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Methodology for Determining the Benchmark Price for Prostheses in Australian Public Hospitals

MTAA Response to IHPA Consultation Paper September 2021

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1 Introduction

MTAA welcomes the opportunity to build on its contribution to Prostheses List (PL) reform through its February 2021 submission to the Department's consultation on the future of the PL through responding to this Consultation Paper (Paper) by IHPA. MTAA has proposed a modified public price referencing system that will save insurers at least $750m over four years delivering the most radical reform of the PL in its history. The Government's Budget announcement is broadly based on this recommendation, although there remain significant elements of outstanding concern to the device industry, including the pricing and phasing methodology. MTAA has also recommended other reforms to the PL to improve administrative efficiency and utilisation.

Public price referencing allows the PL to reference a competitive market without the significant disruptions that would result from trying to restructure the private device market. An essential value proposition of private health insurance is clinical choice. This hinges on the privately insured patient choosing their surgeon and *that surgeon being able to choose the clinical options best suited to that patient*. The PL has been enormously successful in ensuring this arrangement, to the extent that it has often gone unnoticed. However, if the PL were to be disrupted, it would materially impact the value proposition of private health insurance itself.

Nonetheless, MTAA affirms the importance of using an appropriate public price referencing methodology so that a competitive benchmark can ensure benefits on the PL reflect fair value over time without ad-hoc cuts or time-consuming reviews. MTAA is committed to supporting the Government's timetable for benefit reductions from 1 July and to working through the outstanding issues to this end. MTAA has begun collecting industry data to enable this to be implemented.

In recommending the public price reference approach, MTAA identified that it was critical to success of this reform that the price benchmarking approach is reasonable and differences between the public and private markets are recognised. This included the following components:

- Weighted average price methodology and mix adjustment for the private market to set the public price

- Price adjustment to reflect the unique features of the private market that don't exist in the public and vice-versa
- This adjustment to include recognition and payment for the unique cardiac technical support services provided for cardiac implantable electronic devices (CIEDs) in the private

MTAA welcomes the discussion of these issues in the IHPA Paper. This submission will rearticulate the importance of these in the light of the questions posed by IHPA.
To ensure that the medical device industry can continue to provide quality technology to private patients, reforms to benefit setting need to be reasonable, equitable, predictable, and supportive of innovation.

2 Prostheses purchasing arrangements in the public and private hospital sectors

In general, this section of the Paper correctly describes the purchasing situation in public hospitals Australia-wide. It is important to realise that all tendering arrangements except the 'registration' type referred to in the Paper trade off volume for price to some extent. A product that is listed for use under most tender arrangements will attract more volume because there will be other devices that were excluded from the tender or whose sponsors decided not to participate because of the price reductions required. Any specific market share arrangements will build upon this. These products listed for use under these arrangements are typically described as being 'on panel'.

However, sponsors of products that are not on panel will not be able to price without constraint. Typically, the price is still negotiated with the buying institution and above-market pricing would lead to minimal use. Therefore, whether or not there is tendering, competitive pricing is still occurring but without the focused volume and choice trade-offs. The Paper also accurately notes that tendering arrangements are usually not on a product-by-product basis but for a group of products. Therefore, there is often no immediate relationship between volume of an individual product and its individual price.

The Paper states that price is not a function of volume at a state level. It is true that both institutional and bundled purchasing arrangements confound a clear relationship between volume and price at a state level, as the illustration in Table 1 shows. However, it is not true that volume at a state level plays no role. If there is a state-wide tender that limits participation, being on that tender will lift volume to some extent in exchange for a lower price than generally would have been the case.

Nonetheless, it is often at institutional level that suppliers can achieve greater efficiencies through significantly higher volume, allowing a lower price to be offered.

It is quite appropriate that the PL does not operate on the basis of a price/volume trade off. The role of the PL is there to ensure clinician choice and so needs to allow any supplier's product to be available across the private sector at any time if the entry criteria are met for the group of like products (MTAA terminology – 'Benefit Group'). Therefore, there can only be one benefit level. However, this means that price competition does not routinely adjust

the benefit level over time. This can be overcome by reference to the competitive public market without sacrificing choice.

Another key consequence of the PL is that suppliers generally do not have any guaranteed volume. Usage of devices is dependent on the choice of self-employed clinicians and the hospital generally orders products in response to the clinician's selection of device. For example, in the case of a primary knee replacement, a surgeon would select a single device that fits that specific patient's requirements, the hospital would then request for that one device to be available on the day of surgery, and the supplier would ship that one device to the hospital. Purchasing is therefore more reactive, and typically more frequent and at lower volumes per order than in the public system.

Generally speaking, rebates to private hospitals play a minimal role, usually covering private hospital costs to manage inventory. The testimony from Ramsay Healthcare in the 2017 Senate Inquiry into *Price Regulation associated with the Prostheses List framework* was that rebates were in the vicinity of 5-7%[1], not 5-10% as stated in the Paper.

3 Data Sources

Which data source should IHPA utilise as the primary data source for determining the public sector benchmark price?

As noted in the Paper, MTAA has proposed that the primary data source for public prices is the device industry. The industry has the best ability to match sales and pricing data in the public system to actual billing codes on the PL. State and territories procurement agencies often rely on suppliers themselves to provide them actual market volume and even pricing data of the products that they actually buy. Furthermore, they have limited knowledge of the PL and which billing codes would match to products in their records. There are also confidentiality arrangements between the multiple suppliers and states and territories that would limit sharing of data by the latter. Therefore, industry is a more accurate and efficient source of data.

Are there any other sources of data IHPA should consider for determining the public sector benchmark price?

Aggregated data from states and territories could reasonably be used to validate industry data while ensuring confidentiality is not breached. IHPA has requested data from the industry broken down by state and territory for this purpose.

What risks should IHPA consider if DRG level information were to be utilised? Are there alternative approaches IHPA should consider?

In its submission in response to the Department's Consultation Paper: Options for Reforms and Improvements to the Prostheses List in February 2021, MTAA highlighted its significant concerns with using DRG data from the NHCDC. The first and most significant concern is the reported differences between public and private prices coming from IHPA's analysis of the

[1] Senate Community Affairs References Committee Public Hearing Transcript Friday, 31 March 2017 p.13

NHCDC. The Department's PL reform consultation paper cited an estimate in this report that the gap was 130 per cent in 2017-18. In contrast, for FY2018-19, MTAA's billing code level data collected from sponsors covering 81% of the value PL showed an overall gap of just 13%. The vast gulf is explicable only in terms of the problems of classification and aggregation that make DRG-based data from the NHCDC on prices of medical devices inappropriate as a reference for public pricing and benefit setting on the PL. Fortunately, with data collection from industry, discussion of DRG accuracy for device pricing should become moot.

4 Methodology for calculating the benchmark price

Do you support IHPAs proposal to establish the public sector benchmark price using a volume weighted average approach? Please provide rationale.

MTAA considers the weighted average approach to be critical to the success of the reform for several reasons.

Firstly, the PL benefit reflects a whole-of-market price for the PL. Therefore, if it is being benchmarked against the price in another market, that price should also reflect the whole of that market. Otherwise, it is not a like-for-like comparison. As happens in a competitive market with confidential negotiations, there are many different price points for products in the public sector that reflect a range of individual circumstances for companies and payers both at institutional and state level. It would not be appropriate to select one of these price points for the whole PL market. Nonetheless, taken as a whole, these price points reflect a reasonable benchmark if adjustments for any differences between markets are included. As the Paper notes, this is consistent with IHPA's approach to setting the National Efficient Price. It is also consistent with the weighted approach used in the Price Disclosure methodology for the Pharmaceutical Benefit Scheme (PBS).[2]

This point equally applies to the Benefit Group as it does to the individual billing code. Since the benefit is being set at a group level, the appropriate comparator is the collective weighted average price for that group in the public sector, not any individual product within the group.

Secondly, using the lowest price point in the public market would likely result in worse access in the private sector, undermining the value proposition of private health insurance, where patients should reasonably expect more choice. As the Paper notes, the lowest price in the public market will reflect particular conditions such as tender pricing and market share awards that won't be replicated either across the whole public sector or reflect the nature of the PL. As a result, setting the PL benefit at this lowest point would make it non-viable for a number of products to continue to be sold on the PL, leading to their withdrawal. This loss of access may also lead to some procedures being pushed into the public sector.

[2] Department of Health *Pharmaceutical Benefit Scheme Price Disclosure Arrangements. Procedural and Operational Guidelines* June 2016 Version 6

This is reinforced by the fact that major overseas markets are increasingly looking at published prices in Australia (i.e. the PL benefit) to set their own prices. MTAA is aware of a recent instance where a major technology was not launched in Australia because of the implications of the PL benefit for prices in another major market. Fewer major product launches are likely to occur in Australia if lowest price points are taken and published on the PL, to the detriment of patients. Device access in the public sector is also likely to be affected by taking a lowest price point.

Once again, this point equally applies to the Benefit Group as it does to the individual billing code. A company with a product that is less preferred by clinicians than others in the same Benefit Group may choose to overcome this through a discounting strategy in some or all of the public sector. A lowest price point methodology would result in the entire group being brought down, even though the others have a stronger value proposition for clinicians and their patients. This may make it difficult for sponsors of devices with enhanced features to list or sustain their presence on the PL or in the Australian health system generally, especially as international price referencing by other markets continues to be a factor. Overall, the methodology should reflect genuine clinician choice in the private market and support innovation even within Benefit Groups.

The other key element in calculating the public price is to weight the public pricing by *private volumes* within the Benefit Group. While the proposed benefit review references the public market, it is setting benefits for the private market and therefore should reflect the volume mix in that market. The private volumes will more closely reflect the patient population being treated, the circumstances of treatment and clinician choice in the private sector. MTAA understands that the intention of the Department and IHPA is to calculate the public price and make adjustments at the Benefit Group level. This is relevant to the price methodology because inappropriately sized groups that combine a range of technology regardless of clinical differentiation will cause any pricing methodology to be dysfunctional and magnify any inherent issues it has. Therefore, it is critical that both the pricing methodology and the grouping is appropriate to achieve fair benefit setting that maintains patient access. For this reason, consultation with industry and clinical societies on proposed changes to grouping can't be rushed and will likely require much longer than is currently planned by the Department. Since benefit reductions can't be calculated without final groups, this may place pressure on the current timelines for 1 July if consultation is not brought forward.

Are there any alternative approaches that IHPA should consider? Please provide rationale.
No

5 Appropriate adjustments to account for legitimate differences between the public and private hospital sectors

What factors, if any, should be considered as legitimate and unavoidable difference between the private and public hospital systems with respect to prostheses pricing?

The Paper names some differences between the public and private sectors that MTAA considers legitimate and should be recognised by an upward adjustment from the public price. MTAA highlights the following factors:

Price/volume arrangements in the public market

The most significant of these is the existence of price/volume arrangements in the public that are not and should not be mirrored in setting the PL benefit. The weighted average price methodology will partly reflect the existence of these price/volume trade-offs that occur when payers demand, and suppliers offer, a lower price in exchange for guaranteed volume. This does not mean that payers who are getting a higher price without this volume guarantee are paying the *wrong* price, but simply that the supplier has been able to offer a lower price in exchange for efficiencies and predictability of revenue. However, the corollary of this price/volume arrangement is a narrowing of choice. The payer must restrict clinicians' ability to choose their preferred device in order to achieve the greater volume on the payer's preferred device. This scenario is common in the public sector, particularly on high expenditure, high volume products.

However, in the case of the private sector, its core value proposition is clinician choice. Consequently, the PL is an open system of reimbursement, where any product that meets the threshold criteria can be listed at the same price as competitors, or higher if it can show differentiation. Therefore, the PL benefit level can't and shouldn't simply reflect a public sector price where price/volume trade-offs are contributing to the outcome. The public price needs to be adjusted to remove the impact of these trade-offs. The remaining price still reflects a competitive market as states and territories will negotiate prices with the threat of removing access even without volume commitments.

Higher servicing requirements in the private

There are groups of products where the service burden is unavoidably greater in the private sector than in the public. Cardiac technical support services for CIEDs are a very significant example of this.

A considerable portion of Section 5 of the Paper relating to legitimate and unavoidable differences between the public and private hospital sectors is dedicated to post implant services of cardiac implantable electronic devices (CIEDs). CIEDs consist of pacemakers, implantable cardioverter defibrillators (ICDs) and implantable loop recorders (ILRs). CIEDs require technical support during the implantation procedure as well as ongoing technical services for the life of the device once implanted. These services can range from providing technical advice about device features through to troubleshooting a device.

The provision of these services differs depending on whether it occurs in a public or private healthcare setting. Hospital staff typically provide these services in a public setting.

However, in a private healthcare setting, e.g. hospitals or clinics, staff at companies supplying CIEDs, also known as industry employed allied professionals (IEAPs), support physicians who conduct the implantation procedure or request for the follow-up consultation.

While IEAPs work closely with physicians to provide technical services for patients, these individuals are directly employed by companies supplying CIEDs. Even though the Commonwealth Government provides reimbursement for follow-up services listed on the Medicare Benefits Schedule, these payments are for the physician's services and time only, and do not incorporate the services component provided by IEAPs. As such, these technical services do not attract any further reimbursement to companies supplying CIEDs beyond the cost of providing the device at the point of implantation.

Demand for CIED services is often variable and unpredictable. As such, meeting this demand is challenging. Companies supplying CIEDs are tasked with managing the delivery of services even if they occur concurrently across multiple locations without notice, or if the service is required in a regional or remote area across Australia. In the presence of such challenges, companies continue to provide timely and accessible services which ensure universal access and equity of care across Australia. The more responsive and the more accessible the level of service provided, the higher this estimated cost to provide CIED support services are to industry.

When CIEDs were originally listed, service costs were formally considered as a factor for setting benefits. The July 2010 Prostheses List Guide states:

> *In negotiating appropriate benefits for products with sponsors, the benefit negotiators take into account the advice of the relevant CAG or PoCE and the advisory committee's advice following its consideration of the clinical assessment conducted by clinicians.*
> *In addition to the clinical advice, negotiation on the benefit for a product is based on:*
>
> - *current benefits for similar listed products;*
> - *group/subgroup benefit;*
> - *utilisation data;*
> - *the information the sponsor provides about* ***the costs associated with the supply of the product, such as technical support, warranty, provision of consignment stock and freight and loan set fees;*** *and*
> - *the benefit the sponsor proposes in their Prostheses List application to list a product…*
>
> *Negotiated benefits include standard freight and loan kit costs and reflect the most appropriate benefit consistent with ensured supply of a product.*[3] [emphasis added]

[3] See Department of Health *Prostheses List. Guide to listing and setting benefits for prostheses* July 2010 p.36

This means that current PL benefits for products originally listed on these terms, and those that have since been listed at a price parity to them, do incorporate the costs of technical support. As outlined, this support is most significant in the case of CIEDs and must be appropriately funded under these reforms.

It is the view of the Cardiac Forum of MTAA, representing all CIED manufacturers on the PL, that the gap between public and private sector prices cannot be reasonably reduced for CIEDs without considering the sustainability of these services and the potential unintended consequences for patients and physicians. This view is also shared by a large proportion of cardiologists who are actively supporting these patients in their day-to-day clinical care and rely on the support services provided by industry. We have attached an open letter to the Health Minister signed by over a third of cardiologists involved in the insertion and post-implantation care of patients with these devices.

The IHPA Pricing Methodology Paper states the following:

> *It is widely accepted that these ongoing services are critical to patient outcomes, but there is a range of views on how these should be funded in the future, given that the Prostheses List was not intended to cover the costs of ongoing services related to technical support for devices.*

IHPA's recognition that CIED services are critical to patient outcomes reflects the Government's view that support for these services is essential and that these services should continue and not be compromised through the PL reform process. The Department has recognised that these services are clinically necessary, and that industry has carried the burden of delivering these services to privately insured patients through the device reimbursement offered through the PL.

In relation to IHPA's observation that there are a range of views on how these services should be funded in the future, the Department has set out to CIED manufacturers potential funding mechanisms for CIED technical support services. The Cardiac Forum has engaged with the Department seeking to work through a sustainable and appropriate funding mechanism that protects patient access to support services provided by industry. In working with the Department on these alternative funding models it is evident that any viable alternative will take significantly longer than 1 July 2022 (first 40% differential benefit reduction) to implement.

The Cardiac Forum is seeking for the costs of providing CIED support services, estimated at $103 million[4], to be accounted for in IHPA recommendations for adjustments to the public benchmark when determining PL benefit changes commencing 1 July 2022. This will enable sufficient time for the process of developing the most appropriate future funding model.

[4] KPMG *Cardiac Implantable Electronic Device (CIED) service valuation* Report for Medical Technology Association of Australia, February 2021

However, other groups on the PL can also have a higher service burden. This is typically due to the absence of paid support services or multidisciplinary teams in the private sector that exist in the public sector. The industry is reviewing the relevant data to provide as part of any assessment of this.

Freight and distribution

Public systems often assume or break out freight costs, for example by setting up centralised distribution warehouses for some items, as happens in NSW. This means that the price reflects the fact that suppliers only need to make large quantity shipments to one location, and the state system manages the remaining distribution. Generally, the public system has larger warehousing and stock management capabilities, meaning that order sizes are larger and ordering frequency is less, lowering overall costs for suppliers. In orthopaedics, instrumentation kits are often consigned to public hospitals, while in the private hospitals they are typically shipped on loan at suppliers' cost for every procedure.

Other costs

There are a range of other relevant factors. In the public sector all bad debts are covered by a liability guarantee, but this is not the case in the private sector. There are also instances where accessories are not covered by the PL whereas in the public sector they are explicitly priced. Furthermore, applying to list a product on the PL, particularly for innovative devices, often involves significant cost to prepare and lodge a submission. Fees to apply for and maintain listings are set to increase under the reforms. The public hospital system also does not charge either for participating in tenders or selling into the market.
Collectively, these factors add up to a higher overall service cost in the private sector than in the public sector.

Furthermore, when calculating the new price for a PBS medicine subject to price disclosure, the price does not fall if it is less than 10% above the average price for all brands of the same item. If there is the same benefit applied to a whole group on the PL, then this effective 'buffer' can't be applied. Nonetheless the principle seems to apply more readily to unique devices in the same group on the PL than for generic copies of the same medicine. This provides further grounds for not reducing benefits for groups of products where there is a smaller difference between the public price and the PL benefit.

Under the Government's proposed phasing methodology, smaller differences below the adjustment can scarcely be accounted for at all. This is because, contrary to MTAA's recommendation, the adjustment can only occur in the 4th year as a 'remainder' of any difference between the public price and the PL benefit, rather than as an adjustment included in the upfront calculation.

An immediate consequence of this is that benefits that are only slightly higher than the public price will be forced to come down when they are already competitive. This contradicts the principle applied on the PBS, where there is the 10% margin compared to the benchmark within which an item's price can remain unchanged. This can only be rectified by calculating an acceptable difference up front and phasing any reductions *with this calculation included*.

It is very concerning to the device industry that this is not the current intention of the Department.

How should the extent of any such differences be quantified?

MTAA has developed a set of methodologies for accounting for these additional costs which it will discuss with IHPA and the Department. Not every cost described above may be quantifiable and there is a significant amount of data on the differences between public and private that the industry has not routinely collected in the past, as this hasn't been necessary. However, in each case costs can be mapped if there is a reasonable expectation for justification that doesn't far exceed the adjustment being requested.

The extent of CIED services has recently been quantified through the analysis conducted by KPMG[5]. According to this analysis, there are an estimated 220,172 Australian patients with CIEDs. The number increases at a rate of approximately 18,000 a year (net). The patient's wider carer and family networks mean well over half a million Australians are impacted should IEAP services change significantly. The annual cost of providing these services has been estimated by KPMG to be $103 million by the end of 2022. It is important to note that the cost of providing these services and continuing to ensure coverage across the country is increasing at a higher rate than the increase in the demand for CIEDs. Any solution needs to be able to sustain the current high quality, universal service model that industry delivers.

In developing an appropriate funding mechanism, consideration of patients in rural and regional areas is particularly important. Many regional and rural locations have no service alternatives except for cardiac services provided by IEAPs.

Solutions need to be developed jointly with relevant stakeholders including the Department, cardiologists, private hospitals, patients, and industry taking a variety of factors into account (access issues, equity of care, care settings, scheduled vs emergency services, etc.). This can simply not be achieved within the tight deadline of 1 July 2022 when benefit reductions are scheduled to commence.

[5] ibid