



Complementary Healthcare Council of Australia

*'enhancing health and wellbeing
..... naturally'*



**Additional Comments to the Productivity Commission's Public Hearings
- 13 June 2001**

The CHC wishes to congratulate you on an excellent draft report and to thank you for the opportunity to speak with you today.

In our original submissions to the inquiry, the CHC pointed out the difficulties resulting from being regulated under a drug regulatory system, and supplied additional comments in relation to the TGA submission to the inquiry which clearly omitted to identify that our products, market and industry differ substantially from the drug/pharmaceutical sector.

The CHC welcomes the Draft Report of the Productivity Commission as a significant contribution to community understanding of the implications of cost recovery by Governments.

The CHC notes that our expressed concerns about the cost recovery regime applying to complementary healthcare products are shared by the Commission.

The CHC strongly supports the view expressed by the Commission that activities that are not directly related to the agencies (TGA's) regulatory activities (such as internal administration, policy development, ministerial and parliamentary services, contributions to international organisations and obligations and public information) should not be recovered from regulated firms.

CHC urges the Government to act quickly to implement review and change in line with the recommendations of the Productivity Commission following their inquiry into cost recovery. The suggested five years to review current cost recovery arrangements is far too long, and any schedule of review developed by Government should place TGA cost recovery arrangements as the first to be reviewed.

CHC concurs with the following statements, findings and recommendations in the draft report:

- Cost recovery can have a significant impact on both actual and potential users of regulatory and information agencies [CHC comment- fees and charges estimated to be equivalent to 15% of after tax profit of small business in the Complementary Healthcare Products Industry]
- ... cost recovery lacks Clear rationale, accountability, transparency, performance assessment and review.

- Nor is it clear why some agencies recover costs while comparable agencies do not [e.g ANZFA]
- TGA's fees and charges being the highest in the world (that apply to regulation of Complementary Healthcare Products (CHPs)) as a result of the Government's 100% cost recovery policy are unacceptable because we believe that:
 - They are a barrier to trade
 - They potentially stifle competition
 - They create undue burden on start-up companies ; and
 - They prevent the public from access to medical devices [and low risk CHPs] and higher quality healthcare.

[The CHC is aware of some companies going off shore to establish businesses that can mail order direct back into Australia as a direct result of the costs associated with regulation under the TGA. We are also aware of US companies wanting to set up operations in Australia as the door into the Asian market but have not done so because of the cost and regulatory burden imposed by the TGA system- i.e barrier to trade]

- ... there is some uncertainty about the legal standing of some cost recovery charges.under certain circumstances – for example where charges are not directly related to the costs of providing a service to a particular user- fees may be subject to challenge as inappropriately amounting to taxation. *[Advice of Legal Counsel confirmed that TGA “charges appear clearly to be such as to constitute taxation rather than fees for service.....and that where it could be established that an evaluation fee “was not reasonably related to the service provided to a particular applicant that fee would not be properly imposed”]*
- To the extent that agencies become in effect self funding, there is less incentive for their respective portfolios and expenditure review processes to subject them to close scrutiny. *[The CHC has long been calling for greater transparency and greater accountability in relation to TGA budgetary processes.]*
- cost recovery has impaired government efficiency by leading to regulatory creep. *[The CHC would strongly support this statement and has numerous examples of ‘regulatory creep’ that have been imposed on the CHP industry.]*
- The CHC notes with interest the comment that under the Constitution, all money raised through cost recovery must be credited to the Commonwealth's Consolidated Revenue Fund, and all agencies and Departments funded through appropriations. The CHC is not aware that this is so in the case of the TGA.
- ..generally it is not appropriate for regulatory agencies to have what is, in effect, automatic access to cost recovery revenues, independent of adequate budgetary and parliamentary scrutiny. *[Strongly supported by CHC]*
- Cost recovery should be subject to the same public administration principles that apply to all government activity.
- The proposal to establish Efficiency Audit Committees (EAC) as Agency Specific Committees including industry and consumer representatives and reporting directly to the Minister. *[The CHC would support further consideration of this proposal so long as the EAC was independent of the TGA, and there is some imperative for findings and recommendations to be acted upon.]*
- The prompt release of endorsed guidelines would enable the Government to act quickly into the review of existing cost recovery arrangements. *[Given that concerns with the current cost recovery arrangements have been identified, this should be a government priority and review of these arrangements should be undertaken within a much tighter timeframe.]*

Additional Issues:

Increase in TGA rent

The CHC has provided additional information to the Inquiry in relation to the government decision to substantially increase rent by 166% on the TGA premises on the basis that the building was to be sold off and thereby make it a more attractive investment property. Despite TGA awareness of this increase, and the impact on the fees and charges paid to the TGA this was not brought to industry's attention until December last year, to be introduced on 1 July this year.

The increase is to be phased in over a 3 year period but it can be expected that with the current real estate market in the ACT there is every likelihood that the rent itself will increase annually.

2. TGA Submission on the Regulation of Complementary Medicines

- The TGA comment about a unique regulatory system for complementary medicines that enables stream-lined, reduced cost access to the market- is perplexing to say the least. Reduced from what?? In all other comparable countries these products are not required to be evaluated before going to market and therefore there is no associated pre-market evaluation costs.
- The comment on page 3 about fees and charges is also bemusing. The TGA claim a discount on the various fees and charges from what would have been imposed had they doubled the fees and charges. However the system is such that the TGA decide how much it will cost to regulate the industry and then it is up to each sector to negotiate how that revenue will be raised in levels of fees and charges. The claim that there is no charge for some variations is not quite accurate. There is no charge for notification of some minor changes to a sponsors ARTG records, but that has been at CHC's request and the dollars are then met by increasing other fees and /or charges.
- Reference on page 4 to important areas that are covered by the fees include several areas that the CHC has argued are either public interest or government responsibility (or both) and should not be funded by industry- a view that is supported by the Commission's findings and recommendations in this draft report.
- The TGA claim at the top of page 5 that these public interest activities would not be necessary if the complementary medicines industry did not exist is considered inappropriate. It could be well argued that if the complementary healthcare products were regulated at a level commensurate with their low level of risk and more in line with international trends.
- Levels of evidence guidelines that are claimed to be a deliverable are not necessarily a benefit to the industry. Their implementation has resulted in a significant cost and resource burden to the industry at the same time as the industry has been hit with a new 10% tax in the form of GST, plus a 395 increase in fees and charges. The net result of these various factors has resulted in an across the board downturn in the industry of around 20%

The CHC would likely to thank you once again for the opportunity to be involved in this important review and we are hopeful that the government will take due and timely action in relation to the Commission's recommendations arising from the review.

Val Johanson
Executive Director

From:

Medical Industry Association of Australia, PO Box 497, Roseville NSW 2069

Australian Self Medication Industry, Private Bag 938, North Sydney NSW 2059

Complementary Healthcare Council of Australia, PO Box 206, Deakin West ACT 2601

Australian Pharmaceutical Manufacturers Association, Level 7, 88 Walker Street North Sydney
NSW 2060

25th May 2001

Senator The Hon Grant Tambling
Parliamentary Secretary to the Minister for Health & Aged Care
Parliament House
Canberra ACT 2600

Dear Senator,

**Increases to TGA Costs Resulting from
Sale and Leaseback of Government Property**

You will be aware that TGA is in contact with industry regarding reviewed fees and charges. The first component of these relates to TGA's increased costs resulting from CPI and WCI increases. From an industry perspective we accept the need to work with the National Manager to arrive at agreed increases in these indices.

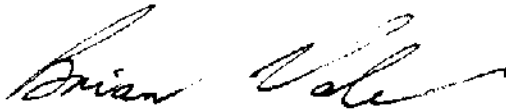
An additional cost driver is the decision within DoFA to sell and leaseback the TGA property. Industry was first advised of this proposal at the December 2000 TICC, but negotiations between TGA and DoFA had been ongoing for two years at that time.

You may be aware that the original proposal from DoFA was to increase the rent from \$1.995m to \$8.4m. TGA advised that they had been able to reduce the DoFA expectation to an agreed rent of \$5.312, phased in over three years. The first round of increases requires an additional \$1.5m with effect July this year. At the December TICC where this advice was first presented, industry expressed both surprise at the proposal and appreciation of the attempted and somewhat successful renegotiation by the TGA of the proposed increase. Industry also pointed out that the timing of the advice did not recognise industry budget planning cycles. Mr. Slater was asked to seek deferment to accommodate this need.

At the TICC meeting held last week in Sydney Mr. Slater advised that deferral had been refused and increases would apply from 1 July 2001. The rent increase to be paid by industry equals 166%.

We seek your intervention. This is an unusual case in the process of Government sale and leaseback. We have a Government Agency, occupying Government premises, fully funded by industry. Yet industry cannot of itself, direct reforms within the Agency that might offset the increases. We ask that in conjunction with the Minister for Health and Aged Care and the Minister for Finance you propose that the sale and leaseback not proceed. As matters stand, with TGA the only prospective tenant for the building, the process becomes no more than another means for government to tax industry.

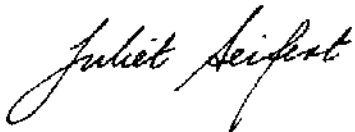
Yours sincerely,



Brian Vale
Chief Executive Officer
MIAA



Alan Evans
Chief Executive Officer
APMA



Juliet Seifert
Executive Director, ASMI



Val Johanson
Executive Director, CHCA

cc Mr. Terry Slater – National Manager, Therapeutic Goods Administration
The Hon John Fahey, MP – Minister for Finance
The Hon Dr Michael Wooldridge, MP – Minister for Health and Aged Care