Complementary Healthcare Council
of Australia

Regulatory Burdens – Manufacturing and Distributive Trades
Productivity Commission
GPO Box 1428
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To whom it may concern

CHC Submission – Annual Review of Regulatory Burdens on Business, Manufacturing and Distributive Trades – Draft Research Report

Thank you for the opportunity to make a submission to the above report dated June 2008.

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 sections relating to food and therapeutic goods regulation.

Food manufacturing regulation

Delays in implementing and amending food standards (3.2, Page 32)

The CHC supports recommendations that improve the timeframes in amending the *Australia New Zealand Food Standards Code* (the Code). The CHC has highlighted concerns regarding this matter to Government and FSANZ on a number of occasions.

As an example, the CHC notes proposal P236 - Review of Standard 2.9.4 Formulated Supplementary Sports Foods was included on the FSANZ Work Plan for review in **2001**. The CHC supports the regulation of sport supplement products through the Code to ensure the health and safety of consumers. However, the CHC considers the current standard to be restrictive resulting in compliant Australian and New Zealand manufacturers and marketers of such products being non-competitive on the export market and at a disadvantage on the domestic market.

The CHC notes the expected timetable on the FSANZ Work Plan is currently on hold pending policy guidance from the Ministerial Council. The CHC considers the lack of progress in revising Standard 2.9.4 (over 7 years) to be seriously affecting the sport supplement industry as companies complying with the Code are finding it increasingly difficult to compete with innovative products widely available from overseas.

In 2005 the CHC wrote to FSANZ requesting again that the revision of this standard be progressed. FSANZ responded that finalization of the health claim standard was expected to be possibly another 12-18 months due to resource constraints. The health claim standard is

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yet to be finalized. The CHC does not agree that a review of this Standard should wait for further policy or standards development work given the impact to the sports supplement industry, as the Code presently stands, is immediate and significant.

In addition, many of these supplements are also being imported from New Zealand (under their broader Dietary Supplements Regulations) via the Trans Tasman Mutual Recognition Arrangement (TTMRA). The Dietary Supplements Regulations are currently being amended for New Zealand and planned to come into effect early in 2009; this will further restrict product range available in Australia as products currently considered to be 'foods' will be classed as 'therapeutic goods' and will therefore be exempt from the TTMRA scheme. This is anticipated to result in a significant decrease of available (compliant food type) sports supplement products that are currently permitted on the Australian market. The CHC draws to your attention that there is also considerable consumer access to non-compliant product as a result of direct purchasing by consumers from overseas and lack of enforcement in Australia.

Food regulation and public health (3.5, page 43)

The CHC agrees that this is an issue that requires addressing. It was an issue identified in our submission to the proposal for the mandatory fortification of bread with folic acid. Similarly, the issue is exemplified by the now longer standing fortification of bread with thiamine (vitamin B1) which has not been monitored or evaluated for its public health outcomes.

The CHC notes that the public health issue example cited in the report may have had a policy response based on the promotion of complementary medicine (folic acid supplement) usage. One reason that an alternate policy may not have been adopted is the paucity of data in relation to complementary medicine use in the population (noting that the ingredient folic acid is the same one used in both food fortification and supplements). The CHC considers that lack of information on complementary medicine use (such as vitamins, mineral and nutritional supplements – similar to components of food composition) leads to the potential for distorted dietary intake data.

The issue of identification of appropriate policy responses can not be fully addressed without the required data. The CHC calls on government to commence the collection of this information to properly inform future public health policy recommendations.

For example, in relation to food fortification with folic acid, the CHC recommended that any monitoring program must include the impact of folic acid supplement use. This is considered an essential part of the program as public health messages relating to fortification continue to be stating that supplementation may still be required as folate needs are unlikely to be met by foods alone. At this point in time the CHC is not aware if this is being accounted for in the monitoring framework being implemented by the Australian Institute of Health and Welfare. Without this information FSANZ cannot establish the impact of fortification as many factors may influence any reduction in the incidence of NTD, including increased supplement use.

Therapeutic Goods Regulation

Many of the issues raised in the report also apply to the complementary medicine sector of the therapeutic goods industry, particularly timeframes for audits/assessments. Of note, the current MRA's only apply to pharmaceutical and not complementary medicines as these are by in large not regulated as 'medicines' internationally. Although recognising that the TGA is making progress towards reducing the unlevel playing field between Australian and overseas based manufacturers the current situation continues to discriminate against Australian based manufacturers.

Timeliness and cost of manufacturing audits/GMP assessments (page 61).

The issues raised in the report also apply to the complementary medicine sector. The CHC supports the draft responses (4.1 at page 67).

In relation to wider recognition of international processes and acceptance of GMP certificates the CHC notes that not all other regulatory agencies eg US Food and Drug Administration currently audit complementary medicine manufacturers as these products are not regulated as medicines. The CHC suggests that other options for reducing audit costs and improving timeliness should also be considered. For example, overseas based third party accredited auditors could be more cost effective, reduce timeframes and reduce the requirement for multiple TGA auditors visiting overseas manufacturers.

Other concerns relating to TGA registration process (page 67)

The CHC has some concerns regarding transparency and timeframes for the application process for registered complementary medicines noting that there are no legislatively prescribed timelines for applications to 'register' a complementary medicine or for approval of a new ingredient for use in listed medicines. The CHC welcomes the TGA's commitment to improving the transparency of the approval process; however, as this is only an internal procedural matter it does not provide certainty for industry. However, the implications of the setting of regulatory fees and charges under a full cost recovery policy, substantial application fee required by one applicant with no market advantage, and no prescribed approval process timelines do act as a disincentive for new ingredient applications by industry.

Unlike registered medicines, sponsors of listed medicines have limited intellectual property or data protection avenues available to them. The ability to recoup the application fee (many thousands of dollars including additional resources to prepare an application) as well as overall uncertainty of approval timeframes discourages new ingredient applications (noting that an ingredient is available for use by any sponsor once approved). Although an extraordinary example the following illustrates the uncertainty and barrier to market entry of the current system. To assist industry the CHC submitted, on behalf of a number of members who shared the costs, an application for a new ingredient (widely used as a traditional medicine overseas) for use in listed medicines in June 2003. The ingredient was gazetted for use on 31 July 2008; i.e. 5 years later.

Concerns about marketing and advertising rules (page 78)

The CHC does not support the draft response 4.4 re the implementation of the Australia New Zealand Therapeutic Products Authority (ANZTPA) reforms. The CHC supports a review of the regulation of advertising in an Australian-only context (noting the ANZTPA model accommodated differing country requirements). However, the ANZTPA model can no longer be regarded a suitable model as considerable time has elapsed (4-5 years) since it was developed and there was also considerable industry concern expressed about the proposed model at the time.

We note that the regulatory environment for the advertising of prescription medicines differs significantly between the two countries – can be advertised to the public in New Zealand but not in Australia. It also differs from the regulation of advertising for other therapeutic goods, including complementary medicines. These are governed by legislative provisions including adherence to the Therapeutic Goods Advertising Code, requirement for pre-approval of advertising in broadcast media and a prescribed complaints process. The reforms proposed in relation to prescription medicines were only one aspect of the advertising reforms.

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

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4 August 2008