



Ms Robyn Bilston
Human Tissue Review
Private Health Insurance Branch
Acute Care Division
MDP 86
Department of Health and Ageing
GPO Box 9848
CANBERRA ACT 2601

Dear Ms Bilston

On behalf of the Australian Private Hospitals Association (APHA) I attach a submission to the Human Tissue Review (“the review”), as announced earlier this year.

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.

This submission is not confidential.

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
CHIEF EXECUTIVE OFFICER
26 June 2009

SUBMISSION BY THE AUSTRALIAN PRIVATE HOSPITALS ASSOCIATION TO THE REVIEW OF HUMAN TISSUE (Part B of the Prostheses List)

Overall Comments

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 and human tissue are listed on the Prostheses List. In particular, APHA was actively involved in the *Review of the Prostheses Listing Arrangements* (the Doyle Review), out of which the human Tissues Review has come.

The APHA believes that it is important not to complicate further an already complicated and complex system whilst the Health Technology Assessment (HTA) Review is proceeding. It is not really clear why the review of Human Tissue Items is not being dealt with as part of the HTA Review. APHA urges that the report of the Human Tissue review be brought to the Stakeholder Reference Group of the HTA before any report to the Minister is made.

In its submission to the HTA Review, APHA stated:

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, measureable 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 submits that these comments and recommendations apply equally to the way that human tissue and human tissue products are dealt with, save that, in place of the reference to MSAC, the Department of Health and Ageing should be substituted. APHA acknowledges that the Department has a difficult role in assessing whether human tissue items approved by TGA ought to be listed on Part B of the Prostheses List. There is no formal clinical input, although clinical advice is sought, nor, as we understand it, is there any formal input from a safety and quality or cost effectiveness perspective. APHA considers that human tissue items ought to be dealt with in same rigorous and transparent manner that we recommend for health technology.

Responses to Questions in the Issues Paper

APHA confines its specific comments on questions raised in the Issues Paper to those within its competence. We therefore offer no comment on some of the questions posed, as they are best considered by other stakeholders.

Term of Reference 1 Question 2: Should autologous items be removed from the Prostheses List?

APHA noted the recommendation of the Doyle Review that items that did not fit the definition of prostheses be removed from the list. However, if autologous items are removed, what funding mechanism is proposed to enable these items to be provided to patients? Neither hospitals nor patients should be asked to absorb these costs simply because of a definitional issue. The financial implications are significant. APHA **recommends** that autologous items be specifically be included within the scope of the Prostheses List to remove any ambiguity and confusion. APHA acknowledges the technical issue, but contends that it is within the capacity of the Commonwealth Department to come up with an expanded name for the List that includes autologous tissue items.

Term of Reference 2 Question 1: Should there be more categories or sub-categories?

With the exception of the creation of a category for autologous items, the introduction of more categories or sub-categories should only be undertaken if there is true ambiguity.

Term of Reference 3 Question 1: What cost components should be included in the setting of the benefit?

The Department will be well aware of previous difficult discussions, most recently in 2007, in regard to freight and handling charges for prostheses items. Private hospitals have found this a difficult area; with some suppliers attempting to charge hospitals for freight and delivery even though the suppliers should be

aware that the benefit payable includes this provision and therefore suppliers' prices are assumed to include freight and handling charges. APHA strongly **recommends** that freight and special handling charges continue to be included in the benefits for human tissue items. However, APHA also believes that these costs can be better contained. It is not acceptable for any organisation to attempt to increase profits by "loading up" freight and handling charges. APHA believes that any new application for benefit should include a clear statement of freight and handling charges before the benefit for an item is approved. This would also remove any later ambiguity for all parties.

Term of Reference 4 Question 1: What is an appropriate model for assessing (both clinically and financially) human tissue applications?

See the Overall Comments section of our submission above.

Term of Reference 4 Question 2: Are there merits in applying the current arrangements for assessing applications for Part A to assessing applications for Part B of the Prostheses List?

See the Overall Comments Section of our submission above. However, given that the results of the HTA Review will not be known or implemented for a considerable time, APHA **recommends** that, in the interim, human tissue items are subject to the same process as for part A of the List.

Term of Reference 4 Question 4: is the Prostheses List the appropriate tool for establishing the benefit to be paid by Private Health Insurers?

APHA believes that the List is the right tool. The process gives hospitals a firm basis on which to negotiate with suppliers and insurers. For private hospitals, it is essential that there be this discipline around price, as the private hospital sector does not make the choice about what items to use: this is up to the doctor, who also discusses this with the patient.