March 2003

Dietitians Association of Australia

Submission regarding P242 Foods for Special Medical Purposes (FSMP)

The Dietitians Association of Australia appreciates the opportunity to comment on the abovementioned Proposal as FSMP are important products used by dietitians as a treatment modality for specific clinical conditions. DAA supports the development of a standard that will help to ensure continued availability of these foods at a reasonable price. DAA recommended in its original submission that option 3 Co-regulation was the preferred regulatory option to provide flexibility and development of a code of practice for the advertising and promotion of FSMP.

In general, the draft assessment report from FSANZ is overly prescriptive given:

- DAA is not aware of reports of adverse effects in the provision of FSMPs;
- manufacturers of FSMP have acted responsibly to date and restricted the promotion of FSMP to health professionals and not the public at large; and
- 99% of products are manufactured overseas and the size of the Australian market is relatively small such that compositional and labelling changes of FSMPs could severely negatively impact on availability of products to dietitians and their patients.
- Reduced availability of products as treatment modality could result in a return to in-house modular feeds affecting efficiency and patient safety.

In relation to Very low Energy Diets (VLED) DAA concurs with the September 2002 NHMRC report 'Draft Clinical Guidelines for Weight Control and Obesity Management in Adults' that VLEDs can result in quick, short term weight loss, but should be closely monitored and not be used for extended periods of time.

DAA offers the following specific comments on issues raised in the draft assessment report P242.

Definition

The Codex definition of foods for special medical purposes is appropriate as a basis for developing a definition for the foods standards. However DAA reiterates that the FSANZ

definition should state that these foods are to be used under medical supervision (DAA supports clarification of the term 'medical supervision' to include the day to day management of a dietitian.)

Compositional Assessment

Whilst acknowledging that FSMP, particularly complete formulations need to be nutritionally adequate for use as the sole source of nutrition, any directives on composition should not adversely affect the availability and price of currently available FSMP. DAA believes that some of the prescriptive maximum levels set out in P242 are impractical as its effect is to render even the core FSMP products, standard tube feeds, in breach of the proposed standard. The table below highlights that for each of the companies currently marketing FSMP, the following nutrients fall above the maximum prescribed levels. Each company's core products, tube feeds for example, exceed levels of Magnesium.

/100kJ	Max levels proposed	Osmolite (Abbott)	Isosource (Novartis)	Nutrison Standard (Nutricia)
Mg mg	4	5.99	6.9	5.48
Niacin mg	0.4	0.61	0.3	0.43
Biotin mcg	1.8	0.94	5.16	0.95
Folate mcg	11.5	11.95	13.7	6.43

The maximum levels proposed for the nutrients listed above are exceeded such that these products may become unavailable or only available at an inflated price due to resultant manufacturing changes. This will have enormous negative impact on both dietitians and medical staff but mostly on the vulnerable patient groups who require such products.

This non-compliance of currently available products with the proposed FSMP standard does not only affect tube feeds but other nutritionally complete oral feeds.

Given that these products have been in use over a long period, DAA is unaware of clinical evidence that exceeding the maximum levels of these nutrients has had any deleterious effects in this group of patients.

There is a problem with the maximum levels of nutrients being expressed as a proportion of energy when energy is not one of the nutrients being supplemented. An example of this is the protein, vitamin, mineral and trace element supplements used for consumers with PKU. The aim of the supplement is to replace normal protein containing foods with a low phenylalanine amino acid mix fortified with vitamins, minerals and trace elements. To allow consumers to eat as much normal low protein foods as possible, the energy level

of the supplement is kept low. Therefore 'maximum permitted' nutrient levels cannot meaningfully be expressed on an energy basis to cover all types of FSMP.

The table below highlights this problem where maximum levels proposed in the draft standard are exceeded by the protein supplements used by sufferers of PKU.

/ 100kJ	**Max Amount**	**XP Maxamaid (Nutricia/SHS)**	**XP Maxamum (Nutricia/SHS)**	**Phenex 2 (Abbott)**
Vitamin A mcg	34	40	34.77	38.28
Thiamin mg	0.12	0.11	0.06	0.23
Niacin mg	0.4	2.22	1.63	1.84
Folate mcg	11.5	38	6.1	26.68
Vitamin B12 mcg	0.17	0.27	0.08	0.56
Vitamin D mcg	0.57	0.912	0.85	0.57
Biotin mcg	1.8	9.12	2.14	7.54
Pantothenic Acid mg	0.35	0.28	0.23	0.81
Calcium mg	28.7	61.56	35.38	51
Magnesium mg	4	15.2	10	13.05
Iron mg	0.5	0.91	0.86	0.75
Phosphorus mg	46	61.56	29.28	51.04
Zinc mg	0.46	0.99	0.61	0.75
Copper mcg	114	140	60	60
Chloride mg	42	34.2	35.67	54.52

Ingredients

DAA believes there must be flexibility within the regulations to allow manufacturers to add new compounds and/or increase existing compounds to FSMP, based on sound nutritional research, which also considers safety aspects. Imposing prescriptive maximum levels of micronutrients will limit current and future product innovations, which may ultimately negatively affect patient care.

With respect to VLEDs DAA agrees that such products should be required to provide the recommended daily allowances of minerals, vitamins, trace elements and fatty acids in the recommended dose/serve.

Supply

DAA reiterates its position that consumers should only be able to purchase FSMP from pharmacies and hospitals or direct from the supplier or medical distributor, in conjunction with consultation with a health professional. DAA would like to emphasise that a health professional may also include a retail pharmacy.

Advertising

Advertising to health professionals not only includes professional publications such as scientific journals and professional newsletters, but also product information and leaflets, conferences, other educational forums, meetings, direct mail campaigns, e-mail and websites. Advertising to health professionals should be defined to encompass these forms.

DAA recommends VLEDs be treated separately for advertising and labelling with respect to claims and warning statements.

Labelling

The first aim should be to reduce the need for manufacturers to have different labels in Australia to those used in the country of origin. Such a need could potentially result in the product becoming unavailable in Australia.

Sufficient information regarding ingredients and nutrient composition is required to ensure appropriate product selection and dose prescription to meet individual needs of clients. Accurate clinical information would be used to determine volume and nutritional requirements.

Given the labelling requirements set out in P242 it would seem that manufactures would need to implement a number of changes to current labels in order that FSMPs comply. This would appear to be rather onerous on manufacturers given current labels comply with either EU (European Union) or American labelling requirements.

DAA believes that where manufacturers are unable to include all the necessary information on individual labels this information should be provided in product brochures distributed to health professionals and pharmacies. This is reflective of the current system, which is complemented by most companies providing a free 1800 clinical care line where product information can be sourced.

Although the Association recognises that warning statements on some of these products should be mandatory, DAA believes the inclusion of warning statements on other products could cause unnecessary concern for consumers. For example.

- DAA supports labelling 'not for parenteral use' to be placed on all products in this standard produced specifically for oral and enteral consumption to avoid inappropriate use.
- DAA supports including a list of known side effects, contraindications and product-drug interactions where known, e.g. for patients with Galactosemia using products labelled low lactose it should be clearly labelled whether the lactose has been split to glucose and galactose and not just removed.
- DAA supports labelling VLEDs with 'health hazard' warning statement. For this reason, they should only be used under medical supervision. However, apart from VLEDs, rarely can FSMP be classified as a health hazard. Instead of using a hazard statement, DAA supports labelling of specific formulated products used for treatment of medical conditions regarding appropriate use e.g. product for PKU should be labelled for use in PKU.
- The requirement to declare a serving size and nutrient analysis per serving size or dose may be inappropriate in some circumstances:
    - Where clinically the dosage is patient-specific and dependent upon blood biochemistry e.g. phenylalanine levels (in PKU).

Given the range of products and their uses included in this standard and the likelihood of new products in the future, DAA recommends further discussion with dietitians working in this area of practice regarding the composition and labelling of FSMP before prescriptive generic labelling specifications can be supported.