Food Medicine Interface

As you would be aware, the *Therapeutic Goods Act 1989* defines therapeutic use in or conjunction with: (a) preventing, diagnosing, curing or alleviating a disease, ailment, defect or injury in persons or animals; or (b) influencing, inhibiting or modifying a physiological process in persons or animals; or (c)(d)(e)and (f)….However, if there is already an established food standard, the product at the food/medicine interface will generally be classified as a food. The CHC recognises that the joint food–therapeutics working group, comprising of representatives from the Therapeutic Goods Administration, FSANZ and the Department of Health and Ageing, are focusing on the food/medicine interface and identifying where the gaps and inconsistencies lie. It is their view that this will help to address issues and inconsistencies in regulation, monitoring and enforcement of products at this interface.

Notwithstanding the above, as it is intended that the definition would apply to FSMPs that are suitable as a sole source of nutrition as well as those FSMPs that are used as a supplementary food product, the CHC considers that the allowance of health claims for foods will increase the already concerning 'grey area' of the food/medicine interface. There is already existing confusion between a complementary medicine and food product (particularly in specialised areas such as sports foods and FSMPs) by regulators, industry and consumers.

A key issue is how to secure a continuum in relation to health claims across food products and therapeutic claims across complementary medicines. The introduction of health claims in the food regulatory regime will make more urgent the resolution of these interface problems.

- Clear interfaces should be established between food labelling requirements and other requirements of therapeutic goods and dietary supplements.
- Breaches of labelling regulatory requirements should be dealt with in a timely and consistent manner with sufficient severity to deter further breaches.
- All food laws need to be consistent with COAG principles for national standard setting.

Given complementary medicines are regulated by a different regulatory agency to foods, there must be 'cross-over' or regular communication between the agencies to ensure that definitions for foods making therapeutic claims and the levels and types of claims being made are consistent and/or appropriate across both industries.

Therapeutic Claims for FSMPs

The CHC notes that the 2010 version of the draft Standard included the requirement for FSMPs to meet the conditions contained in Standard 1.1A.2 – Transitional Standard for Health Claims, except for the prohibition on the reference to a disease or physiological condition (subclause 3(d) of Standard 1.1A.2), to allow for recognition and identification of the purpose of their use. Subsequently, the proposed new Standard to regulate Nutrition Health and Related Claims (Standard 1.2.7) would apply to FSMPs. However, in targeted consultations with industry

representatives in mid 2011, FSANZ suggested that the Standards regulating health claims should not apply to FSMPs. This decision was made due to the similarities between the labelling statements required on FSMPs under draft Standard 2.9.5 and the types of claims proposed for regulation under Standard 1.2.7, which was likely to cause confusion.

By allowing FSMPs to opt out of the requirements of the Standard for Nutrition Health and Related Claims, this should mean health claims are not allowed to be made outside of the specific medical purpose of the FSMP, as evidence substantiation for any of these claims will not be required to be assessed.

The CHC notes that FSMPs are targeted to a specific group of individuals with existing medically diagnosed disease states. Generally, the CHC is of the opinion that foods should not be permitted to carry health claims. If health claims are to be allowed for FSMPs, however, enforcement needs to be applied consistently and the claims should be substantiated by appropriate scientific evidence.

As noted in the South Australian Government submission to the Review of Food Labelling Law and Policy, 'It is important that foods should not be permitted to make claims that are not allowed on complementary medicines and that the levels of evidence required to substantiate claims are at least equivalent'.

The CHC strongly recommends that any company wanting to make health claims on foods should be subjected to comparable quality manufacturing standards as required for complementary medicines. The CHC considers that without these standards in place, there is an un-level playing field for the complementary medicine industry as complementary medicines are strictly regulated and rules enforced. If Listed, complementary medicines are only permitted to make low to general level health claims. Allowing any food category to make health claims without requiring similar manufacturing standards or evidence substantiation is not only unfair and misleading, but would cause biased competition with foods.

The CHC believes, therefore, that health claims should only be permitted – to be used following evaluation by a government body such as FSANZ – where the scientific evidence supports the level of claim to be used for the product. FSMP manufacturers must be expected to undertake equivalent quality control, stability and regulatory oversight and should be provided with specific enforceable guidance with regard to health claims. Guidelines will assist manufacturers/sponsors in the production of compliant labelling that does not make unacceptable claims.

Level of Risk

The medical purpose of FSMPs – by the draft definition means, "a food that is represented as being for the dietary management of a disease, disorder, or medical condition or a food for special medical purposes or a medical food" – suggests a level of risk that is at least equal to or higher than complementary medicines.

However, there is no requirement in the proposal for FSMPs to be manufactured according to Good Manufacturing Practices (GMP). A quality system similar to that which applies to Listed medicines should apply to FSMPs to ensure product stability and safety. This would ensure, for example, that not only is an ingredient present but present in sufficient quantities supported by the evidence to which the claim is based. It is our position that foods making general level and high level health claims should require premarket substantiation and approval.

Requirement of a Labelling Statement

The CHC supports the requirement of a labelling statement on FSMPs to the effect that the food must be used under medical supervision, and agrees with the purpose of the labelling statement to alert consumers to seek medical/health professional advice on the use of FSMPs (and help facilitate consumer access to such advice). The CHC believes the main priority of the food regulatory system must be to meet broader public health objectives. Food regulation should protect and promote public health by ensuring safe and high quality foods are available and promoted to the Australian population in such a way as to assist in the appropriate use of these products.

The CHC is of the opinion that the label should stipulate, as a minimum, all allergens as noted in the FSANZ Food Code. The individual prescribing the FSMP must have all the necessary details to correctly and safely prescribe the product.

Enforcement

Any standard that is put in place for foods for special medical purposes must be enforced appropriately and effectively. Current enforcement of food standards is inconsistent and not adequately applied, which in turn creates an un-level playing field for the complementary medicine industry due to the similar nature of the health claims. Enforcement of Foods Standards requirements for health claims on foods is non-existent or rarely enforced.

Enforcement of standards for complementary medicines is rigorous and strict. One reason is that complementary medicines are regulated by a national authority, which generally results in consistent decision making. Foods, however, are regulated by state authorities, which allows for inconsistency in outcomes and inadequate enforcement. Having a national authority responsible for enforcement of foods, and therefore health claims on foods, would assist in resolving this public health issue.

The enforcement agency would need to assess the evidence to substantiate the claim. However, compared with complementary medicines, the penalties for non-compliance under the Food Act are less substantial. The CHC reiterates that enforcement measures need to be of a sufficient level so as to deter non-compliance. Therefore, government needs to resource adequately.

Please note, the CHC's submission on Food Regulation, Labelling and Advertising (attached) as submitted to the Labelling Review Secretariat, outlines CHC's detailed Position on theses issues.

Further Comments

The CHC provides the following further comments for consideration:

It is proposed that FSMPs should not be supplied to a consumer except to "(c) a person who holds a written request from a business or person mentioned in (a) or (b) for the food to be supplied to the consumer." This is reasonable, however, consideration should be given to how long the written request can remain in effect and the quantity each request will entitle a consumer to obtain.

The proposed labelling requirement has been revised to alert consumers to seek medical/health professional advice on the use of FSMPs. The CHC again strongly suggests the definition of healthcare professional be expanded to be consistent with that defined in the *Therapeutic Goods Act 1989* which includes:

- Medical practitioners, psychologists, dentists, pharmacists, optometrists, chiropractors, physiotherapists, nurses, midwives, dental hygienists, dental prosthetists, dental therapists or osteopaths; or
- Persons who are:
  (i) Engaged in the business of wholesaling therapeutic goods; or
  (ii) Purchasing officers in hospitals; or
- herbalists, homeopathic practitioners, naturopaths, nutritionists, practitioners of traditional Chinese medicine or podiatrists registered under a law of a State or Territory.

The Therapeutic Regulations have a schedule of approved associations, members of which are accepted by the TGA as professionals. FSANZ could restrict the supply of FSMPs by accepting only those members of the professional associations listed in Schedule 1 of the *Therapeutic Goods Regulations 1990.*

Noting that many naturopaths and other 'complementary healthcare professionals' may prescribe products which will be captured under the proposed Standard, and provide ongoing medical supervision, the CHC recommends inclusion of such professions in the Standard.

Following the 2010 public consultation, FSANZ decided to exclude Very Low Energy Diet (VLED) products from Proposal P242. VLED products are formulated foods intended for use under medical supervision as part of the dietary management of obesity. The CHC questions the removal of VLED products from the Standard, in particular how the dietary management of obesity is not considered to meet the definition a) for the dietary management of a disease, disorder, or medical condition.