



Mr David Learmonth  
Deputy Secretary  
Department of Health and Ageing  
GPO Box 9848  
CANBERRA ACT 2601

Dear Mr Learmonth

On behalf of the Australian Private Hospitals Association (APHA) I attach a submission to the Commonwealth Health Technology Assessment Review (“the review”), as jointly announced by the Minister for Finance and Deregulation and the Minister for Health and Ageing on December 18 2008.

APHA is the peak national body representing the interests of the private hospital sector, with a diverse membership that includes large and small hospitals and day surgeries, for profit and not for profit hospitals, groups as well as independent facilities, located in both metropolitan and rural areas throughout Australia. The range of facilities represented by APHA includes acute hospitals, specialist psychiatric and rehabilitation hospitals and also free-standing day hospital facilities

APHA appreciates the opportunity to make a contribution to the review through this submission, as well as through bilateral discussions and our membership of the Stakeholder Reference Group for the review.

Please contact Dr Barbara Carney, Director, Policy and Research, on 6273 9000 if you have any queries. APHA looks forward to further discussions with you on the review.

Yours sincerely

Michael Roff  
EXECUTIVE DIRECTOR  
21 May 2009

# **SUBMISSION BY THE AUSTRALIAN PRIVATE HOSPITALS ASSOCIATION TO THE COMMONWEALTH REVIEW OF HEALTH TECHNOLOGY ASSESSMENT**

## **Background**

As the peak body representing the private hospitals sector, APHA has been involved in previous reviews and discussions about the way in which health technology is assessed in Australia. APHA's principal concerns have focused around the processes that lead to the listing of prostheses for private health insurance coverage. APHA has been an active participant in the lengthy consultations that resulted in the development of the current legislative and regulatory framework that underpins the prostheses arrangements. While not perfect, the current arrangements represent a substantial advance on those it replaced, which were cumbersome and inefficient. That said, APHA believes that there is room for improvement, and our suggestions are set out below.

The APHA also considers that there is significant opportunity for streamlining current HTA processes, as well as strengthening the rigour of the overall regime. Our submission canvasses these.

Before specifically addressing the terms of reference for the review, the APHA wishes to make some general comments.

## **Overall comments**

### **Better regulation**

It is encouraging that this area of activity has been selected as one of the Government's Better Regulation Ministerial Partnerships. However, "better regulation" is a subjective term, the meaning of which varies according to the interests of various parties. The APHA notes that in discussions to date the Department of Finance and Deregulation has appeared to focus on "speed to market" as the key indicator of regulatory efficiency and effectiveness. The APHA believes that, in the HTA context, "better regulation" must comprehend not only the streamlining of processes and removal of regulatory barriers to market access for HTA, but also the introduction of transparent and well-communicated measures that strike the right balance between rigorous safety and quality assessment and timely market access. The regulatory regime for HTA must therefore include clinically based risk assessment and economically based cost-effectiveness analysis. This will be neither simple nor easy, but this is the best way to deliver value for money. Better regulation is also sustainable regulation, able to deal with advances in technology in a robust way.

## **Value for the taxpayer**

As it is the taxpayer who funds a significant portion of the HTA regime (MSAC and PDC), it is important for the credibility of any reforms that are recommended by the review that they be able to demonstrate increased value for the taxpayer through the elimination of duplication of processes, improvement of processes, greater transparency, improved cost effectiveness and rigorous attention to safety.

At the Stakeholder Reference Group meeting on 30 April, the comment was made that there is at present no consolidated figure available for what non-cost recovered HTA processes actually cost the public. Given the plethora of processes in place, this is perhaps not surprising. The APHA urges that DOHA produces a consolidated statement of costs for MSAC, MBS and PDC processes to provide a starting point for discussions about efficiencies.

The APHA understands that the HTA review is not a savings exercise, but believes that an understanding of costs can only inform, rather than impede, discussions about reform.

## **Not an industry subsidy**

In the current difficult economic climate, it is inevitable that manufacturing industries will seek to maximise both market access for product and access to taxpayer funded subsidies. The APHA believes that the focus of the review should be on better, more transparent processes, value for money and appropriate access to safe and necessary technology for patients, not on producing an outcome that is in fact a concealed subsidy for the medical devices sector.

## **Safety and Quality**

In its supporting papers for the review, DOHA quite rightly points out that there is “no systematic national process for HTA findings to be linked to clinical practice guidelines to assist in closing the gap between research evidence and contemporary clinical practice”. APHA supports and welcomes the participation of the relevant learned Colleges in the Stakeholder Reference Group. We also recommend that the Australian Commission for Safety and Quality in Health Care be invited to be a formal member of this Group. The ACSQHC’s national, whole of sector perspective will add both depth and breadth to discussions and formulation of recommendations.

## **A National System**

HTA is another area of activity in health where Australia's federal system has led to significant duplication and inefficiency. For such a small population, and a relatively small market, there is no logical reason for some States to have their own HTA regime. Whilst out of scope of the review, APHA urges the Commonwealth, through the Australian Health Ministers' Council, to negotiate with the States with a view to removing this area of duplicated regulation and re-direct State resources to health delivery.

## **Eliminate confusion of processes**

The APHA believes that it is important not to complicate further an already complicated and complex system whilst the HTA is proceeding. Therefore, we urge that the current review of Human Tissue Items (Part B of the Prostheses list) be brought to the Stakeholder Reference Group of the HTA before any report to the Minister is made, and that the Issues Paper for the Human Tissue Review be issued as soon as possible so that review processes can dovetail.

APHA also notes that the 2009-10 Portfolio Budget Statements contain the statement that the Department will move to progress those recommendations of the Doyle Review which the Government has accepted. In the interests of clarity and consistency, we urge that this work not proceed in parallel to the HTA Review, but explicitly within its framework, and that **no** changes be made that would need to be undone when the system is reformed.

## **Terms of Reference**

The APHA offers the following comments on the review's Terms of Reference.

1. Simplification and better co-ordination between the Commonwealth HTA processes
2. Improving role clarity, and addressing duplication between processes
3. Reviewing post marketing surveillance mechanisms
4. Strengthening transparency and procedural fairness in the assessment, decision making and fee negotiation arrangements
5. Enhanced arrangements for assessment of co-dependent and hybrid technologies

In preparing this submission, the APHA has reviewed, inter alia, the Productivity Commission's 2005 Research Report, *The Impact of Advances in Medical Technology in Australia* and submissions to it, the 2006 Report prepared by Gary Banks, *Rethinking Regulation*, and submissions to the Banks Review, and the 2007 Doyle *Report of the Review of Prostheses Listing Arrangements*, and

submission to it. The common thread amongst all of these reports and submissions is the need for greater clarity, transparency and rigour in the HTA process, and end to duplication, and streamlining of processes.

These goals are fundamental to reform. If the HTA review cannot achieve recommendations that go to action in these areas, then it will have been a great opportunity missed, at a high cost.

The APHA believes that it is time for real reform. Instead of considering HTA in isolation, and seeking to reinvent a process from the ground up, or doing some minor reforms at the margins of existing arrangements, the Government should grasp the nettle. Much of the current complexity and duplication of processes has arisen due to historical factors. Parts of the HTA system have been reformed, or changed over the past 20 years, but in a piecemeal way. The key to real reform is to examine the whole system, with clear, measurable goals and accountabilities.

The APHA believes that MSAC, set up to fill a vacuum in the process through which new items were approved for listing on the MBS, has done the best job that it could given resource constraints and the wide scope of its brief. It is arguable whether MSAC has ever been resourced to fulfil its charter of conducting a full, “ground-up” evidence based assessment of the effectiveness of new medical technologies submitted to it. A glaring omission in both MSAC and PDC processes is explicit and rigorous assessment of cost effectiveness. The APHA believes that cost effectiveness analysis should play a major role in any assessment of HTA for funding, and that this analysis should occur quite separately from negotiations around price.

Therefore, APHA believes that the Commonwealth should draw on the PBAC model to effect HTA reform.

The reasons for this are as follows:

- The PBAC processes have been reviewed and refined over a number of years and subjected to intense scrutiny through the Parliament;
- These processes are well understood by the health industry;
- The model is linked closely to access to market through TGA;
- Adoption of such a model would remove duplication and overlap, and impose transparency, especially if a review process for unsuccessful applications for funding were adopted ;

- This model requires explicit cost effectiveness and comparative clinical effectiveness data to be presented by sponsors, and also involves independent assessment of these factors;
- The model enables pricing decisions to be better informed;
- The model can accommodate explicit input on patient safety;
- There would be scope for industry and funders (governments, private hospitals and health funds) to be involved at appropriate points in the process;
- The PBAC model also comprehends more rigorous post-market surveillance and reporting which could be adapted to the HTA sector;
- The model would also cope well with emerging technology, including co-dependent and hybrid devices and therapies;
- The model could also include mechanisms for dealing with highly specialised, high cost items (as the Highly Specialised Drugs Committee does now for pharmaceuticals)

APHA therefore **recommends** that the Commonwealth move to adopt a model for HTA that draws on the well-established PBAC model as a basis for reform. We are not recommending simple replication; obviously, there will be many issues to be ironed out, not least because government is not the sole purchaser, as with the PBS. It will be essential for the government, medical devices sector, the Colleges, the ACSQHC, private and public hospitals and health insurers, to be consulted on setting up a new HTA body.

APHA also offers some specific comments on Term of Reference 1.

### **1. Simplification and better co-ordination between the Commonwealth HTA processes**

APHA believes steps could be taken now to harmonise and streamline the processes by which technology is approved by TGA for inclusion on the Australian Register of Therapeutic Goods (ARTG) and then approved for listing on the Prostheses List for reimbursement by health funds.

One example suffices. Although it is a prerequisite for inclusion on the Prostheses List that devices must be first approved for the ARTG, sponsors are able to launch concurrent applications with the TGA and the Prostheses Secretariat of DOHA, although processing of the latter is slow until ARTG listing is achieved.

Applications to the TGA are lodged electronically. However, multiple hard copies of applications for prostheses listing together with supporting clinical data must be lodged with the PDC. This seems illogical and inefficient. Whilst there is separate data required of applications to the TGA and the PDC, there is also considerable overlap of clinical data. The APHA considers that a single dual purpose application submitted electronically would deliver economies and efficiencies for sponsors of relevant technology.

In addition, APHA understands that it is still up to the sponsor of health technology to inform the PDC Secretariat when TGA approval is received so that the application for Prostheses List inclusion may progress. It seems strange that organisations within the one Department cannot communicate with each other directly. A single application point would address this; even without it, surely the ARTG processes would be able to include a notification to the PDC.

Consistent with our overall recommendation for reform, APHA **recommends** that a single entry point and tracking system for applications for market registration and funding be explored as soon as possible. Such an examination should specifically include secure on-line lodgement, protocols for communication between the relevant areas of DOHA and TGA, explicit targets in regard to timelines, clear identification of duplicated processes that will be rationalised or eliminated, and clear accountabilities for performance by all parties involved.

APHA also **recommends** that, as part of the ARTG process, HTA sponsors be required to provide clinical data to support the labelling of devices as “single use”. The significant increase in the number of such items is a major cost driver in the health system, and should be addressed at the point of application for market access. APHA urges the Commonwealth to examine this issue specifically in HTA reform.