Inquiry into the regulatory standards for the approval of medical devices

Submission by Medibank Private

Date: **July 27th 2011**

Medibank welcomes the Senate's inquiry into the regulatory standards for the approval of medical devices. Healthcare expenditure makes up nearly 10% of GDP and has been growing faster than the economy over the last decade. A major challenge for government is containing the growth in health costs while maximising individuals' access to the best quality of healthcare available, particularly given the demographic challenges facing Australia today.

Innovations in medical technology can play a major role in improving patient outcomes and it is critical that individuals have access to high quality and appropriate technology.

However, medical technology is also a major driver of increasing healthcare costs and it is important to have robust and sophisticated mechanisms for assessing the clinical and cost effectiveness of new products.

Prostheses in particular make up a significant component of surgical technology and account for 2% of annual healthcare expenditure at around $1.5 billion. Prostheses include all surgically implanted medical devices such as artificial joints, stents, pacemakers and ocular lenses.

Over 60% of prostheses implanted in patients involve the use of private health insurance. Private insurers spend almost $1 billion on prostheses annually with patients currently contributing only around 0.2% of this amount. In 2010, Medibank including ahm spent 10.7% of our benefit outlays on prostheses, or $406 million. This is reasonably representative of the PHI industry with the rest of the industry spending around 10.6% of their outlays on prostheses.

Prostheses expenditure does not include the cost of surgery, hospital admissions or rehabilitation. Prostheses thus have a significant impact on insurance premiums and consequently the affordability of private health insurance. Maintaining downward pressure on private insurance premiums is important as it in turn ensures private health insurance remains accessible for as many people as possible and encourages uptake.

Several shortcomings exist in the current arrangements for funding prostheses, which, if rectified, offer significant scope for overall savings to both the public and private sectors of the healthcare system.

About Medibank

Medibank is Australia's largest integrated private health insurance and health services group.

We have been providing health insurance to Australians since our inception in 1975 and currently cover 3.4 million members, equal to 32% of the national private health insurance market. In addition to our resident members we also cover over 200,000 overseas visitors and students and provide access to life, pet and travel insurance.

In the last two years, we have undergone a dramatic and exciting transformation, growing the role we play in our customers' health and evolving into a provider of broad range of health services, including mental health services.

In 2009, we acquired Wollongong-based private health insurer Australian Health Management (ahm) and merged with another Government Business Enterprise, Health Services Australia (HSA). Renowned as a leader in customer service and customer satisfaction, ahm introduced around 200,000 people to our customer base. More importantly, it also brought ahm's pioneering health coaching and disease management business, Total Health, into the Medibank family.

The amalgamation of Total Health and HSA, together with Medibank Private's legacy health and wellbeing programs, led to the creation of Medibank Health Solutions, energising our health services capability and marking our transformation into a health company.

Following this, in 2010, we acquired the telephone and online health service provider, McKesson Asia-Pacific, further expanding our health and wellbeing capability. As a result today, we offer one of Australia's largest range of telehealth programs, ranging from online health and wellbeing services to help individuals achieve their health goals through to intensive telephone based support services for people living with chronic disease and mental illness.

Responses to terms of reference

(a) The role of the Therapeutic Goods Administration in regulating the quality of devices available in Australia

The TGA, in regulating the quality of devices, considers the technical performance of a sponsor to consistently deliver the device as assessed through its documentation processes e.g. GMP and IEC compliance. In terms of quality assurance versus quality performance, the TGA does not assess quality on the basis of clinical outcomes. Rather, its primary role is as gatekeeper to ensure no unsafe or non-efficacious devices are allowed to enter the Australian market.

Regulatory authorities, such as the US Food and Drug Administration, consider the gatekeeper role and post market surveillance to be the key function in controlling devices. Clinical and cost performance selection are determined by the market rather than the regulatory. The UK Medical and Healthcare products Regulatory Agency, however, has a global role in determining guiding clinical and cost performance. Consideration needs to be given in expanding the TGA's role where there is no positive craft group engagement in selecting and monitoring the global 'quality' performance of such technologies.

(b) The cost effectiveness of subsidised devices

The market and reimbursement systems are accountable for making such choices based on clinical and cost effectiveness. Formalised processes for determining cost effectiveness include the Pharmaceutical Benefits Scheme for medicines, the Medical Benefits Scheme for procedures and the Prostheses List Advisory Committee for prosthetic devices. At present, these systems are fragmented and do not benefit from a global approach.

Lack of formal reimbursement pathways to the Private Health Care Market:
The lack of a defined process for assessment and funding of a number of new medical device technologies inhibits private hospital uptake of devices. Specialists are introduced to new medical devices by suppliers or the supplier goes direct to the hospital and the hospital provides these to facilitate improved patient outcomes without any clinical evidence other than Therapeutic Goods Approval (TGA), or formal industry accepted process for reimbursement (such as that that exists for prostheses).

Performance of Current Formal Re-imbursement Pathways (Prostheses List)
The prostheses sector has been subject to a suite of regulatory changes in recent years designed to contain costs. These changes have created a complex and highly regulated approach to the approval, funding and use of a new prosthesis in Australia, particularly in the private hospital sector.

The Final Report of 2009 Review of Health Technology Assessment (HTA) in Australia demonstrated a strong understanding of some of the challenges facing benefit setting and regulation at the broadest level. However, the following features of the industry were not explicitly acknowledged and these continue to affect the success of changes to existing arrangements. These include:

- Despite the significant efforts and calibre of Prostheses and Devices Committee (PDC) members, the scale and scope of the Prostheses List is such that attempts to group products on the basis of clinical effectiveness is a complex and slow process. One particular review that involves around 2,500 products remains incomplete after almost two years.[1] There is also a major backlog of reviews of listings and benefits intended to be undertaken by the PDC, resulting in inconsistent benefits set for products with similar clinical effectiveness.[2]
- Benefit setting arrangements for prostheses which differ between the public and private hospitals sectors, with private health insurers having to reimburse prostheses at much higher levels in the private hospital sector where clinicians are not required or encouraged to consider cost effectiveness. While some level of differential pricing reflects differences in training and product support between public and private hospitals, benchmarking indicates variation that exceeds this justification.[3]
- It is difficult to encourage device suppliers (or sponsors) to develop and support generic prostheses in a market where clinical decisions in the private sector are not required to consider cost effectiveness. While the regulatory framework needs to ensure that there are appropriate incentives for sponsors to invest in prostheses, innovations to develop generic products where they achieve the same or better results in more cost effective ways are similarly important.
- Market competition between sponsors needs to be encouraged to help offset the market failures which exist in relation to prostheses. These include information gaps for consumers who rely on clinical guidance, which is not required to reflect cost effectiveness considerations in any meaningful way.
- While the National Joint Replacement Registry (NJRR) has performed a very useful function, there remains a paucity of information regarding clinical best practice to guide the choice of prostheses. This undermines the substitution of certain devices for more cost effective selections where clinical effectiveness is maintained. Significant investment is required to further develop this information base, evaluate evidence and develop appropriate guidelines. They must also be adequately adhered to once developed.[4]
- There is a significant degree of discounting on prices actually paid by parties along the supply chain (sponsors, private hospitals, and possibly clinicians). However private health insurers and ultimately of course the consumer, miss out on sharing in the discounts and no price disclosure or other comparable mechanism exists for sharing discounts.

These challenges have led to unintended and unwanted outcomes for the Australian health system, including that:

- Arrangements for prostheses lack genuine competitive pressure, resulting in excessive costs for the health system;
- Product selection is predominantly determined by clinical choice without reference to cost effectiveness; and
- Different classes of prostheses with widely differing benefits may be used with no clinical justification for the higher cost.

[1] Department of Health and Ageing (2009), Review of Health Technology Assessment in Australia, p 18

[2] Ibid

[3] Western Australian public hospitals often procure the very same prostheses as listed on the Prosthesis List for 30-70% less than the listed benefit paid by private health insurers. French benefits are usually set at 30-70% lower than the benefits for similar items on the Australian List.

[4] PricewaterhouseCoopers (2010), Review of the existing model for setting private health insurance reimbursement benefits for medical devices, prepared for Medibank Private Ltd, pp 11, 72

(c) The effectiveness and accuracy of the billing code and prostheses list

In the private hospital environment, prostheses costs are negotiated at a national industry level and the hospital then serves as the conduit by which prostheses are supplied to patients by their treating doctor.

As guided by the treating surgeon's request, private hospitals generally order and pay for prostheses and then recoup the cost from private health funds and, in some instances, from patients. Under the *Private Health Insurance Act 2007*, private health insurance funds are required to pay benefits for a range of prostheses provided as part of an episode of hospital treatment or hospital substitute treatment for which a patient has cover and where a Medicare benefit is payable for the associated professional service.

The Department of Health and Ageing manages the Prostheses List which contains prostheses and human tissue products that attract benefits from health funds. The Department, with implementation of the HTA Review recommendations underway, is now accountable for grouping devices and determining the benefit to be paid.

The Prostheses List is approved by the Minister for Health and Ageing and his or her delegate. Once approved, this allows surgeons and their patients access to over 9,000 prostheses, the majority of which are available without a gap or patient co-payment.

It is widely acknowledged that the current prostheses system as it operates in the private health system could be improved and the Government has sought views in both the Doyle review in 2007 and the more recent HTA review.

Inherent problems of the Prostheses List still remain. These include:

- Errors in prostheses listing of legislated requirements – MBS/ARTG numbers are absent, generic or incorrect;
- Benchmarked benefits are generally overpriced compared to overseas examples and Australian public markets;
- The constructs of the list are overly complicated with individual components of a prostheses being listed;
- No common identifier or coding system is in use. Billing code identifiers for manufacturer codes are not publicly available;
- There is no audit of performance as a commercial instrument which creates unnecessary error rates and acceptance of poor practice;
- No benefit setting processes have been investigated or proposed post the HTA review; and
- The list has an inadequate classification system in that substitutable devices cannot be easily identified.

(d) The processes in place to ensure that approved products continue to meet Australian standards

There are reasonably well documented rules that sponsors need to comply to in order to maintain their ARTG listing and these are more onerous the higher the risk classification. Greater transparency around the implementation and performance of these rules would be of benefit, something recognised by the TGA's recent consultative report which identified a stakeholder communication strategy as a key issue.

The TGA is accountable for post-market surveillance where there is currently limited reporting and visibility. Due to resource limitations, the TGA tends to be more reactive rather than proactive in post-market surveillance activities, a situation which could be addressed by prioritising implementation of HTA recommendations 13, 14 and 15 involved in improving post market surveillance.

Importantly, the establishment of high risk patient data registers should be a first order priority as they have a whole of industry benefit in both safety and performance monitoring and, if managed through the TGA, would reduce their administrative load on the industry as a whole. Just as the National Joint Replacement Registry is funded through a levy imposed on sponsors for listing on the Prostheses List, high risk patient data registers could be established and be funded by the stakeholders who benefit. Currently industry bodies have expressed a willingness to fund a cardiac and bariatric register.

Similarly the cost to maintain post market dossiers with the TGA would be transferred to this process which could provide some savings. Savings by early identification of poorly performing devices would be significant to both the public and private health market, particularly as prostheses represent $1.38 billion or 7.5 % of the total episode cost as reported by HCP data. With a total cost to the private market of $18.25 billion for devices, even a small decrease in the revision rate or reduction in total rehabilitation costs would pay for the registers.

(f) The processes in place to notify the relevant authorities and the general public of high revision rates or possible faulty devices

The TGA has good reporting facilities for device incidents or failures and procedures but the requirement should also cover ongoing education and awareness campaigns across the industry in maintaining awareness (again covered as an issue in the recent TGA Transparency Report). In addition, reporting should be made compulsory rather than the current practice under which it is voluntary. High revision rates – which can be caused by surgical technique, device failure, disease progression, patient profile, hospital or rehabilitation – are not captured by the TGA unless reported.

A process could be set up that monitors the MBS revision codes and flags the TGA when they hit a certain threshold (as set in conjunction with the craft groups). A second trigger could be generated from the patient data registers. An early warning system on procedures or devices which may fail should be mandatory.

(g) The effectiveness of the current regimes in place to ensure prostheses with high revision rates are identified and the action taken once these devices are identified

Specialist colleges can play an important role here and Medibank are encouraged by the lead taken by the Orthopaedic Association in establishing a register. The TGA's recall and alert procedures once triggered are also excellent. Medibank would like to see more transparency when a recall or alert is triggered. A number of the technologies are imperfect and failures are anticipated. For example, stent grafts and aortic grafts have a high failure rate but there are no alternatives so the trigger thresholds need to be set and monitored by the appropriate craft groups.

Recall awareness for the industry would be significantly improved if all reimbursement systems were frozen until a recall has been completed. Alternatively, a flag could go up against each of the lists – PL, MBS etc – when under recall.

Using the National Prescribing Service could also be an option but it might not be the patient's first port of call before undergoing a procedure. An alternative idea is that the hospital could be required

to supply a performance list of procedures, specifying the device, within their hospital against a national average when the patient books their operation.

(h) The effectiveness of the implemented recommendations of the Health Technology Assessment

Medibank welcomed the HTA Review's focus on addressing the regulatory burden of HTA processes on business and the desire to ensure that those processes are efficient, measured and appropriate.

With regard to surgical prostheses, the Review's recommendation that clinically equivalent prostheses should be grouped together with similar benefit levels would help to limit price increases on similar items and form the basis for competition and switching to more cost effective devices. We acknowledge the work being done to deliver this recommendation.

Work still remains in progress for neurosurgical products with clinicians currently considering and providing feedback on submissions from sponsors. It is anticipated that this review will be implemented for the February 2012 Prostheses List. Proposed grouping schemes are with clinicians for final feedback for vascular and cardiac prostheses. Sponsors' submissions have been received for plates and screws and external fixateurs. Clinicians have analysed spinal products with proposed groups and benefits. This information is currently with sponsors for comment. Clinicians have analysed cardiothoracic prostheses with proposed groups and benefits. This information is currently with sponsors for comment. Work is continuing with urogenital, general/miscellaneous, ear, nose and throat, plastic and reconstructive and the remaining specialist orthopaedic prostheses. It is anticipated that the remainder this phase of work will be implemented for the February 2012 Prostheses List.

While Medibank has welcomed the Review's broad recommendations, further incentives to drive behaviour change are needed.

More needs to be done to improve the sustainability and efficiency of the reimbursement system for prostheses in Australia and to provide enough incentives to ensure device selection is both clinically appropriate and cost effective. It is also critical to ensure that the over-selection of more expensive devices is addressed in a more timely and effective way.

Medibank maintains that:

- With careful application, some level of co-payments can be used to improve cost effectiveness whilst maintaining health outcomes, and co-payments should not be removed from future consideration;
- Benefit setting should set purely the maximum price. In the event that the market can drive a lower price, private health insurers should be able to provide the lower benefit in alignment with that lower price.
- In addition to encouraging price discounting, mechanisms should be put into place to ensure that discounts flow through to payers to reduce system costs and continue to put downward pressure on health insurance premiums; and
- Processes need to be put in place to provide clinicians with incentives or signals to consider cost effective device selections.

In conclusion

The prostheses sector has been subject to a suite of regulatory changes in recent years to contain costs. These have created a complex and highly regulated approach to the approval, funding and use of new prostheses in Australia, particularly in the private hospital sector.

Several shortcomings still exist in the current arrangements for funding prostheses, which, if rectified, offer significant scope for overall savings to both the public and private sectors of the healthcare system.

The following continue to affect the success of changes to existing arrangements:

- The scale and scope of the Prostheses List is such that attempts to group products on the basis of clinical effectiveness is a complex and slow process;
- Benefit setting arrangements for prostheses differ between the public and private hospitals sectors, with private health insurers having to reimburse prostheses at much higher levels in the private hospital sector where clinicians are not required or encouraged to consider cost effectiveness;
- It is difficult to encourage device suppliers (or sponsors) to develop and support generic prostheses in a market where clinical decisions in the private sector are not required to consider cost effectiveness;
- Market competition between sponsors needs to be encouraged to help offset the market failures which exist in relation to prostheses;
- There remains a paucity of information regarding clinical best practice to guide the choice of prostheses; and
- There is a significant degree of discounting on prices actually paid by parties along the supply chain (sponsors, private hospitals, and possibly clinicians). However private health insurers do not capture these discounts and no price disclosure or other comparable mechanism exists for sharing discounts.

These challenges have contributed to the excessive costs in Australia's health system. Furthermore, product selection is predominantly determined by clinician choice without reference to cost effectiveness and different classes of prostheses while widely differing benefits continue to be used with no clinical justification for the higher cost. The Government's review of Health Technology Assessment sought to rectify many of these challenges but implementation of the recommendations has been slow. Accelerating this process and ensuring that it is resourced appropriately should be a priority.

Medibank welcomes the opportunity to contribute to this inquiry and would be happy to discuss our submission further.