Complementary Healthcare Council
of Australia

Mutual Recognition Review
Productivity Commission
LB2 Collins Street East
MELBOURNE VIC 8003

To whom it may concern

CHC Submission – Review of Mutual Recognition Schemes (June 2008)

Thank you for the opportunity to make a submission to the above review.

The Complementary Healthcare Council (CHC) is the leading expert association exclusively committed to a vital and sustainable complementary healthcare products industry. We are unique in representing all stakeholder groups in the industry. Our members, both Australian and New Zealand businesses, include importers, exporters, marketers, manufacturers, raw material suppliers, wholesalers, distributors, retailers, practitioners, consultants, direct marketers and consumers.

The CHC has a particular interest in the Trans-Tasman harmonisation of therapeutic goods regulation and the Trans-Tasman Mutual Recognition Arrangement (TTMRA) in relation to food type 'dietary supplements'.

The CHC in principle, supports the Trans-Tasman Mutual Recognition Arrangement, however, considers that there are a number of matters that should be addressed. In particular the CHC wishes to highlight the issues of:

- 'level playing field' for industry – both food and therapeutic goods;
- consistency in interpretation and enforcement of legislation; and
- proactive (cross-sectoral) government policy and strategy in relation to mutual recognition and the development and implementation of harmonisation, including the impact on industry in an Australia only context.

These issues have been raised by the CHC with the current, as well as former, government.

Re: Rationale for mutual recognition

TTMRA – 'Dietary supplements' imported from New Zealand

The TTMRA provides an avenue for significant imports of products that currently would not conform to either therapeutic goods legislation or the *Australia New Zealand Food Standards Code.*

Although there is a benefit for both Australian (operating from NZ) and NZ 'dietary supplement' manufacturers, as well as Australian consumers, as a result of increased product range from imported products regulated by the *New Zealand Dietary Supplements Regulations* into Australia, this has also come at a cost as far as 'level playing field' for both Australian regulated food and therapeutic good suppliers. In particular, the TTMRA has:

AFA House, 39 Geils Court
Deakin ACT 2600
PO Box 104
Deakin West ACT 2600
P +61 2 6260 4022
F +61 2 6260 4122
W www.chc.org.au
E chc@chc.org.au
ABN 34 874 859 470

- created a situation where Australian food manufacturers of 'dietary supplements' are disadvantaged by a wider range of products available from New Zealand that are not required to conform to Australian legislation. Australian manufacturers are required to comply with either the much more restrictive Food Standards Code or therapeutic goods legislation (the latter at substantial registration and regulatory compliance costs);
- provided an entry for products in breach of NZ dietary supplement regulations due largely to the NZ government's acknowledged lack of enforcement;
- added a compliance burden (and cost) to Australian regulators and industry bodies (through self-regulatory mechanisms); and
- created confusion in relation to regulatory compliance (which is complex) for industry, regulators, retailers and consumers in Australia (also due to limited enforcement of compliance in Australia).

From late 2003 to July 2007, the Australian and NZ Governments, as well as the therapeutic product industry which includes the complementary medicines sector, worked towards the establishment of a joint regulatory scheme for therapeutic products. During this time, the NZ Government also commenced action to amend their Dietary Supplement Regulations (under food legislation) with the view that most of the products currently available under this regulation would become 'complementary medicines' regulated under the therapeutic product legislation (similar to that in Australia).

In response to industry concerns, the CHC hosted a well attended seminar on 28th February 2008 to inform industry of the proposed NZ dietary supplement regulatory changes, originally planned to be implemented in mid-2008 but now anticipated for early 2009. We acknowledge the support of regulatory agencies on both sides of the Tasman for providing officials to speak at the seminar.

An outcome of the seminar was the assessment that the current substantial trade in food-type 'dietary supplements' imported into Australia from New Zealand under the provisions of the TTMRA will be significantly reduced as a result of regulatory changes in New Zealand. This is a direct result of products currently considered to be 'foods' becoming 'therapeutic goods' and therefore exempt from the TTMRA. In addition, due to the unlikely prospect (at this time) of the *Australia New Zealand Food Standards Code* being amended in time (based on current experience) to accommodate those products currently being imported into Australia under the TTMRA, those products will no longer be able to be marketed as foods. The lack of amendments to the Code continues to hinder an efficient and internationally competitive industry.

These matters have been raised by the CHC, on behalf of industry, with relevant ministers with outcomes still awaited.

Re: Special Exemptions

Harmonisation of Therapeutic Products Regulation

Australia and New Zealand Governments gave, in principle support, to establish a joint regulatory agency in 2000 with the earliest date for commencement mid-late 2004. In July 2007, the Australian Government announced that legislation to introduce the joint regulatory system was unlikely to pass through the existing New Zealand parliament, and that the project was to be put on indefinite hold. To date no further statements have been made in Australia regarding the 'post trans-Tasman' environment (including in relation to the situation outlined above).

Currently, businesses that trade between Australia and New Zealand continue to bear the cost of meeting the two sets of regulatory requirements for therapeutic goods. There will be significant additional costs involved for Australian companies to continue to market many of their 'dietary supplements' in New Zealand as 'medicines' and it is expected that others will withdraw from the market altogether as the costs involved would not be sustainable. The majority of industry participants are small to medium sized businesses with often limited market share for individual products.

It should be noted that some businesses in the complementary healthcare industry are prepared, at significant cost, to ensure regulatory compliance for their products. However, industry faces great uncertainty at this time both as to what the regulatory model and requirements will be in New Zealand and to what extent this will be an interim arrangement pending resumption of progress towards a joint regulatory scheme and its ultimate introduction.

The CHC wishes to draw to the attention of the Productivity Commission that another aspect of harmonisation that appears not to be considered as part of the implementation process is the impact on the domestic industry. During the four year development period, considerable resources were expended by the governments, as well as industry, towards the development of the joint regulatory scheme. In that time, the introduction in Australia of a number of policy and legislative changes to improve the current therapeutic goods regulatory system had been delayed as they were to be addressed under the new regulatory scheme. The CHC considers this to be to the detriment of the Australian industry, regulator and consumers. For example, many of the recommendations of the (then) government commissioned Expert Committee on Complementary Medicines in the Health System (2003), accepted by government in March 2005 and to be implemented during the harmonisation process are still to be implemented. Considerable consultation was undertaken during the harmonisation process to develop a new regulatory system, much of which would be applicable to improving the current Australian legislation. No significant regulatory reform has been formally progressed in the Australian context since that time.

The CHC would welcome the opportunity to discuss any matters relating to this submission. If you require further information please do not hesitate to contact me.

I look forward to further information on the outcomes of this consultation process.

Yours sincerely

Trixi Madon
Technical Director

22 July 2008