Medical Technology Association of Australia Ltd
ABN: 61 129 334 354
Lvl 12, 54 Miller St, North Sydney NSW 2060
PO Box 2016, North Sydney NSW 2059
P: (02) 9900 0600
E: mtaa@mtaa.org.au

Comparison of prostheses pricing across different markets October 2018

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1. Executive Summary

MTAA presents this submission to inform the content of the preliminary options papers being drafted by ThinkPlace on international reference pricing and price disclosure for reviewing benefits on Prostheses List (PL) as MTAA is of the view that the paper would benefit from clarifying the objectives for benefit review using these tools together with a thorough analysis of the issues. This will ensure informed options are ultimately put to the Minister for consideration.

Based on some of the discussions that occurred at the 21 September Benefit Setting and Review (BSR) IWG meeting, there appeared to be misunderstanding about the objective of price disclosure and price referencing across different markets. The objective of benefit review using these methods is to leverage market competition to adjust benefits in an evidence-based manner as underpinned by the *Principles* of the MTAA – Government Agreement through *Improved Value*[1] and *Transparency*[2] *and also the Terms of Reference (TOR) of the IWG*[3].

Achieving price parity across different markets is not an appropriate ultimate objective as fails to recognise and account for differences between different markets and is likely to fail to meet the intent of the Agreement or the TOR of this IWG. Additionally, it places unnecessary limitations in how a benefit review model is operationalised. For example, price parity as the aim will not allow for a buffer on benefit reductions to be put in place. This flexibility is built into the PBS model where prices are only reduced if the weighted average price differential exceeds a particular percentage and there is no valid reason this should not be available for prostheses.

The key questions that need to be explored in the options paper are, at a minimum, as follows:

1. *Why are there price differences across different markets?*
2. *If comparisons across different markets are undertaken, what adjustments should be made?*
3. *How does a price comparison for benefit review across different markets meet the intent of the revised PL Framework under the Agreement?*
4. *Based on the above, what is the appropriate market for price referencing?*

As identified in the papers provided at the latest BSR IWG meeting, the different markets against which price referencing can occur are as follows:

- Referencing prices across the same market (domestic - private)
- Referencing prices across the public and private market (domestic - public)
- Referencing prices across international markets (international)

As price disclosure is purely one of several mechanisms to enforce a price referencing model which adjusts PL benefits based on competition across a market of choice, the arguments made in this submission are relevant to both the price referencing and price disclosure options being discussed.

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[1] **Improved value** of private health insurance for consumers through benefits that enable access to safe, effective and cost-effective medical devices supplied within a competitive market.
[2] **Transparency** of decision-making for all stakeholders that is informed by sharing of high quality data.
[3] Function of the IWG on Revised Benefit Setting and Review Framework:
d. is informed by robust and relevant evidence, including, for market considerations, credible data
e. encourages competition

1. Why are there price differences across different markets?

As MTAA has stated repeatedly, expecting prices to be the same across different markets is inappropriate as prices are influenced by the range of factors outlined below:

a) Differences in healthcare systems;
b) Differences in purchasing arrangements and market segmentation;
c) Differences in price / benefit determination;
d) Differences in volumes of devices being used;
e) Differences in the level of technical manufacturer support required;
f) Geographical differences; and
g) Economic differences.

All the above, except geographical and economic differences also apply in understanding prostheses price differentials across the public and private sector in Australia.

The above points are consistent with a 2001 Productivity Commission report[4] which, in relation to international price comparisons of pharmaceuticals, states:

It is difficult to identify robust specific explanations for the observed bilateral price differences. Rather, the price differences are probably due to a combination of influences, including systemic differences in health systems, pharmaceutical subsidy and cost-containment mechanisms, and production costs (including marketing and liability costs).

The difficulty of comparisons across international jurisdictions was acknowledged by Bupa, one of the largest PHI companies in Australia, in an article published in The Age on 21 September 2016. When asked why Australian families are paying up to $400 more a month for private health insurance than consumers in comparable countries like Britain, a Bupa spokesperson said that:

…. the 'private health market in Britain was "very different", with insurers able to pick and choose customers and force patients to seek their approval before being referred to a specialist'.

2. If comparisons across different markets are undertaken, what adjustments should be made?

The literature identifies a range of methodological challenges that apply to comparing prices of pharmaceuticals across different countries, with many of these being applicable to medical devices. Based on the totality of the information in this document, MTAA would recommend that studies that are intended to conduct price comparisons for prostheses make the following adjustments:

a) Ensure country selection is based on similarity in terms of income and cost of living, disease patterns and having a private healthcare market like Australia with a similar level of fragmentation, prostheses choice, patient co-payments and initial pricing being based on HTA;
b) Ensure the study compares the same iteration of the prosthesis and pack sizes and presentation

[4] Productivity Commission 2001, International Pharmaceutical Price Differences, Research Report, AusInfo, Canberra.

c) Ensure that the technical or other support services provided by the device company are factored into the price/benefit the same way.
d) Ensure the study adjusts for volumes;
e) Ensure conversion to a common currency with consideration for currency fluctuations;
f) Ensure differences in regulatory and reimbursement costs to enter the market are taken into account;
g) Procurement and service costs, and how these may vary for hospitals in rural and remote areas.

Not adjusting for these factors would result in inappropriate comparisons and inequitable outcomes. However, they are likely to be very resource intensive and unlikely to be cost-effective.

MTAA considers that the only viable option is for price referencing to occur based on the domestic private market i.e. private price disclosure, because this would:

a) be administratively simple as no adjustments to the data included in the calculations will need to be made;
b) deliver results that are consistent with the principles outlined in the Agreement and the Terms of Reference of the BSR IWG; and
c) be consistent with how PBS pricing is administered.

2. Analysis of issues with reference pricing across different markets

The PL includes over 10,000 items supplied by 206 companies, across 13 therapeutic categories. The vast majority of these companies are small businesses with a low number of products and consequently they do not have the product breadth required to absorb significant cuts to PL benefits.

Despite its very small contribution to the proportion of the total private health insurance (PHI) spend (11 %), the PL contributes significantly to one of the key value propositions of PHI for consumers over the public hospital sector – choice. The PL provides privately insured patients certainty of access and cost (currently nil) to a wide range of prostheses in the private sector compared to the public sector and the choice of prostheses the surgeon can make for his/her patient is not constrained.

The current reimbursement framework for medical devices has set benchmark prices relative to other products. This system recognises the value of the product compared to other products and thereby meets the IWG's ToR as follows:

- All products on the list have already undergone a rigorous assessment process, including CAG, HESC and PLAC;
- The current system provides certainty for patients knowing they will have products covered by PHI, certainty for hospitals knowing they are not going to be left out of pocket, clinical choice of product and simplifying financial aspects for patients and doctors as no gap payments are required;
- The current system provides equity of access to devices for patients.

The PL has also contained inflation in the level of the average benefit for device-related treatments, thereby assisting in reducing private health insurance costs below the level they would otherwise have been. Recent claims from private health insurers that the cost of medical devices "was already over budget this year" do not reflect reality - the benefits on the PL continue on a downwards trajectory,

particularly as the full impact of the $1.1 billion cuts to the PL under the MTAA-Government Agreement becomes a reality.

Recent quarterly figures by Australian Prudential Regulation Authority figures show the total benefits paid for prostheses decreased by 13% in the March quarter 2018 compared to the December quarter 2017, representing a $72 million saving to private health insurers.

As MTAA has repeatedly stated, the increase in utilization of prostheses is principally related to Australia's ageing population and earlier identification of chronic diseases.

This context is important in framing discussions around any market-based benefit review model but is particularly relevant to models based on prices in markets other than the domestic private market as these comparisons will inappropriately distort prices and have a disproportionate impact on patient access to prostheses and out-of-pocket costs. This is in addition to the fact that pricing comparisons across different markets are inappropriate for a range of reasons and would require significant methodological adjustments to be even close to comparing apples with apples.

2.1 Factors influencing pricing across different markets

This section outlines the factors which influence pricing of medical technologies across different countries and the Australian public sector and why it is inappropriate that these prices determine the PL benefit.

2.1.1 Differences in healthcare systems

The structure of healthcare systems in individual countries, the split between public and private healthcare and the source of funding will impact on the price of prostheses given they will be subject to different political, policy and economic drivers. It is therefore impossible for prices to be the same across each jurisdiction and it would be inappropriate to use these prices to set or adjust private market prostheses prices in Australia.

A simple example of these differences can be found domestically when comparing the incentives for the public hospital sector and the private hospital sector and the services they provide. Public hospitals are incentivised to provide necessary and efficient care at the lowest possible cost through Activity Based Funding (ABF). As a result, purchasing of prostheses occurs through centralised tenders which trade off prostheses choice against prostheses volume (either directly or indirectly[5]), with control about what is available to the hospital being made by hospital administrators.

The private hospital sector is not constrained by ABF and clinicians rather than hospital administrators make the decisions about services and care provided, including the types of prostheses they would like to use. These differing incentives influence in different patterns of use and possible economies of scale.

It is important to note also that some countries may appear to have comparable healthcare systems to Australia but, when analysed in greater depth, may actually be quite different.

For example, based on OECD statistics in Table 1, Canada and Australia appear to have similar healthcare structures with similar population proportions being covered by PHI and a similar percentage of expenditure as a proportion of total healthcare expenditure.

[5] Some State tenders commit sponsors to price volume arrangements whereas others set a price based on volume and individual hospitals will negotiate a price-volume discount consistent with that in the State tender in their contract.

However, there is no private market for prostheses because the Canadian healthcare system does not allow for private health insurance to cover services provided by the public sector, including hospital procedures which include prostheses.[6]

Private health insurance is predominantly used to pay for services not considered medically necessary under individual provincial and territorial interpretations of the Canada Health Act. Medically necessary services generally include in-hospital and laboratory services, while services not publicly covered include some in-hospital services such as cosmetic surgery, ambulance or transportation before admission or upon discharge, private duty nursing, non-medically required x-rays or other services for employment or insurance purposes, as well as drugs and appliances issued for use after discharge from hospital. Purchasing and procurement decisions largely take place at the level of regional health authorities or individual hospitals that are private not-for-profit institutions.[7].

In contrast, Australia's healthcare arrangements allow for duplicative health insurance, meaning there is a private market for prostheses, with purchasing occurring at the individual hospital level (around 600 hospitals), noting that some private hospital groups undertake centralised purchasing for the hospitals in their groups.

Table 1:

	Public health expenditure as % of total healthcare expenditure[8]	**Public system coverage[9]**	**PHI as % of total healthcare expenditure [10]**	**Population covered by PHI[11]**	**Types of private coverage provided (source: OECD Health Statistics 2016, http://www.oecd.org/els/health-systems/health-data.htm)**			
					Primary PHI	**Duplicative PHI**	**Complementary PHI**	**Supplementary**
Australia	66.7%	100%	7.3%	55.2%		•	•	•
Canada	70.8%	100%	11.4%	67%				•
France	78.6%	99.9%	12.7%	95.5%			•	
Germany	85.0%	89%	12.6%	33.8%	•		•	•
Japan	84.9%	100%	0.3%	Negligible			•	•
New Zealand	79.9%	100%	6.3%	29.3%			•	•
Sweden	83.7%	100%	Not available	Negligible			•	•
Turkey	77.2%	66% (1997)	0.7% (1994)	5.8%			•	•
UK	79.0%	100%	3.3% (1996)	10.5%		•		
USA	49.4%	34.5%	35.1%	61.6%	•		•	

6 Private insurance can be classified as follows:
- **Complementary insurance** – to cover any cost-sharing left after basic public health coverage
- **Supplementary insurance** – to provide additional services to those covered by public health
- **Duplicate insurance** – to provide faster access, or larger choice of providers for the same services available under the public health system

7 Medical device and diagnostic pricing and reimbursement in Canada, first edition – Institute of Health Economics Alberta Canada

8 http://stats.oecd.org/index.aspx?DataSetCode=HEALTH_STAT (2015 - Health expenditure and finance)

9 http://stats.oecd.org/index.aspx?DataSetCode=HEALTH_STAT# (2014 - Social Protection: Government/social health insurance)

10 http://www.oecd.org/officialdocuments/publicdisplaydocumentpdf/?cote=DELSA/ELSA/WD/HEA(2004)6&docLanguage=En

11 http://stats.oecd.org/index.aspx?DataSetCode=HEALTH_STAT# (2014 - Social Protection: Government/social health insurance)

In relation to the potential reference countries outlined in the papers presented at the 21 September BSR IWG, MTAA would like to note that, while the US healthcare system is very different to that in Australia, the private market for prostheses in the US is more akin to the Australian market than many of the other countries outlined as potentially relevant.

2.1.2 Differences in purchasing arrangements and level of segmentation of the market

The greater the level of market integration, the greater the capacity to purchase at lower prices through improved economies of scale and market volume guarantees for medical device companies. Therefore, the number of prostheses purchasers in any particular market is important in determining price variations.

For example, in Sweden, the healthcare system is integrated to a high degree with county councils being responsible for both the financing and organization of health care services, and most hospitals are owned and operated by the county councils[12]. In Sweden, as in the Australian public market, the cost of prostheses are included in a DRG and are centrally purchased by a small number of entities through tendering.

2.1.3 Differences in how price / benefit was determined and what is included

Prostheses prices differ across markets, particularly across different countries. Prices will vary depending on the costing methodology and inputs (delays in market access, regulatory costs, support services), whether value / HTA was part of the price determination and if the prices were subject to further negotiation. These are discussed in more detail below.

2.1.3.1 Costing methodology

In Japan, there is almost no private health insurance market. The Japanese Government provides universal healthcare and patients are required to pay a 30% co-payment for the cost of their treatment, including the cost of prostheses.

The cost of prostheses is based on a complex system which has determined prices for a large number of functional prostheses groups on a specific formula which included an analysis of costs associated with developing and manufacturing the product along with a reasonable mark-up.

Purchasing is based on tendering arrangements and prices are reviewed every few years using a local market-based survey of prices and, for a subset of these functional groups (around 10%), the price adjustment will be based on a comparison against a number of other countries.

Prostheses prices in Japan are therefore based on a mathematical formula that does not consider the healthcare value of the prosthesis but does factor in market competition, mostly across the same market.

It should be noted for the record that the Japanese system is complicated and has placed Japan behind most other advanced economised which are using HTA to make decisions on funding medical technologies. As such, Japan is now trialing an HTA process with a view to future adoption across the spectrum of health technologies. [13]

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[12] Anell, Anders and Glenngard, Anna H. and Merkur, S (2012) Sweden: health system review. Health systems in transition, 14 (5). pp. 1-159. ISSN 1817-6119

[13] New decision-making processes for the pricing of health technologies in Japan: The FY 2016/17 pilot phase for the introduction of economic evaluations Takeru Shiroiwa et al; Health Policy 121 (2017) 836-841

2.1.3.2 Level of industry support services

The level of service required from the device company varies in each country and by prostheses category, and this can impact on the price attributed to a prosthesis. The level of service required may depend on the expertise available within the hospital, the hospital specialty areas and the volume of procedures undertaken with specific brands of prostheses.

Based on advice from MTAA member companies, for some European countries, for certain device types companies do not provide post-procedure follow-up technical support services. Funding for these services is allocated to clinicians in hospitals with support from highly trained staff, and therefore these services are provided with little support from manufacturers. This is more similar to the Australian public market.

In contrast, the private market in Australia, Japan and the USA have a high demand for manufacturer support and in Australia, the cost of these services over the life-time of the device is factored into the PL benefit.

A clear example relates to active implantable cardiac devices where the significant technical support costs are embedded into the PL benefit. While Japan and the USA also demand high manufacturer technical support, it is not clear as to how and to what extent these services are captured in the price of these prostheses.

2.1.3.3 Other costs

In addition to the cost of providing technical support services, the PL benefit includes factors such as logistic costs and handling fees. These may or may not be included in the public-sector price. This may also include additional costs of doing business in the private market in Australia such as having additional evidentiary requirements to be listed on the PL (and where relevant, preparation of an MSAC submission for a new or amended MBS item).

2.1.4 Differences in volumes of devices being used

Different countries will have variations about what comprises standard clinical care and different levels of need based on prevalence of disease resulting in different patterns of prosthesis use as well as different restrictions on usage based on cost-containment or other local measures.

As volume of use impacts on the capacity to discount prostheses prices, these variations will impact on prostheses pricing and as such, it would be inappropriate to make pricing adjustments using price point data without reference to volume.

It should also be noted that while some countries such as France and the UK have 'list prices' for certain products, companies may not supply these products to the market as the price is not viable – i.e there is a price without a market. This is another reason volume is an important adjustment factor for any price-referencing activity.

2.1.4.1 Different indications for use

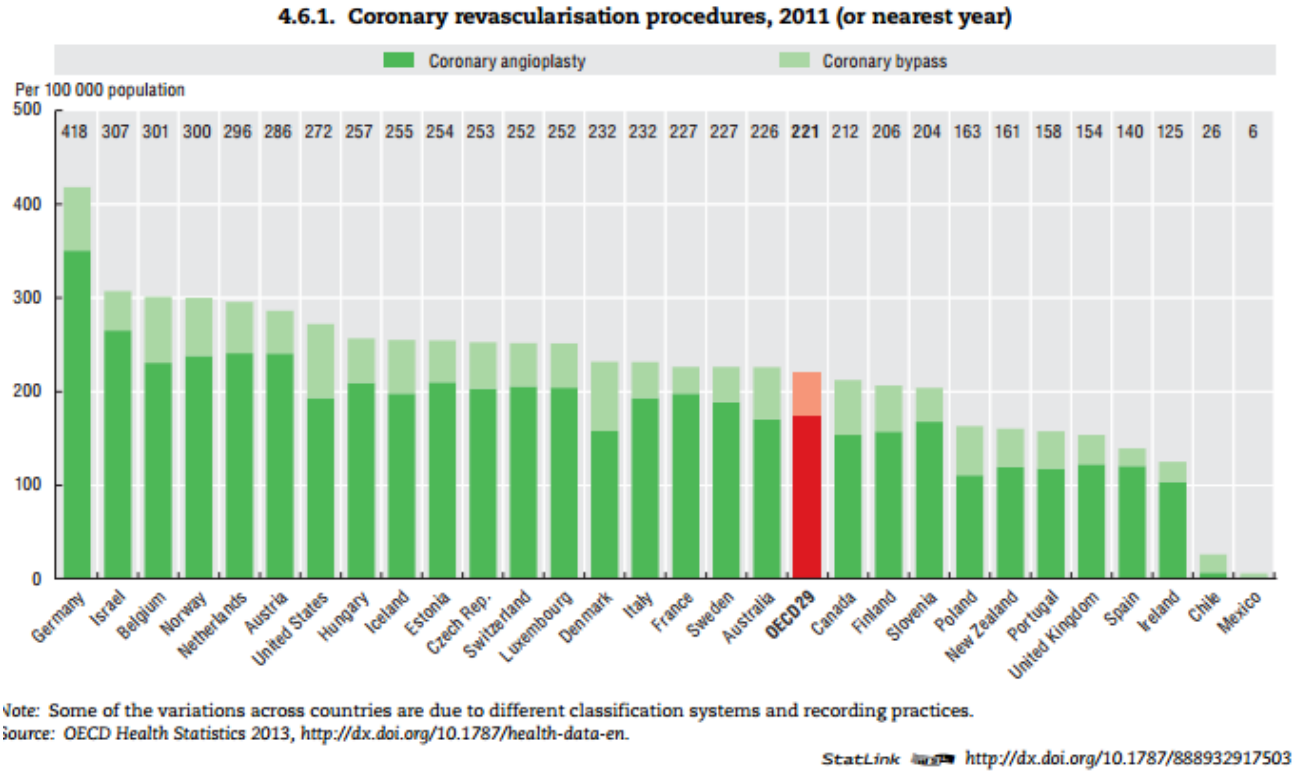
The indications for marketing approval and/or reimbursement can vary between countries and impact on the volume of devices used.

For example, the WATCHMAN left atrial appendage closure device is approved by the TGA to prevent thrombus embolization from the left atrial appendage and reduce the risk of life-threatening bleeding events in patients with non-valvular atrial fibrillation who are eligible for anticoagulation therapy or who have a contraindication to anticoagulation therapy. This is therefore the indication for use in the public system. However, in the Australian private market physician reimbursement through the MBS restricts use of the product to patients with a contra-indication for life-long anticoagulation therapy and are at increased risk of thromboembolism (MBS item 38276).

2.1.4.2 Differences in medical practice and patient need

Some countries undertake certain procedures using medical devices more frequently than other countries. For example, based on the OECD Health at a Glance 2013, Germany conducts almost twice as many coronary angioplasty procedures per 100,000 compared to Australia and its population is 4 times higher than Australia's. This means that there is a significantly greater volume of devices associated with coronary angioplasty procedures in Germany compared to Australia and can result in higher prices of prostheses in Australia compared to Germany (See Table 2).

Table 2: Coronary revascularisation procedures per 100,000 per OECD country



Note: Some of the variations across countries are due to different classification systems and recording practices.
Source: OECD Health Statistics 2013, http://dx.doi.org/10.1787/health-data-en.

StatLink http://dx.doi.org/10.1787/888932917503

2.1.5 Comparing the same device and pack sizes

It is difficult to determine if the prices of exactly the same iteration of devices with the same functionality are being compared. Additionally, it may be difficult to ensure the same quantity and presentation of the product is being compared. This is particularly the case when given some devices are presented and supplied as 'kits' but individual components of the kit are listed and priced individually in some jurisdictions but priced as a kit on others.

Media stories such as the story in the Australian on 8 February 2017 – *Health insurers seek a halt to $800m prosthetics wastage*, where significant pricing differentials for purportedly the same product

across different countries have subsequently been found to be untrue because the stories were based on pricing information for essentially different products or were using pricing for completely different pack sizes.

If informed entities such as health insurers are having this level of difficulty ascertaining they are undertaking appropriate comparisons, it will be difficult for an external provider that will largely be uninformed about the peculiarities of devices to make these judgements.

2.1.6 Geographical differences

Geographical considerations can influence price differentials. Australia's isolated location, its low population density and enormous land mass have a significant impact on the cost of bringing devices into Australia and then distributing domestically. The cost of bringing goods into Australia can be much higher (based on member feedback can be in some instances around 1000% higher) than bringing goods into the USA or Europe.

The cost of freight in Australia is also very high due to our large land mass and low population density. Based on member feedback, costs may be up to 500% higher than in other countries (when corrected for volume). These costs can be significant, not only for the implanted devices but also for accompanying loan kits in the case of orthopaedic prostheses, which are both heavy (around 1 tonne) and large in volume.

Table 3: Population density
Source: World Bank (data.worldbank.org/indicator/EN.POP.DNST) – 2015 population

Country[i]	Land mass[i]	Population[iv] [i]	Density per km2[ii]	% Population > 65i[iii]
Australia	7,692,024 km2	~ 23 million	3	14.4%
Canada	9,984,670 km2	~ 35 million	4	15.2%
France	643,801 km2	~64 million	122	17.7%
Germany	357,168 km2	~80 million	234	21.1%
Japan	377,972 km2	~127 million	348	25.1%
New Zealand	268,021 km2	~5 million	17	14.2%
Sweden	450, 295 km2	~ 10 million	24	19%
Turkey	783,356 km2	~ 79 million	102	N/A
United Kingdom	241,930 km2	~ 64 million	269	17.1%
USA	9,833,517 km2	~ 324 million	32.98	14.1%

2.1.7 Economic differences

Price differentials are also influenced by economic differences. For example, facility costs are significantly higher in Australia compared to other countries where some manufacturers require a warehouse in every State/Territory whereas in European countries, one warehouse per country is sufficient.

Local costs such as wages and costs of living can influence the price of prostheses. This is particularly where prostheses are associated with high level of professional service and support as these costs include a large component of wages, travel costs (petrol, airfares) and time to cater for the distance travelled and level of intensiveness of the service (checking and packaging and distributing loan kits, on-call to see patients around Australia 24/7). Issues such as currency fluctuations and exchange rates will also influence price differences.

3. If comparisons across different markets are undertaken, what adjustments should be made?

The literature identifies a range of methodological challenges that apply to comparing prices of pharmaceuticals across different countries, with many of these being applicable to medical devices.

F. Anderson 1993 suggests that a methodologically sound study of price comparisons for drugs needs to address the following before informing important policy decisions in healthcare:[14]

a) the selection of similar countries –country selection needs to be based on similarity in terms of disease patterns, therapeutic tradition, level of drug consumption, drug distribution, drug reimbursement methods and distribution of income, age and gender;
b) selecting a representative basket of drugs where the intention of the comparison is to form a generalised view about comparative device prices;
c) using the same price for comparison as drugs are priced at different levels along the supply chain;
d) comparing the same pack sizes, forms and indications;
e) weighting for volumes; and
f) conversion to a common currency.

Many of these methodological adjustments also apply to devices. However, there are other factors unique to devices that should be adjusted for. These include:

a) confirming the devices being compared are the same iteration of the device with the same functionality;
b) confirming the devices being compared reflect the same quantity and presentation of the product given some devices are presented as 'kits' and may be priced as an entire kit or, like in Australia, the individual components are listed and priced individually;
c) confirming that the technical or other support services provide by the device company are factored into the price/benefit the same way.

Based on the above, MTAA would recommend that studies that are intended to conduct price comparisons for prostheses make the following adjustments:

a) Ensure country selection is based on similarity in terms of income and cost of living, disease patterns and having a private healthcare market like Australia with a similar level of fragmentation, prostheses choice, patient co-payments and initial pricing being based on HTA rather than tenders;
b) Ensure the study compares the same iteration of the prosthesis and pack sizes and presentation;
c) Ensure that the technical or other support services provided by the device company are factored into the price/benefit the same way;
d) Ensure the study adjusts for volumes;
e) Ensure conversion to a common currency with consideration for currency fluctuations;
f) Factors in regulatory and reimbursement costs to enter the market, including the cost of meeting unique evidence requirements; and
g) Procurement and service costs, and how these may vary for hospitals in rural and remote areas.

These adjustments are very resource intensive but are required in order to ensure appropriate comparisons and equitable outcomes.

[14] Methodological Aspects of International Drug Comparisons; F. Anderson, PharmacoEconomics 4(4):247-256, 1993

4. How does a price comparison for benefit review across different markets meet the intent of the revised PL Framework under the Agreement?

Under the Agreement, the BSR IWG is intended to develop options for a revised framework for setting and reviewing benefits for devices on the Prostheses List that will:

a) promote the sustainability of privately insured healthcare to help maintain affordability of private health insurance for all Australians;
b) minimise patient out-of-pocket costs, thereby protecting the value proposition of private health insurance;
c) preserve patient access to the device recommended by their physician; and
d) support a viable, innovative and diverse medical technology sector in Australia.

The function of the BSR IWG is to review the current framework for benefit setting and benefit review for medical devices under the PL to ensure the future Prostheses List framework:

a) is tailored to medical technology;
b) has a structure and associated processes that are simple, administratively efficient, pragmatic and sustainable;
c) is not duplicative of other HTA processes;
d) is informed by robust and relevant evidence, including, for market considerations, credible data;
e) encourages competition;
f) is built on transparent processes with appropriate protections around commercial-in-confidence data;
g) provides flexibility to differentiate between product groups/sub-groups;
h) is compatible with the incorporation of new and cost-effective technologies; and
i) recognises improvements in value.

MTAA contends that comparisons across different markets will result in PL benefit adjustments that will not meet the principles and intent of a revised PL Framework as they would:

a) reduce patient access to the device recommended by their physician;
b) result in patient out of pocket costs;
c) result in a structure and associated processes that are NOT simple, administratively efficient, pragmatic and sustainable; and
d) result in NOT being informed by robust and relevant or credible evidence.

5. Conclusion

MTAA considers that the only viable option is for price referencing to occur based on the domestic private market i.e. private price disclosure, because this would:

d) be administratively simple as no adjustments to the data included in the calculations will need to be made;
e) deliver results that are consistent with the principles outlined in the Agreement and the Terms of Reference of the BSR IWG; and
f) be consistent with how PBS pricing is administered.