analysis of registry evidence'	
OK (Eligialia	and wates)	4.05%	2003-2021	National Joint Registry of England and Wales, 2021 Annual Report p 63	
Sweden		4.1%	2010-2020	Swedish Arthroplasty Register Annual Report 2021 p 103	
Sweden		5.8%	1995-2006	Mäkelä (2014), Acta Orthopaedic Journal, 'Countrywise results of total hip replacement'	
New Zealand		6.4%	1999-2016	Nugent at al (2021), Bone and Joint Journal, 'The lifetime risk of revision following total hip arthroplasty'	
Knee replace	ment				
Australia	Private hospitals	5.5%	2003-2016	Harris et al (2019), ANZ Journal of Surgery, 'Outcomes of hip and knee replacement surgery in private and public hospitals in Australia'	
Australia	Public hospitals	4.7%	2003-2016	Harris (as above).	
UK (England and Wales)		4.01%	2003-2021	National Joint Registry of England and Wales, 2021 Annual Report p 149	
Sweden		3.8%	2010-2020	Swedish Arthroplasty Register Annual Report 2021	
New Zealand		4.4%	1999-2016	Stone et al (2022), Bone and Joint Journal, 'The lifetime risk of revision following total knee arthroplasty'	

#### Approach to modelling and assumptions (1/3)

stimates	Method summary		1	Key assumptions		
D24 price reduction npacts  chibits 1-3, 9, 13-15	the reform reductions comparing prices publ  March 2022 price July 2022 price price July 2023, after These 2024 prices can 20% reduction of the gobserving the price chas well as July 2022 ar The overall impact was aggregate effect of pritotal cost of the PL. Du	not yet published and the public reference properties are undisclosed. 2024 prices were therefore ished by the federal Department of Health: prices, pre adjustments es, after a 40% reduction of an x gap with a price of a 20% further reduction of the x gap be estimated as the price in July 2023 with a gap. The value of this 20% reduction can be dranges seen between March and July 2022 (40 and July 2023 (a further 20% of the gap). It is calculated by holding utilisation of devices of the delayed reductions to cardiac devices, the to delayed reductions to cardiac devices, the price reductions utilisation constant.	calculated by  public reference  an additional lerived from 0% of the gap)  constant. The uction in the	2020-21. The da obtaining data frexpenditure. General Use iter from the Depart the PL to PHI was utilisation constant. This estimate lik once they reach	rom hospitals, so has ms being removed from hospitals. The ment of Health. The as estimated at \$328 ant at 2020-21 levels sely overstates reduct +7% of the public re	ed from hospital casemix protocol data complete due to expected delays in been extrapolated to represent total from the PL on 1 July 2023 was sourced ir total cost as a share of the 2022 cost million or 15.2% of the PL's value, hold s.  tions, as prices are not reduced further ference price (per the Memorandum of ister Hunt & MTAA 2022)
PL costs p		March 2022	Price of			Utilisation of each



#### Approach to modelling and assumptions (2/3)

Estimates	Method summary	Key assumptions
Forecasting volume growth for hip, shoulder and knee joint replacements  Exhibit 11	<ul> <li>Total hip, knee and shoulder joint replacements were modeled for 2030 using high and low forecasts based on historical data from Australian Orthopaedic Association National Joint Replacement Registry (AOANJRR) and a study by Ackerman et al. 2019.</li> <li>The chart shows data from the AOANJRR from 2007 to 2022, and a trend line to 2030 based on the pre-pandemic 2009-2019 ten-year growth rate of 3% per annum.</li> <li>The chart also shows two forecast ranges based on Ackerman et al 2019's two scenarios in their forecast study: scenario 1 – a low forecast, and scenario 2 – a high forecast, which correspond to the two forecasts used in this report.</li> <li>The low forecast shown uses Ackerman et al 2019's scenario 1 2030 modeling for hip and knee replacements for osteoarthritis (OA), extrapolated to total hip replacement (THR) and total knee replacement (TKR) using a constant ratio of the proportion of OA hip and knee replacements based on the final year of data used in the model (2013). Shoulder surgeries were held constant at 8,606 (2021 level) to 2030 as rate breakdowns were not available.</li> <li>The high forecast shows Ackerman et al 2019's scenario 2 predictions added to total shoulder replacements. Ackerman et al's OA forecast were not adjusted to represent other knee and hip replacements beyond OA. This is because in 2022, modeled OA knee replacements already exceeded observed TKR by 63%.</li> </ul>	<ul> <li>The number of shoulder surgeries was held constant at 2022 levels of 8,606 to be conservative.</li> <li>For low forecasts, age- and sex-specific OA knee and hip replacement procedure rates were held constant from 2013.</li> <li>High forecast age- and sex-specific OA knee and hip replacement procedure growth rates were modeled using Poisson regressions and extrapolated forward.</li> <li>Demographic projections assumed to change in Australia per ABS estimates detailed in Australia Bureau of Statistics (2018) Population Projections catalogue 3222.0.</li> </ul>
Estimating the costs of medical devices to Australian taxpayers  Exhibits 13-15	<ul> <li>The costs of medical devices to Australian taxpayers were estimated for patients funded through PHI, the Dept of Defence, Department of Veterans' Affairs and Workers' Compensation.</li> <li>For patients funded by PHI, the federal government rebate was estimated to cover 25% of costs. PHI expenditure on prostheses is reported in Australian Prudential Regulation Authority (APRA) Quarterly Statistics.</li> <li>For patients funded by the Dept of Defence, Department of Veterans' Affairs and Workers' Compensation, taxpayers were assumed to cover costs in full. Each funding source's average hospital charge per separation and number of separations in private hospitals is reported in the Private Hospital Data Bureau (PHDB) Annual Report Statistics. These figures were used to estimated total private hospital charges and using a ratio of prostheses as a share of total private hospital charges of 15.8% (PHDB, 2021-22) were estimated for medical device spend only.</li> </ul>	<ul> <li>Prostheses charges as a share of total hospital charges is based on the overall proportion for all patients of 15.8% (PHDB, 2021-22).</li> <li>General use items were assumed to represent 15.2% of the value of current expenditure by payor type.</li> </ul>

#### Approach to modelling and assumptions (3/3)

Estimates	Method summary	Key assumptions
International price benchmark  Exhibits 9, 13-15	<ul> <li>The international benchmark price estimate was based on a study by Evaluate in 2022 which calculated an average price difference across eight peer markets based on 46 device codes representing 14% of the value of the PL in 2022.</li> <li>The study found that prices in peer markets were an average of -58% lower compared to Australia's PL in February 2022.</li> <li>This -58% price difference was used as a proxy to estimate Australia's overall PL markup as the price paid on top of the average of what peer markets paid.</li> <li>The -58% price difference being lower than the -46% found for the public versus private prostheses charges for the same surgeries (by DRG-code) is likely due to the larger bargaining power of country-level markets compared to Australia's individual state markets. Each Australian state can only bargain using a fraction of Australia's total market share that resides in that state.</li> <li>Evaluate's (2022) study noted that if Australia accessed the lowest prices in each market the price would be -79% lower.</li> <li>The study also noted that outside the 8 countries selected for benchmarking, even lower prices had been achieved in markets such as China. China used a competitive tender process offering guaranteed market share. This process achieved significantly lower prices. For instance, a drug eluting stent on Australia's PL in 2022 costed ~\$2,300, while in China it costed ~\$155. Hip and knee replacement costs in China are now around \$1,500 and \$1,100 respectively, while in Australia these costed ~\$8,500 each in 2022.</li> <li>Hence, using the average price from the 8 benchmark countries was considered a conservative representation of the prices that could be achieved.</li> </ul>	<ul> <li>The -58% difference represents the average prices across 8 peer markets for 46 common devices, not the lowest prices (-79%).</li> <li>In markets not studied, prices can be even lower. Australia's prices are between 800-1,000% higher than China for hip, knee replacements and drug eluting stents which make up half of PL costs.</li> </ul>

#### **ABOUT MANDALA**

Mandala is an economics, strategy, and policy consulting firm. Mandala's staff include former advisors to Prime Ministers and senior officials across Australia's economic regulators, global leads at companies, researchers and data scientists, and strategy consultants. We serve governments in Australia and abroad, as well as globally significant firms. We have presented our work in prestigious economics and policy journals, and in partnership with leading think tanks and universities.



