



AUSTRALIAN SELF-MEDICATION INDUSTRY

BETTER HEALTH THROUGH RESPONSIBLE SELF-MEDICATION

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

7 December, 2001

Dear Sir/Madam

RE: PROPOSAL P242- FOODS FOR SPECIAL MEDICAL PURPOSES

The Australian Self Medication Industry (ASMI) wishes to thank the Australia New Zealand Food Authority 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 interfaces 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 3- Co-regulatory proposal is an appropriate approach to the issue given the limited number of market players within this industry sector and the current marketing practices.

Industry members have expressed concerns that Option 4 for Full Regulation or Option 5 Regulation by Pre-market Evaluation could result in unique Australian compositional requirements that may not be harmonised with existing controls in international markets, such as Europe, where these products may be manufactured. These products are currently manufactured with global formulations and labelling, and the introduction of specific Australian requirements could result in the deletion of particular products lines in Australia and increased costs in production which may impact consumers relying on these products due to existing medical conditions.

As identified under Option 3, there would be a reduced regulatory burden on ANZFA, although Proposal P242 also raises the potential of government/industry co-regulation as compromising regulatory objectives and public health and safety.

ASMI members, which include manufacturers of FSMP, are experienced in working under co-regulatory arrangements, such as the control of advertising

and promotion of therapeutic goods through the ASMI Code of Practice and the Therapeutic Goods Advertising Code.

Proposal P242 does not identify any current instances of where public health and safety has been compromised by these products as a result of the way they are formulated or the current marketing practices of the importing/manufacturing companies. The report does identify that these products are predominantly provided through healthcare settings under the supervision of an appropriate health care professional, thereby minimising risks associated with these products.

We would support the inclusion of a definition of FSMP in Volume 2 of the FSC. We would also support that the formulation of FSMP's should be based on sound medical and nutritional principles, and that manufacturers should hold the required rationale and evidence to support the safety and efficacy of their product.

ASMI is concerned to ensure consistency of approach with foods and therapeutic goods for "Health and Related Claims" and on this basis support the continued prohibition of specific "health claims" other than those confined to nutritive function. ASMI does acknowledge that the indicated use for these products requires the declaration of appropriate use within particular disease states or conditions for nutritive purposes, and would not consider that mention of 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.

Manufacturers have identified their willingness to participate in the creation of an Industry Code of Practice under a co-regulatory arrangement to help manage the continued ethical marketing and promotion of medical foods and their provision under suitable medical supervision or recommendation. This Code of Practice will need to be developed and managed by manufacturers and the relevant industry associations, such as ASMI, who represent manufacturers marketing FSMP. It would therefore be desirable for ANZFA to liaise and coordinate with these associations in a suitable forum to discuss this option further.

Should you wish to discuss any of the points raised in further detail please do not hesitate to contact me on 02 9922 5111 or at jonathan@asmi.com.au.

Yours sincerely

