Dear Sir/Madam

**Proposed Section 7 Declaration: that products in capsule, tablet or pill form are therapeutic goods**

Thank you for the opportunity for the complementary healthcare industry to provide comment on the proposed Section 7 Declaration consultation which suggests that products in capsule, tablet or pill form be considered to be therapeutic goods (dated October 2009).

**General Comments**

The Complementary Healthcare Council (CHC), in principle, supports the intention of the Therapeutic Goods Administration (TGA) and the Food Standards Australia New Zealand (FSANZ) in trying to address the issues relating to the food/medicine interface in Australia and welcomes movement within this area. However, the CHC does not support the proposed Section 7 Declaration as it currently stands as it will not remove the ‘grey area’ that exists between certain food and medicine products – under the proposal, products could still be sold on the market in a powder or liquid form therefore any concerns around consumer public health and safety would not necessarily be addressed.

Historically, the definition of a therapeutic good has been based on the claims being made about the good i.e. the product has a therapeutic effect and/or has a therapeutic claim. The CHC notes the intention of this proposal is to move away from this and instead base the definition on dosage form. Whilst the CHC strongly opposes foods making illegal therapeutic claims and does not support any products doing so, basing the definition solely on the dosage form is not perceived to be appropriate.

In addition, the CHC is aware that ‘legitimate food products’, which are currently complying with the relevant food standard, may be unintentionally captured by this proposal suggesting that dosage form is not the most suitable mechanism for defining medicines from food.

It appears that the products creating the greatest concern for the regulators are non-compliant food products. The CHC considers enforcement of such products needs to be enhanced to address this issue rather than a broadly applied Declaration such as the one being proposed. The CHC has been pushing for better enforcement within the food industry for some time and considers this to be an important issue which still needs to be addressed appropriately.

The CHC also points out that this proposal will have a significant impact financially on many companies within the complementary healthcare industry which will potentially reduce consumer product choice in the short term and possibly reduce market competition in the longer term. No real data has been provided in the consultation document that justifies the rationale for this proposal (for example, the number of food products posing a risk to public safety) and it is noted that if this proposal is progressed any further that a full regulatory impact statement will be conducted. The CHC strongly urges the regulators to consult industry on the impact of the Declaration as several CHC members have indicated the impact will be substantial to their companies.
Finally, the CHC suggests affected complementary healthcare sectors i.e. functional food companies and the sports supplement industry, be involved in meaningful and constructive consultation with the regulators to reach a compromise of how to address the current concerns around the food/medicine interface.

**Specific Comment**

The CHC provides the following responses to the questions outlined in the consultation document:

1. **Do you feel that the proposed Section 7 Declaration will provide more clarity for consumers in determining the difference between goods regulated as foods and goods regulated as therapeutic products?**

The Australian population expects all products designed for ingestion to meet suitable safety and quality standards, regardless of whether the product is classified as a food or medicine. The CHC considers that how this is done i.e. whether they are regulated by the TGA or state food authorities is not of great concern to consumers, as long as it is being monitored adequately. The CHC does not believe the proposal will provide any additional clarity to the ‘reasonable’ consumer purchasing these types of products.

The CHC recognises there are a small number of food products on the Australian market which really fall under the definition of a therapeutic good however the dosage form alone is not the only factor in deciding this; labelling and advertising, in addition to its presentation, are also likely to influence the impression of the type of products being purchased by the consumer.

It is understood that often consumers make their decision to purchase a type of product based on the perceived nutritional benefit. In fact, research has shown that price and taste are the primary factors considered by the consumer when purchasing a nutritional item\(^1\),\(^2\),\(^3\). Therefore, given this data, we can assume final purchase decisions would most likely be based on the taste and price of the product suggesting that dosage form alone is not the only aspect considered when making an ‘informed choice’.

The CHC does not consider the proposed Section 7 Declaration will provide clarity for consumers in determining the difference between goods regulated as foods or medicines as this is not the only factor considered when consumers purchase their products.

2. **Can you think of any ways in which this Declaration would negatively impact on consumers choices?**

Consumers may purchase food products in a capsule, tablet or pill form due to either dietary reasons (vegetarian, vegan etc), for certain health conditions (difficulty in chewing etc) or simply for convenience. The implementation of this proposal may require such consumers to choose alternative products if they are removed from the market or consider taking different dosage forms such as powders – ultimately removing true consumer choice.

Food products are also often presented in a tablet, capsule or pill form due to the unpalatable taste of the ingredient; dosage forms eliminating unpleasant tasting ingredients are considered to be important to the overall general wellbeing of the Australian public as it offers them an option to consume the product in a form which they find preferable.

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The CHC considers the immediate impact of the Declaration to consumers would be the removal of certain products from the market, limiting consumer choice. In addition, if certain food products would be required to undergo the Listing process due to the fact that they are presented in a tablet, capsule or pill, the cost associated with compliance requirements would either be passed on to the consumer or would result in the removal of the product from the market altogether.

The proposed Declaration may also create confusion amongst consumers, particularly if they are made aware of the Declaration. This confusion would come from the fact there would be equivalent food products available on the market, in different dosage forms however consumers would be aware that those presented in tablet, capsule of pill form would be regulated differently. The CHC believes this may cause consumers to presume that the risks and benefits of taking similar products in various dosage forms differ significantly.

In summary, the CHC has identified a number of factors that indicate the proposal would have a significant negative impact to consumers in relation to choice of products.

3. **Would the proposed Section 7 Declaration have negative financial implications for your business? If yes, please indicate the approximate cost to your business (such information should be identified as confidential in the consultation submission cover sheet).**

Members of the CHC have indicated there would be significant financial impact to their company if the Declaration was implemented. One financial implication for manufacturers of specialised food products is setting up their manufacturing facilities to TGA Good Manufacturing Practice (GMP) standards; currently these companies are set up to meet food standard requirements. The cost to each individual company to establish these standards and undergo TGA’s evaluation would be substantial.

Products presented in capsule, tablet or pill form, under the proposal, would be required to be listed on the Australian Register of Therapeutic Goods; each product placed on the register incurs an initial listing cost and annual costs thereafter. This process will result in a significant financial loss to each company which would need to either be passed onto the consumer or alternatively result in the product being removed from the market.

In addition to this, some of the ingredients currently used in food products are not approved for use in Listed medicines. This means each non-approved ingredient would need to be submitted to the TGA for evaluation of quality and safety. This evaluation incurs a cost to the applicant which is substantial. It is also possible many of the foods ingredients requiring evaluation may not have sufficient evidence to support a therapeutic claim as per the requirements of the TGA.

In summary, the main areas affected by the declaration may include, but are not limited to:
- Withdrawal of products from the market i.e. product recall costs;
- Write off costs associated with packaging and raw materials;
- Purchasing efficiencies lost through volume discounts on some raw materials;
- Research and Development invested in products soon to be launched on the market;
- Increased testing costs; and
- Greater costs involved in meeting regulations.

4. **Are there any other negative implications for business?**

The CHC considers that the proposed Declaration will limit the availability of food products on the Australian market. Consumers may be reluctant to try an alternative product and will resort to other means of obtaining the same product for example via online stores. The CHC points out the global nature of business and the ease of accessibility afforded by the internet to the global market enables Australian consumers an easy means of bypassing the TGA’s efforts to limit their access to these products.
‘Pushing’ consumers to purchase products online due to their unavailability in retail stores, will have a significant impact to the complementary healthcare industry and, as the TGA has stated, still allows for the potential of a public health and safety risk as they are not regulated as therapeutic goods. Online purchasing also flows through and negatively impacts on Australian retailers who contribute significantly to the Australian economy. However, the proposal as outlined will potentially facilitate the sale and distribution of these types of products via overseas retailers who compete directly with our domestic retail stores.

5. **Do you have any further comments?**

The CHC recommends that the first step in addressing the food/medicine interface is to increase enforcement around food. Currently there is an unlevel playing field between those companies complying with the current food standards and those that do not by making illegal therapeutic claims. The CHC believes that by addressing the enforcement issue, many of the concerns of the regulators would be addressed and consequently render the need for the proposed Declaration unnecessary.

The CHC notes that the TGA must develop policies in accordance with the competition policy principles adopted by the Council of Australian Governments (COAG) which is that any proposed regulation must provide for ‘minimum effective regulation’. The proposed Declaration is not consistent with this principle.

**Conclusion**

The CHC strongly supports the regulators providing clarity around the ‘grey areas’ of the food/medicine interface and commends the initiation of this proposal. However, the CHC does not support the proposal put forward and strongly urges the regulators to consult with industry before progressing this matter any further. The CHC recognises there are products that are non-compliant and believes action needs to be taken but not based on defining products by their dosage form.

The CHC does not consider that the Declaration will address concerns relating to public health and safety – noting that the rationale or data for this statement was not provided in the consultation document; how much of a public safety issue are these types of products? Companies will simply continue to provide these products in an alternative dosage form to capsule, tablets or pills which will not rectify the concerns relating to safety.

Enforcement of non-complaint food products needs to be enhanced by the state food authorities to address the concern of both industry and the regulators. The CHC considers this initial step to be more appropriate than initiating the proposed Section 7 Declaration.

The impact of this proposal is significant to both industry and consumers and is not in keeping with the COAG principles of ‘minimum effective regulation’. The CHC believes that industry and the regulators could work together on establishing some concepts which may minimise the impact whilst still addressing the issues; the relevant committees and working groups within the CHC would be an appropriate starting point.

If you would like to discuss any matters within this submission further please do not hesitate in contacting me.

Yours sincerely

Kristy Tomas
Scientific & Technical Manager

Complementary Healthcare Council