AUSTRALIAN SELF-MEDICATION INDUSTRY

BETTER HEALTH THROUGH RESPONSIBLE SELF-MEDICATION

Project Officer – Proposal P242
Food Standards Australia New Zealand
PO Box 7186
CANBERRA ACT 2610

ACKNOWLEDGED

ENTERED IN DATA BASE

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28 March 2003

Dear Sir/Madam

RE: PROPOSAL P242- FOODS FOR SPECIAL MEDICAL PURPOSES

The Australian Self Medication Industry (ASMI) wishes to thank Food Standards Australia New Zealand for the opportunity to respond to the above proposal

ASMI is the peak organisation providing both advocacy and representation for the full spectrum of the non-prescription manufacturing sector, both "Over the Counter" and Complementary Medicines. Our interest in this proposal is driven by the potential interface of Foods for Special Medical Purposes (FSMP) between both food and therapeutic goods and how they should be regulated under the Food Standards Code (FSC).

On consideration of the options presented, ASMI believes the Option 1- maintain Status Quo, is appropriate at the current time given the number of unresolved issues.

ASMI has concerns that Option 2 as it is currently presented may be commercially disadvantageous to companies supplying these products by requiring unnecessary relabelling and reformulation of existing products. If the existing mainstream commercial supply is made difficult, it will place a burden on health institutions and patients by requiring procurement of these products through other importation mechanisms.

ASMI is disappointed that the original Option 3- Co-regulatory proposal was not considered in the final report given the potential for effective management through an Industry Code of Practice.

Advertising of FSMP

With regard to limiting advertisement of FSMP to "healthcare professionals", ASMI believes FSANZ should refer to those professionals recognised as such under the Therapeutic Goods Regulations 1990 Part 2 Division 1 s4 as a precedent.

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ASMI believes that the proposed restriction of advertisement to "health professional publications" is unnecessarily narrow and does not refect the full spectrum of acceptable advertising that may be presented to healthcare professionals without exposure to the general public.

There should also be consideration for the capacity of some forms of advertising to target population groups through appropriate organisations representing the needs and interests of those population subgroups with specific medical conditions. The control of this can be addressed through other mechanisms described below.

ASMI can only reiterate that there needs be a consistency of approach with foods and therapeutic goods for "Health and Related Claims" and on this basis supports the continued prohibition of specific "health claims" other than those confined to nutritive function or as may be allowed under an appropriate regime for health and related claims under P 153. ASMI does acknowledge that the indicated use for FSMP and VLED's requires the declaration of appropriate use within particular disease states or conditions for nutritive purposes, and would not consider that stating these conditions should be considered a contravention to the prohibition on "health claims" when presented within this context for foods meeting the final definition of FSMP.

ASMI are awaiting the release of the final report of Michael Codd's "Review of Advertising Therapeutic Products in Australia and NZ" which is anticipated to contain recommendations that advertising to the general public of any therapeutic claim, whether it be in a medicine or food, should be subject to pre-clearance provisions. FSMP and VLED products may be captured under such an arrangement ensuring that inappropriate advertising to the general public does not occur. Therapeutic advertisements directed to professionals are not expected to require pre-clearance but it is expected there could be potential for mechanisms for complaint handling via relevant industry Codes of Practice.

Composition

FSMP are used for the provision of nutrition, and are not used for the treatment of diseases or conditions. Formulation standards for efficacy must not therefore be interpreted within the paradigm of disease cure/management.

Medical conditions requiring the use of FSMP may require specific nutritional or energy profiles determined by healthcare professionals/dieticians, or specified by larger healthcare administrative bodies such as the Pharmaceutical Benefits Scheme, Department of Veterans Affairs or any other relevant healthcare institutions which put out to tender formulations to meet a particular need. ASMI is concerned that any inflexible regulation (ie upper limits for vitamins and minerals) of the compositional standards of FSMP may unintentionally impede suppliers in being able to provide products to meet the nutritional specifications set by individuals and institutions prescribing FSMP.

Labelling

ASMI is concerned about the prescriptive labelling standards proposed for FSMP and questions whether the proposed format has been tested with health professionals and consumers to ensure it provides better information and less risk compared to current label standards with accompanying literature.

Performance Based Labelling is gaining interest as a means to ensure correct interpretation of a label and appropriate use of product from the label information. Performance-based/outcomes-based requirements give specified outcomes but leave open the means of meeting the outcomes. Work in this area has been undertaken by the Department of Small Business and Consumer Affairs, and is currently being reviewed by the TGA for use in medicines labelling. ASMI would suggest to FSANZ that these principles would be useful and valid to consider whether the existing labels meet the needs of healthcare providers and patients who require these products.

ASMI disagree with the FSANZ view that product literature cannot deliver the risk management provided by a label. For higher risk medicines in the Pharmacist Only (S3) and Prescription Only (S4) categories, Consumer Medicines Information (CMI) leaflets are a primary tool in ensuring the safe and effective use of these medicines, particularly in prescription products where the indication, specific warnings or contraindications are not carried on the label. ASMI is unsure why the FSANZ does not believe accompanying literature for FSMP cannot meet similar health outcomes, especially given the manner of distribution of FSMP is akin to Pharmacist Only and Prescription Only products.

Conclusion

ASMI is of the position that there are serious issues that need to be revisited with regards to FSMP, especially with regards to labelling and composition.

ASMI would support the creation of an External Advisory Group if deemed necessary to debate and canvass the opinions not only of the manufacturers of these products, but of the institutions and professional representative bodies representing the prescribers/providers of the these products and appropriate consumer representative groups.

Should you require additional information, please do not hesitate to contact me on 02 9923 9411 or by email at jonathan@asmi.com.au

Yours sincerely

[redacted]

Jonathan Breach
Regulatory and Technical Manager