Australian
Private Hospitals
Association

Dr Ian Holland
Secretary
Senate Community Affairs Committee
Parliament House
CANBERRA ACT 2600

Dear Dr Holland

On behalf of the Australian Private Hospitals Association (APHA), I attach a short submission to the Senate Community Affairs Committee's Inquiry into the regulatory standards for the approval of medical devices in Australia.

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 medical surgical hospitals, specialist psychiatric and rehabilitation hospitals and also free-standing day hospital facilities.

Yours sincerely

Michael Roff
CHIEF EXECUTIVE OFFICER
29 July 2011

SUBMISSION BY THE AUSTRALIAN PRIVATE HOSPITALS ASSOCIATION TO THE SENATE COMMUNITY AFFAIRS COMMITTEE INQUIRY INTO THE REGULATORY STANDARDS FOR THE APPROVAL OF MEDICAL DEVICES

APHA addresses those of the Inquiry's Terms of Reference that impact on the private hospitals sector, namely:

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

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

(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;

(h) the effectiveness of the implemented recommendations of the Health Technology Assessment [Review].

General Comment

Before commenting on the specific terms of reference, APHA believes that it is important to point out that Inquiry is being conducted in the context of the *on-going* implementation of the recommendations of the Government's Review of Health Technology Assessment (HTA Review). The recommendations which are particularly relevant to private hospitals are Recommendations 11 and 12 (b) to (e), as follows:

Recommendation 11:
That the PDC be restructured by July 2010 to ensure that its membership is balanced and:
a. includes individuals with expertise in current clinical practice, health policy and health economics;
b. includes representation from health consumers, health service providers, and the health insurance and health technology industries; and
c. has an independent chair.

Recommendation 12:
That the arrangements for the Prostheses List be changed by 2011, with appropriate consultation, to:

b. establish and maintain groups of products with similar clinical effectiveness;
c. abolish the negotiation of benefits for individual listed products, and instead establish and maintain a single (benchmark) benefit for the products included in each group, with sponsors being required to accept this benefit in order to be listed;
d. abolish the negotiation, setting or publication of maximum benefits, to eliminate the potential for gap payments for patients who have Private Health Insurance (PHI); and
e. permit the establishment of new product groups (or sub-groups) where a sponsor establishes clear superiority of their product compared to those in an existing group.

APHA supported these recommendations and, through its membership of the Health Technology Consultative Committee, is actively involved in the implementation of Recommendation 12 (b) to 12 (e). It should also be noted that the HTA Review involved extensive consultations with stakeholders.

Comments on the Inquiry's Terms of Reference

The effectiveness and accuracy of the billing code and prostheses list
APHA is represented on the Prostheses List Advisory Committee (PLAC), the body which replaced the former Prostheses and Devices Committee. APHA supported the revised arrangements for the PLAC. No concerns have been raised by our members in regard to billing codes.

In regard to price grouping, grouping arrangements for Phase 1 (hip, knee, arthroplasty, bone cement and bone substitute) products and Phase 2 (ophthalmic) products will appear on the August 2011 Prostheses List. Private hospitals will be closely monitoring developments to ascertain what products have been removed from the List because sponsors have not accepted the benchmark price, and what the subsequent pattern of use of these products is. It is important to bear in mind that it is the clinician, not the hospital, who chooses the prosthetic. It is too early in the process to make any definitive statements about how the new list is working.

The processes in place to notify the relevant authorities and the general public of high revision rates or possible faulty devices and 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.
APHA notes that the Government is still considering Recommendations 13 to 15 of the HTA Review, which deal with post-market surveillance of health technology. APHA is represented on the National Joint Replacement Registry Consultative Committee (NJRRCC), which provides guidance on the strategic direction, functions and operations of the NJRR.

APHA believes that the Therapeutic Goods Administration (TGA) should be the body that notifies about revision rates and faults, based on data from collections such as the NJRR. There should be clear criteria established around as to what constitutes a notifiable issue and what does not. It is possible that there may need to be an agreed process for the review process of particular implants before any public notifications are made.

APHA also notes that the final report of the Transparency Review of the TGA was released on 20 July 2011, and the Government has yet to respond to the recommendations of the Review Panel.

The effectiveness of the implemented recommendations of the Health Technology Assessment [Review].
As noted above, APHA is a member of the Health Technology Consultative Committee, is actively involved in the implementation of Recommendation 12 (b) to 12 (e) of the HTA Review. The Department of Health and Ageing will be able to inform the Committee in detail of progress towards the implementation of these recommendations. The terms of reference of the Advisory Committee have been reviewed and refined, and a joint meeting of the PLAC and the Committee has been held in order to clarify roles and responsibilities.

APHA has welcomed these developments.

It is important that health technology arrangement s in Australia are robust, transparent and cost effective. APHA recognises that there will continue to be challenges in this area, not only as price grouping arrangements are implemented, but also in dealing with new technologies.

In respect of how to deal with new technology, APHA together with other members of the Consultative Committee, believes that this forum is the most appropriate one at this stage to consider the issues raised by new and emerging technology. The Department of Health and Ageing has agreed with this contention and the Consultative Committee's Terms of Reference reflect this. Again, it is too early in the process to make definitive statements.

APHA believes that the plethora and complexity of the issues involved in health technology, as canvassed in the HTA Review, and previous reviews, necessitate a rigorous and coherent approach to assessment, funding and surveillance. There are a number of activities currently on foot in this area, and it is important that these be able to proceed without undue pressure from sectional or vested interests.