Regulation Taskforce
PO Box 282
BELCONNEN ACT 2616

Dear Regulation Taskforce

CHC Submission in response to: *Reducing the Regulatory Burden on Business*

Thank you for providing the opportunity for the Complementary Healthcare Council (CHC) to provide comment on the above consultation document dated 25 October 2005.

The Complementary Healthcare Council (CHC) is the peak body representing over 450 industry stakeholders within the complementary healthcare sector. Membership includes therapeutic good sponsors, raw material suppliers, consultants, manufactures, importers, exporters, retailers, regulatory consultants, practitioner associations, practitioners and consumers. ***The primary objective of CHC is to ensure appropriate risk based legislative provisions that allow consumers to have confidence in the safety, quality and efficacy of complementary healthcare products.***

All sponsors of complementary healthcare products in Australia must comply with the legislative provisions of the *Therapeutic Goods Act 1989*. The CHC actively lobbies the Therapeutic Goods Administration and government for regulatory reform to ensure that the industry is sustainable and viable into the future. Complementary healthcare has the potential to reduce the health cost burden on the community however, at this point in time very little government support has been given to this sector of health. Instead, there have been substantial increases in both regulatory compliance costs and government cost recovery, all of which have flowed onto the consumers. The CHC is extremely concerned that these growing cost burdens may be restricting certain sectors of the community from accessing complementary healthcare.

The Trans Tasman Harmonisation Joint Agency offers very little benefit to the Australian sponsors of therapeutic goods. The biggest benefactor will be the New Zealand community and the New Zealand Government. Australian sponsors of therapeutic goods have for many years been supplying complementary healthcare products into New Zealand and the only tangible advantage of the harmonisation for Australian companies is to have a single label for both countries. The CHC's analysis of the cost of harmonisation with New Zealand has indicated that there will be a substantial cost burden placed on the Australian industry which will flow onto the Australian community

Inappropriate and inconsistent risk management has for some time caused substantial problems for the industry. Australian sponsors of therapeutic goods are at a distinct disadvantage in international markets due to competition from markets that do not apply such a strict liability regime as Australia. The Australian complementary healthcare industry fully supports appropriate standards of safety, quality and efficacy, however, the current legislative environment for complementary medicines has inflated the risk basis for managing these medicines; noting that the Therapeutic Goods Act regulates high risk pharmaceutical and over-the-counter medicines as well as devices.

Complementary healthcare is unique in that it is based on a long term wellness model and it should be governed in its own right, separate from pharmaceuticals that are focused on addressing the diseased state. The removal of the influence of the pharmaceutical sector to high risk stakeholders from the risk management of complementary medicines will allow for more appropriate standards to be developed for the latter sector.

The CHC is also active in monitoring the developments within the *Australia New Zealand Food Standards Code* and the compliance policy of the various State/Territory health/food regulators. The current development of a *Health and Nutritional Claims Standard* poses enormous threat to the ongoing viability and sustainability of the complementary healthcare industry. Illegal health claims, use of traditional substances used in complementary medicines and the lack of enforcement for breaches of the standards has the potential to cause consumers to lose confidence in many valuable complementary healthcare substances. The flow-on affect has the potential to damage the complementary healthcare industries viability and sustainability.

Another major concern with the Food Standards Code is the extremely long time-frame for standards under the code to be reviewed and updated. This is seriously impacting on innovation by Australian manufacturers and the ability to compete (legally) with overseas product that does not meet the Australian standard.

Please find enclosed the CHC submission in response to the consultation document.

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

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

Yours sincerely

Allan Crosthwaite
Technical Director

25 November 2005

Complementary Healthcare Council of Australia

Submission to the
Australian Government Regulation Taskforce

Reducing the Regulatory Burden on Business

November 2005

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Regulation of Therapeutic Goods – Complementary Medicines

The CHC represents the complementary medicine industry sector which encompasses generally low-risk therapeutic goods regulated under the *Therapeutic Goods Act 1989*. The majority of businesses involved in the sponsoring and manufacturing of these therapeutic goods in Australia are small to medium sized enterprises.

The CHC supports the regulation of therapeutic goods in Australia and New Zealand. However, incremental amendments to the Therapeutic Goods Act over a number of years, the management and administration of the legislation by the Therapeutic Goods Administration (TGA) and the government's policy of full cost recovery to administer the legislation, has, and is having an adverse impact on this industry sector as well as consumer healthcare options.

The CHC considers that the full cost burden of the current legislation falls not only on industry but also consumers. The CHC strongly advocates that the government is not fully meeting the primary objectives of the National Medicines Policy (that encompasses complementary medicines), namely:

- Timely and affordable access of healthcare products to consumers
- Viable and innovative healthcare industry.

Strict liability compliance that is not risk-based and the ever increasing recovery of TGA operating costs are forcing consumers to pay ever higher prices for complementary medicines. The CHC is concerned that some sectors of the community may have restricted access to complementary healthcare based on price. Glucosamine is a perfect example, the elderly are the ones that will gain the most benefit from this important complementary medicine, however, they are the least able to afford it in the current market.

Recent TGA accounting figures have indicated that there has been a substantial drop in listings and registration applications and annual fees for complementary medicines. This situation indicates that companies may no longer be viewing the industry as a viable and sustainable one.

The CHC acknowledges that the current consultations developing the Trans Tasman Harmonisation therapeutic products scheme due to come into effect on 1 July 2006 provides an opportunity to address many of the issues of concern. However, the proposed substantial increase in cost recovery and complexity of the joint agency far out weights any gains that may be made from reviewing the legislation.

The CHC's major concerns relating to the current legislation are:

- **Full Cost Recovery**. The impact of full cost recovery (target setting) for the TGA. Not only is this increasing but the industry has also had to pay for inefficiencies and less than optimal management. These issues have all been reported on in the highly critical report by the Australian National Audit Office.

  The *Agreement between the Government of Australia and Government of New Zealand for the establishment of a joint scheme for the regulation of therapeutic products* provides for full cost recovery. However, indications are that a wider range of regulatory functions that will be covered by cost recovery will increase in the new scheme thus increasing the already heavy cost burden on industry. These functions include:

  - Substantial increases in Governance structure
  - Cost recovery of administering advertising provisions
  - Cost recovery of increased number of expert committees
  - Cost recovery of Poison and Drug Scheduling Committee

What is the regulation?

The *Therapeutic Goods Act 1989* and *Therapeutic Goods Regulations.*

What is the underlying objective of the regulation?

The legislation provides a national framework for the regulation of therapeutic goods in Australia to ensure the quality, safety and efficacy of medicines.

Does it achieve its objective?

The *Therapeutic Goods Act 1989* and *Therapeutic Goods Regulations* is achieving its goal of maintaining safety, quality and efficacy standards.

In what way does the regulation impose a burden on business?

It is the TGA's goal to receive international recognition as a world leader in the regulations of medicines. In striving to achieve this goal a strict liability regime has developed that is not appropriately risk managing complementary medicines. In recent times the management of the risk has improved, however, there is still much to be done before more realistic and practical standards are developed.

What is the opportunity cost?

The CHC has been advised by the TGA that there have been recent substantial reduced listing applications for complementary medicines under the Therapeutic Good Act i.e. less product options on the market. The opportunity cost is reduced consumer access to valuable health and wellbeing options.

Australian complementary medicine manufacturers are also suffering as much manufacturing is now undertaken overseas (with product imported back into Australia) as compliance with Australian regulations becomes too difficult and costly. Australian contract manufacturers are finding it increasingly difficult to compete with overseas manufacturers. Anecdotal evidence also suggests that overseas business are not being attracted to Australia as the current regulatory requirements are considered one of the most burdensome of western nations; being too difficult and costly compared to other countries.

Overseas facilities are not subjected to the same regulatory provisions as exist in Australia, as the Australian legal provisions have no affect in other international jurisdictions. Australia's current regulatory environment is creating an un-level playing field for Australian sponsors and manufacturers of therapeutic goods.

Who pays the costs?

Feedback from CHC members has indicated that they do not consider that the increasing range of requirements under the Therapeutic Goods Act have markedly improved the quality or safety of complementary medicines. However, the increasing range of regulatory requirements is affecting the industry's ability to bring complementary medicines to the market and therefore consumers. Many small to medium sized companies cannot pass these increasing costs onto consumers via higher product prices. Members have indicated that to absorb these costs that other activities are restricted, eg reduced marketing, employment opportunities, reduced innovation and a rationalising of product lines. If increasing costs cannot be absorbed by the business (which is the case with small companies) ***consumers will alternately pay the costs of increasing regulatory compliance and cost recovery***.

In what way is the burden imposed by the regulation unnecessary, or in what way is the regulation unnecessarily complex, taking into account the objectives of the regulation?

Post Pan (2003 Australia's largest therapeutic good recall) a regime of strict compliance and liability has been developed by the regulator. This regime has not been based on sound risk management. Australia is now being recognised as being one of the most heavily regulated environments for complementary medicines in the world. The generally low risk status of complementary medicines has to a large degree been lost due to the messages that came out of the Pan recall.

Could the regulation and/or its administration be reformed or simplified to reduce the compliance burden on business, while still allowing the underlying objective to be achieved? If so, how?

Throughout the world complementary medicines have been categorised based on risk. In many countries they are not categorised as foods or medium to high risk medicines, they are managed in their own unique right and appropriate risk management is applied. Complementary medicines in Australia must remain regulated under the Therapeutic Goods Act, however, they must also be categorised separately from other higher risk medicines and there should not be any cross-over policy development.

Greater levels of co-regulation must be applied and supported by the government and regulator. For example, advertising and complaints must continue under a co-regulatory mechanism. All policy and regulation must be based on Council of Australian Government (COAG) principles – "minimum effective regulation".

Could any alternatives achieve the underlying policy objective while imposing less of a burden on business? If so, how?

The TGA 100% cost recovery must discontinue the target setting policy and the government, in the interest of public benefit, must provide budget supplementation to support the ongoing operation of the Trans Tasman Joint Agency for complementary medicines only. Cost recovery should be set to a maximum of 50% of the operational costs.

Australia New Zealand Food Standards Code – Formulated Supplementary Sport Food Standard

The CHC also represents manufacturers and distributors of food products including sports supplements subject to regulation under the *Australia New Zealand Food Standards Code* (Food Standards Code) administered by Food Standards Australia New Zealand (FSANZ). Some sport supplement products making therapeutic claims are also produced under the Therapeutic Goods Act.

The CHC's major issues of concern with the administration of the Food Standards Code are:

- Lack of enforcement of the Code. FSANZ develops the standards whilst State/Territory authorities enforce the standards; and
- Inability of the Code to be amended in a timely way in response to market influences.

What is the regulation?

The *Australia New Zealand Food Standards Code* (and implementing State legislation).

Various standards under the Code including, the Formulated Supplementary Sport Supplement Standard.

What is the underlying objective of the regulation?

The objectives of the *Food Standards Australia New Zealand Act 1991* are to.

- Protect public health and safety.
- Provide adequate information about food, to help consumers make informed choices and to prevent fraud and deception.
- Promote fair-trading in food.
- Promote trade and commerce in the food industry.
- To promote consistency between domestic and international food standards, where differences exist.

Does it achieve its objective?

The Food Standards Code is not fully meeting its obligations to protect public health and safety, provide adequate consumer information and promote fair trading in food. The Code fails in the area of enforcement and compliance at the State levels.

The development and amendment of standards is a slow, costly and time consuming process. The current system cannot cope with changes in innovation or changing market conditions.

In what way does the regulation impose a burden on business?

The implications for industry due to difficulties in amending the current Code are exemplified by the Sport Supplement Standard. The standard was developed in 1998 and is currently on the Food Standards Development Workplan; initiated on 10/5/2001, for FSANZ review, as a Category 5 (highly complex) with no timeframe for completion. The implications of this non-progression for industry are:

- Limited innovation – as the standard includes a defined list of permitted ingredients and ingredient amounts it is not possible for industry to develop new products. Note, other comments regarding imported product not subject to the Australian food legislation.

- Restricted ability to compete in the market. Businesses producing and marketing sports supplements legally complying with the Food Standards Code find it difficult to compete with overseas product that is note regulated to the Australian standard. Consumers can purchase

product directly from suppliers via the internet. The CHC is also aware of illegal product brought, and opening promoted, into Australia with little enforcement action taken by relevant authorities (the CHC is aware of agency resource constraints). Consumers and many retailers are not aware of the regulatory requirements regarding these products and are influenced by the marketing of overseas product.

Under the *Trans Tasman Mutual Recognition Act 1997* some dietary supplements products (foods not therapeutic goods) that do not comply with the Food Standards Code can legally be supplied in Australia if they may be lawfully sold in New Zealand. This has created an 'un-level' playing field as those businesses complying with the Food Standards Code are competing with products (many of which include ingredients not permitted under the Code) that are not required to comply with the regulations.

FSANZ is currently developing a Health and Nutrition Claims standard under the code; the current standard in general does not allow health claims unless specifically provided for (there are limited provisions). However, there is wide-spread use of health claims by the food industry in promoting products. The lack of enforcement has the following implications for business complying with the Code and the complementary medicines industry:

- Creation of an unlevel playing field for complementary medicines for product making similar claims
- A loss of consumer confidence in the complementary healthcare industry
- Increased marketing costs to address illegal food claims
- The lack of enforcement allows international companies to supply non-compliant foods in the market place that puts Australian companies at a distinct disadvantage.

What is the opportunity cost?

Australian manufacturers are at a distinct marketing disadvantage within the market in Australia as well as internationally. This is a result of the current regulatory requirements not allowing those companies to effectively compete with imported products.

It is ultimately the Australian public, as consumers of the products, who lose the opportunity to access a range of quality and safe sport supplements.

Who pays the costs?

Australian business, particularly manufacturers, bear the indirect costs as greater amounts of product is imported and sold in Australia; some of this product would not meet the Australian regulations (either food or therapeutic good). The CHC is also aware that some businesses are moving their manufacturing to New Zealand in order to import (legally) product that is not required to comply with the Food Standards Code.

In regards to foods making illegal health claims it is the complementary healthcare industry that will bear the cost of a reduction in consumer confidence. It is also businesses that are complying with the Code provisions that lose sales to competitor businesses making illegal claims as in general the public is not aware of specific code provisions.

In what way is the burden imposed by the regulation unnecessary, or in what way is the regulation unnecessarily complex, taking into account the objectives of the regulation?

The CHC and industry support effective standards under the Food Standards Code to ensure consistent, quality and safe product for consumers. However, the high cost of applying for an amendment to a standard and the very long time-frames involved for FSANZ to undertake the review and amend the code dissuades businesses from lodging an application. It should be noted, for example, that many of the sport supplement businesses are small to medium sized – the current application fee to amend a standards is $91,000 plus associated submission preparation costs.

Could the regulation and/or its administration be reformed or simplified to reduce the compliance burden on business, while still allowing the underlying objective to be achieved? If so, how?

Improved Food Standard Code amendment procedures and costs would facilitate the review of the code in response to technical and market changes as well as businesses being able to effectively compete with other legally available product.

Could any alternatives achieve the underlying policy objective while imposing less of a burden on business? If so, how?

See above.