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SUBMISSION REGARDING FOODS FOR SPECIAL MEDICAL PURPOSES (FSMP)

This submission is from the New Zealand Dietetic Association (NZDA) the professional organisation for New Zealand Registered Dietitians.

The NZDA is grateful for the opportunity to comment on the proposed legislation for the regulation of FSMP, as dietitians' use these products in their daily treatment of special medical conditions.

General Comment

The NZDA wishes to raise concern over the proposed regulatory standards for FSMP products already used with safety in New Zealand, yet this proposal would exclude these due to the nature of the proposal.

NZDA does support the development of a standard that will assist with availability of products entering New Zealand, for improved accessibility and reliability to the customer, provided the cost remains consistent with current cost structures, such as those products provided through the Pharmac system to those consumers with a clinical need.

NZDA is concerned with the restriction of both minimal & maximal levels for the composition of ingredients. By introducing maximum levels, we believe this to be overly restrictive and unnecessary in the current environment where science is an ever-changing field.

As these FSMP products are generally used under the supervision of *medical or other health* professionals to a small group of the population, NZDA

believes the risk to the public health & safety of New Zealanders is much less than other food types used by the public in this country. These products already meet stringent United States of America & European Union regulatory processes and to adapt to the proposed recommendations, would have major ramifications on cost to the consumer. Labels would need to change & as the Australian and New Zealand markets are small on the world scene, the worth of changing the regulatory requirements is outweighed by the cost.

In New Zealand most of the products used for FSMP are funded by a subsidy through a government-delegated organisation called Pharmac. Our concern is that if the cost of these products increases by a substantial amount, Pharmac is unlikely to continue funding FSMP. This would affect the supervision of FSMP as healthcare professionals who would no longer have control or guidance for the use of these products. Thus the risk to the public is increased.

It is implicated that as the legislation stands, in New Zealand and Australia, the current supply of FSMP are unsafe for their intended purposes, despite having met the strict regulatory restrictions of the United States of America and European Union standards. As end users of these products, NZDA would dispute this.

3. Regulatory Problem

As stated that FSMP *are products formulated for the use under medical supervision, for the dietary management of individuals with particular conditions.,*

NZDA is more concerned about the prescribing of the products we currently have available to us, than …*permission's for composition or specific labelling requirements.* The companies who manufacture these products already provide clear labelling on the content of the FSMP and provide products appropriate in composition to the clinical need the product has been designed to meet. Dietitians understand the content and 'role' of each product.

When health professionals other than dietitians are involved in the prescribing of these FSMP, the public are more at risk by incorrect prescription due to the lack of knowledge and the relevance of specific medical conditions for certain nutrients. This is particularly evident where a patient with Diabetes Mellitus is given a hyper-calorific product, which can affect a patient's blood sugar levels.

4. Objectives

' The protect public health and safety, particularly by ensuring the safe and appropriate use of FSMP '

It has already been established that *the market is heavily supervised by medical or other health professionals….*

It is unclear what the objective of FSANZ is when it has not been established that the current use of FSMP's are either unsafe or have been used inappropriately.

NZDA would like further clarification on what added measures FSANZ aims to establish for this purpose.

5.2 Definition of FSMP

NZDA agrees with the Codex definition for FSMP purposes except for the addition of the words…

Which are specially processed or formulated and presented for the dietary management of patients and may be used only under medical **and dietitian** *supervision.*

Dietitians are the only group of health professionals trained with the knowledge in the management and treatment of FSMP.

It is within our Scope of Practice to prescribe and recommend FSMP.

5.3 Distribution and Access

NZDA agrees with FSANZ that there is no purpose in changing the regulatory requirements for FSMP for New Zealand and Australia.

Because in New Zealand availability is by way of prescription in general, the product is dispensed under the supervision of a health care professional. This could include a retail pharmacy.

NZDA recommends that FSMP are purchased from Pharmacies and hospitals with the consultation of a health professional preferably that of a medical practitioner or dietitian.

5.3.3 Conclusion

' Does the term ' health professional publications suitably reflect the range of publications '

NZDA recommends that the range of 'health care publications' should be broadened to include conferences, other educational forums, trade exhibitions, the web or Internet, and direct mailing opportunities through our member associations.

The concern is to reflect the growing consumer access to the Internet and access to information on FSMP products via this medium.

NZDA recommend consumer access to information of FSMP is restricted to medical, dietitians and other health professional groups for the safety of the

public. However, NZDA would like clarification on the extent of the disciplines considered for other health professional groups.

NZDA recommends Very Low Energy Diets (VLED's) be treated as a separate issue for advertising and labelling in regard to claims and warning statements.

5.4.1 General Compositional Requirements

NZDA seeks clarification on the following statement:
' Harmonisation wherever possible with the compositional requirements for FSMP according to European Union directives '

It is unclear and confusing to NZDA that on one hand FSANZ wishes to harmonise product composition with the European Union and yet on the other, if the proposed FSANZ recommendations regulatory regulations go ahead, 90% plus of the current market in New Zealand and Australia will fall outside the proposed requirements for compositional compliance, if maximum levels of nutrient composition are to be stated.

This recommendation appears to have major limitations when the three major companies supplying product in New Zealand would have almost all of their products rendered non-compliant. As stated previously, it has not been established by FSANZ that product currently utilised in New Zealand poses a safety issue to our consumers.

NZDA asks, why the need to change?

NZDA also recommends that minimum levels only are maintained for the composition of product. We do <u>not</u> support the introduction of <u>maximum</u> levels as science is ever changing as technology, research and information on specific diseases and treatments are learned.

For example, over the years we have seen recommendations on the Recommended Daily Intakes (RDI's) increase for vitamin C and for fibre for the maintenance of good health. When the current RDI's are reviewed, it is likely the levels for calcium may increase.

NZDA also believe that as scientific research provides us with improved knowledge of medical conditions and treatments, legislation must remain flexible to allow manufacturers to not only change levels of composition, but to allow for the addition of new compounds that would benefit the health of the consumer.

If legislation is too prescriptive the benefits for our consumers through improving scientific technologies and research will be restricted, and our consumers penalised through not having access to the most effective modality of treatment for their specific condition. In a world of evolution, New Zealand and Australia must keep abreast of current world innovations in this field.

Compositional Assessment

NZDA believes the prescriptive maximum levels set out in FSMP P242 are impractical as for reasons as stated above.

All complete formulations need to be nutritionally adequate if they are to be used as the sole source of nutrition.

If the proposed changes are approved and brought into legislation, even some of the standard feeds used now by dietitians, will be non-compliant.

For example, the three major companies supplying FSMP all have standard tube feeds as well as oral feeds where levels of magnesium exceed the maximum levels proposed.

Other levels of nutrients to exceed maximum levels proposed are Folate, Niacin and Biotin.

When energy is not expressed as a nutrient, NZDA perceives this is a concern, when maximum levels of nutrients are provided as a proportion of energy.

NZDA stresses that proposed changes to the composition of FSMP should not adversely affect the availability to users and consumers.

It should also not affect the pricing structure so many become unavailable to the consumer and hospitals due to inflated prices resulting for the manufacturing charges.

5.5 Labelling of FSMP

NZDA recommends that all products should be compliant with international labelling requirements. Specific requirements of FSANZ that fall outside of these requirements will have major ramifications for industry and consumers as noted earlier.

Australia and New Zealand make up a relatively small percentage of the world market for FSMP. To have labels specific for compliance of the FSANZ when labelling already meets the requirements of the United States of America and the European Union labelling proposal would: -

- Increase the cost of product ultimately to the consumer as 90% plus of current product would fall into the non-compliant range.
- Reduce the range of product currently available to the New Zealand and Australian markets as manufacturers would limit the range of product due to the cost of complying with the legislation.
- Reduce the range of product available for specific medical conditions for the above reason. Consumers thus will be disadvantaged, if for example, their condition requires a specific ratio of nutrients. This could in turn affect their health and general well being.

- Due to improved technologies and scientific advancements consumers may be disadvantaged because companies will not be able to provide the range of up to date product available in other countries.

Products should have sufficient information on ingredients and nutrient composition to ensure the correct product selection and dose prescription (including frequency and volume) to meet individual needs as prescribed by medical practitioners and dietitians.

5.5.2 Specific Labelling Requirements for all FSMP

Inclusion of a mandatory advisory statement that FSMP's are to be used only under medical supervision, preceded by words to the effect of "Important Notice".

Some products already state that the product should be used under medical supervision.

NZDA would like to recommend the word 'dietitian' be added to that of "under medical or dietetic supervision".

The implication would be that consumers need to seek advice on the use of these products, thus reducing the risk to the public.

However, not all products would need to carry this warning due to unnecessary concern for consumers.

NZDA supports the inclusion of the labelling 'not for parenteral use' for all products specifically for oral or enteral consumption

NZDA supports the inclusion of a list '*concerning the adequate precautions, known side effects, contraindications, and product-drug interactions '*

While we appreciate the reference for the safety of the consumer, this is however difficult to state as a mandatory requirement. Many consumers can achieve detrimental effects to their health by eating a 'normal' diet. For example, patients on medications like Frusemide may be recommended by their doctor to eat bananas to raise their level of potassium. We have no control over the volume eaten and/or the effect this may have on the health of the individual.

NZDA supports the inclusion *'a statement that the product may be unsuitable for use by pregnant, nursing and lactating women or by infants, children, adolescents and elderly'*

'A statement on the recommended daily quantity … by established by the manufacturer of the VLED.'

NZDA does not support this recommendation that the daily serving volume/ dose is established by the manufacturer. Dosage or volume and/or

concentration are patient specific as prescribed by the medical or dietetic practitioner. For example in New Zealand some VLED products are used in the control of insulin resistance for patients with diabetes mellitus. The volume or dose prescribed is dependent on many factors including biochemistry and other medically related conditions, eg the patient's weight and height.

NZDA would recommend that where products are genetically modified or food is irradiated, this is indicated on related information of the product. Consumers are entitled to have this information.

5.6.3 Microbiological Standards

NZDA agrees with this recommendation for guidance on the handling and food safety management of these products, given the higher at risk status of the target population.

7.2.2 Option 2 Regulation by a discrete standard in the Code

While NZDA and dietitians are not directly affected by a Cost – Benefit Assessment, in the interest of the consumer, we recommend further investigation is made to clarify the anticipated costs to both the industry and the consumer before Option 2 is considered for implementation.

8.2 External Advisory Group

The NZDA would welcome the opportunity to express an interest in nominating a representative to participate in the External Advisory Group (EAG).

As key stakeholders in this process, dietitians are the only group of health professionals with the knowledge and scientific background to translate scientific knowledge into language the consumer can relate to.

While it is equally important to have representation on the EAG from industry and regulatory bodies, it is also important to have those who are familiar with the range of products and their intended use, represented as well.