Complementary Healthcare Council *of Australia*

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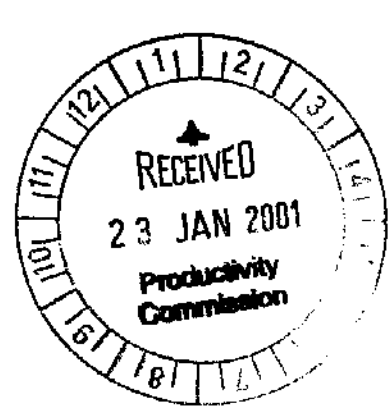

Dear Mr Rance

Productivity Commission Review of Cost Recovery by Commonwealth Agencies
Supplementary submission commenting on Submission by the Therapeutic Goods Administration (TGA).

The CHC wishes to place on the public record its comments on the TGA submission to the Review.

The complementary healthcare industry continues to be dismayed by regulatory statements and submissions from the TGA which overemphasise problems with complementary healthcare products (CHP), while downplaying their overall excellent safety record, and which fail to differentiate between prescription pharmaceuticals and CHP.

The TGA submission to the Review is another example of the failure to separate low risk CHPs from pharmaceutical products, and is misleading in that it fails to indicate that the TGA approach to regulation of CHPs is out of step with the rest of the English speaking world.

Executive Summary

Opening paragraph
The CHC can find no evidence to support the statement that the TGA aims to minimise the regulatory burden on this sector of the industry. Overall, the regulatory burden in this area appears to be increasing significantly despite recent attempts at regulatory reform that were specifically intended to reduce the regulatory burden.

Benefits from government to the therapeutic goods industry
In citing benefits from government to the therapeutic goods industry, all of the government programs quoted apply only to prescription pharmaceuticals and to a small extent, some medical devices. The submission fails to even acknowledge the CHP sector, thereby inferring that these government subsidies apply also to CHPs. They do not. There is no benefit from any of the programs to the CHP sector.

The submission clearly identifies that the above benefits apply to the pharmaceutical industry but does not point out that the CHP industry receives nothing in the way of government subsidy, and in fact is now subject to a new 10% tax.

Costs borne by government as a result of the use of therapeutic goods
Any evidence based examination of the costs borne by government due to morbidity in the community as a result of the use of therapeutic goods will reveal these costs are overwhelmingly due to prescription pharmaceuticals. These costs have been quoted elsewhere in other submissions to the Review including the TGA submission. The TGA submission misleadingly states that

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'these costs are incurred as a result of the use of all therapeutic goods not just prescription pharmaceuticals.' Only a minuscule portion of such costs could be properly attributed to extremely low risk CHP.

Improvements in TGA efficiency that have minimised costs to industry
The claim that "improvements in TGA's efficiency have minimised cost to industry" and the statements that follow regarding so called "discounts" on potential increases in fees and charges are misleading. All government agencies have had to try to introduce comparable efficiencies to the private sector. There have been few "substantial reforms" that have demonstrably benefited the complementary sector or improved profitability.

As a 100% cost recovery agency, TGA has been quarantined from the government requirements for an efficiency dividend. It has resisted introducing contestability as required by competition principles, when carrying on a number of core functions such as audit and licensing of manufacturers, sampling and testing of therapeutic goods, operating a computer database (register) of therapeutic goods, and substance evaluation. There appears to be little regard for government policy of requiring regulatory and business impact statements when making legislative change.

Performance of TGA versus other regulatory agencies
The submission claims that international harmonisation of regulatory standards has minimised its regulatory burden on industry. Again this is misleading. The complementary sector has not benefited from harmonisation because lesser levels of regulation and control apply to CHP in most other developed countries, where these products are sold under food law with no requirement for pharmaceutical standards of GMP.

The submission claims that "Australia's system for listing or registering complementary medicines is unique in the world and is world's best practice for timeliness and public safety." The acknowledgment that the system is unique should surely sound alarm bells to government. It cannot be both harmonised and unique. Why should Australia with its population of 19 million people require a system that is unique particularly for extremely low risk CHPs? CHPs sold as food supplements in most other countries require no evaluation at all before going to market. Contrary to the statement in the submission that they can make no therapeutic claims at all, they can make the majority of health maintenance, structure/function and even risk reduction claims that the TGA permits on CHPs, subject to a costly and complex requirement of holding evidence to justify those claims. The CHP sector contends that it is over regulated in terms of the risk to public safety. The cost recovery quoted in overseas countries does not relate to the CHP sector. The CHC would like to see evidence to support the TGA contention that Australia's unique system is world's best practice for regulation of CHPs.

In relation to the unique process of sector agreements between the TGA and the medicines industry , the CHC does not have such an agreement "setting out time frames that are always much less than the statutory time frames", and in fact has no statutory time frames. However, there was some discussion of reducing turn around times as part of the most recent fee increase negotiations and to the TGA's credit they have reduced turn around time substantially.

Body of the submission.

Background
The claim that the introduction of the TGAct 1989 "greatly simplified the requirements for industry, creating a single set of laws where there had previously been separate non-uniform State laws..." cannot be applied to CHPs. Prior to that time there were only two States (NSW and Victoria) which regulated these products as medicines. From a regulatory point of view, these products were able to be sold uniformly across all States without the current cost impost. Introduction of this legislation incurred significant cost and complexity for this industry, on products with longstanding safety records.

Again CHC would challenge the statement that "TGA aims to keep the regulatory impact on business to a minimum" when applied to this sector. It is indeed one of the most stringent and most costly regulatory systems for CHPs in the world.

Legislation
The statement that "any product for which therapeutic claims are made must either be listed or registered in the ARTG before it can be supplied in Australia" is inaccurate. The Australian New Zealand Food Authority (ANZFA) actively encourages the food industry to use nutrition messages on foods, and these messages are essentially the same claims that are made on CHPs under the therapeutic goods legislation. These food products that make claims are not required to be evaluated or included in the ARTG or any other register.

Benefits to industry from the regulatory framework
Commercial benefit

In a free market situation, Australian registration or listing confers no added commercial benefit. If European or North American registration or free sale was recognised, there would be no need for additional Australian registration or listing.

There are no additional marketing benefits for CHPs resulting from negotiation of international treaties and agreements. For example the recent media release announcing an MOU on manufacturing standards with the FDA in the US gave the industry cause for hope that there may be some relief from the extremely costly audits of manufacturers required for all imported products. Not so! And why? Because CHPs are not regulated as medicines in the US and therefore are not required to comply with pharmaceutical manufacturing standards and therefore this MOU does not apply to CHPs which are manufactured under food law in the US.

Patent and Data protection
Does not apply to CHPs as there is no patent protection for the vast majority of CHP and the data protection provisions are of little use.

Government programs that benefit industry
As stated previously , these government programs do not apply to CHPs and therefore do not benefit this industry.

Managing the risk and consumer confidence post marketing
The TGA quotes only three examples of supposed post market monitoring successes – and all involve CHPs.

a) Cyclosporin and St Johns Wort

The choice of this particular case study for submission to the Commission is evidence of the entrenched negative attitude of the TGA to CHP. St John's Wort is a herb which has been used over many years, globally for the treatment of minor depression. There has never been a death recorded in any incident involving this herb. The publication of a small number of reports of drug interactions involving severely ill patients is siezed upon by the TGA as justifying its unique regulatory regime for CHP.

The same bulletin from which this example was taken carries articles involving hundreds of adverse reactions to prescription medicines. These are not quoted, yet are far more serious and involve many more people. There are many foods including grapefruit juice which are commonly consumed and which carry more risk of interacting with drugs than St Johns Wort.

b) Death due to product containing the herb Guarana
Further evidence of this TGA attitude is provided in the second example quoted in the submission. The guarana containing product implicated in the death of a 22 year old female in Western Australia was marketed as a food. The registration and listing process and all of the TGA administered regulation did not and would not prevent this incident.

c) Chinese medicines containing the herb *aristolochia*
The relevance of the third example quoted of the Chinese medicine supposedly harming people overseas is again disputed. The herbal substance in question was not used in the manner of a Chinese medicine, but rather was included in dietary meal replacements and used as part of a weight loss regime. The herb is used safely in the proper practice of traditional chinese medicine. It has been banned in Australia in therapeutic goods yet can be freely purchased from Chinese supermarkets in Sydney, even today.

These three examples are all quoted in an incomplete and misleading manner in an attempt to justify Australia's unique and costly regulatory system on CHP. The summary states that "it is clear that there is a substantial sum of public money spent on drug related illness, particularly from prescription medicines, but also from OTC and complementary medicines." The TGA has presented no evidence to justify this statement in regard to complementary medicines and should be asked to produce such evidence. If prescription medicines are acknowledged as the main problem, and are reported to result in about 2000 deaths annually according to the Quality in Healthcare Study in 1995, why was there not a single example of adverse effects to pharmaceutical products given? A comparison of the minimal number of adverse reactions related to CHPs, with the recently quoted ANZFA figures of 11,400 food poisonings in Australia daily, confirms the extremely low risk nature of CHPs which cannot justify the costly and stringent regulatory framework that is applied to these products- a cost that is ultimately passed on to the consumer.

Costs incurred by government as a result of the use of medicines
The TGA submission dwells on the fact that "costs incurred by industry are small compared to revenue flowing from governments to the pharmaceutical industry."

The CHC strongly disputes this statement as costs incurred by this sector of the industry are very high and there is no revenue of any kind flowing from governments to the complementary sector. The money paid in fees and charges alone is not the full regulatory cost of regulatory compliance. Industry also bears the costs of finance, staffing, and infrastructure needed to meet

Australia's unique requirements for the sector. These costs are significantly less in most overseas Markets and this places Australian companies who wish to compete in international markets at a disadvantage.

Other activities undertaken by the TGA.
The non transparent activities of the CHP expert advisory and consultative committees is a major grievance of the Complementary Healthcare Industry. Deliberations appear to be hidden behind a veil of secrecy under a guise of commercial sensitivity. This is in contrast to the USA where the deliberations of such committees would be open to the public and hence to both industry and consumers.

The "very modest cost" referred to in the TGA submission for the first two meetings of the Complementary Healthcare Consultative Forum was $96000. The CHC industry is the only stakeholder who contributes financially, although both the membership and the agenda include other industry sectors. As the specific costs of these committees including the Complementary Medicines Evaluation Committee are fully funded by the industry, the CHC contends that the Committee processes should be transparent and accountable as they are in other countries.

The TICC committee which has been referred to in so much of the hearings is managed by the TGA with little opportunity to question expenditure or budget. The transcripts show many conflicting attitudes to the usefulness of this forum.

The CHP Sector supports the existence of a simple premarket notification system, together with an efficient postmarket monitoring system for quality and safety. The present "unique" system is overly complex, interventional and out of step with other comparable countries, and hence costly. The amount contributed by industry under 100% cost recovery is disproportionate to the very low risk to the public posed by CHP.

Transcript of Proceedings of TGA appearance before the Commission on 7 December 2000.
The CHC provides the following comments:

1. The CHC believes that State responsibility referred to by Mr Slater is largely public interest and therefore government responsibility that should not be funded by the industry.
2. The discussion on claims requires clarification between medicinal claims and health claims. The large majority of claims made for CHPs under the Therapeutic Goods legislation are not medicinal claims which refer to cure, treatment and prevention. Many of the claims made on CHPs here in Australia are permitted in many other countries of the world as health maintenance claims, structure function claims, risk reduction claims and biological statements without the need for evaluation or the complex, costly substantiation system that has been recently introduced here. It is relevant to note that ANZFA not only permit many of these claims on food but actively encourage their use on foods without the complex system that applies to CHPs..
3. Contrary to the TGA reference to other countries imposing cost recovery, and as indicated in our supplementary evidence to this inquiry, the CHC has not been able to identify any other country that funds the regulation of these CHPs through cost recovery. Following is a summary of the position for some comparable countries:

- The US imposes fees on prescription drugs to expedite evaluation- no costs on supplements and not expected to be.

- The UK Medicines Control Agency imposes cost recovery on the 'medicines' sector, not the borderline products or Complementary Healthcare Products sector.

- Italy has recently introduced a fee for label notification of dietetic products going to market.

- Canadian Government has allocated $10million towards establishing the new NIIPD and expects that there will eventually be some form of cost recovery.

- There is no cost recovery in New Zealand in relation to the regulation of dietary supplements, but it is expected that there will be some form of cost recovery in the future.

4. As stated above, there is no government subsidy for CHPs.

5. The statement about international contributions and unique standards for Australia is very pertinent to the CHP situation. The TGA continually claims that it is leading the way in the regulation of CHPs. In doing so it is establishing unique standards for these products and as Mr Slater quite correctly states, these do impose additional cost on this sector of the industry, and also act as trade barriers to other products wishing to enter the Australian market.

6. The comment about the industry choosing to market foods because they make a therapeutic promise is not accurate. The law defines what is a therapeutic product and it is certainly not dependant just on the claim- it depends on the ingredients and the dosage form, and then the law requires that therapeutic goods carry a therapeutic promise. There are in fact very few products which can choose to be marketed as either a food or a therapeutic good as the law has been changed recently to clarify that these products are therapeutic goods regardless of the claim unless they are standardised foods in the dosage form in which they are presented. Some confectionary, artificial sweeteners and junket tablets are among the few foods that are standardised in a dosage form, and are hardly likely to be marketed with a claim as therapeutic goods.

7. The comment about "harmonisation and the ability to recognise the decision of highly comparable regulators..... particularly in the area of low risk medicines..." requires clarification as mutual recognition of regulation of these low risk products means that the stringent regulatory approach taken here in Australia would need to be considerably relaxed.

I trust that these comments are helpful and would be pleased to further clarify any of these issues.

Yours sincerely

Val Johanson

Val Johanson
Executive Director
18 January 2001