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FOODS FOR SPECIAL MEDICAL PURPOSES

PROPOSAL P242 – INITIAL ASSESSMENT REPORT

The National Council of Women of Australia Ltd., (NCWA) are dismayed to learn that there are some foods in the market place that are essentially 'unlawful' whatever the reason for this may be. Council supports this situation being remedied with specific regulation catering for each category of special need, including Foods for Specific Medical Purposes. (FSMP)

Our advisors favour option 4, Full Regulation. This is the option based on existing Codex standards and offers the greatest protection to both the government and consumers, besides consistency and assurance for industry. Whilst this option would require some increased costs to industry, so does every other option. We do not accept that a reduction in product range would necessarily follow, in fact it is quite likely that industry will 'innovate' to bring in new products. 'Costs' are consistently used by ANZFA as an excuse for reduced availability and choice of products' to consumers, but proof of this is never provided. Our advisors expressed surprise that very few, if any, of these Foods for Special Medical Purposes are produced locally, and wonder if the market is large enough here to warrant their manufacture in Australia?

Option 1 is clearly no longer acceptable.

Option 2 relies only upon definitions which are open to interpretation. In addition all food should be under a Standard to be consistent with the system. We note there is no definition as yet for FSMP, but favour that of Codex.

Option 3. Co-Regulation, when dealing with such a special class of foods is not acceptable to consumers. Codes of Practice are not enforceable, (unless mandatory and this allows the government and regulators to opt out of responsibility, regardless of whether they helped design the Code or not. Industry should not be responsible for enforcement of a food standard, this is properly the role of the government authorities. Under 'costs' for this option it is recognised that this option may compromise regulatory objectives, increase the ambiguity of enforcement and ultimately lead to reduced public health and safety.' Therefore this option is not supported.

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Option 4 has Council's support for reasons stated above.

Option 5. This option is aimed solely for increasing ease of marketing, not for public health and safety. It is a messy alternative with no clear benefits for consumers. In fact, the benefit claimed for the consumer/health professionals under this option, more correctly pertain to industry, i.e. 'potential for greater regulatory flexibility in approval of a wider range of products'.

Council does not support industry taking a more proactive role in enforcement and monitoring. This is not their role. Council does support patients that have been prescribed FSMP in hospital, being monitored after they leave hospital if they need to continue to use such products. This again is not the role of industry, it is the responsibility of the relevant Authority. Industry should be responsible for the safe formulation and manufacture of these food products and responsible marketing of them, nothing more.

Council agrees with the Codex General Principles applying to the FSMP Standard, i.e. 'the formulation of foods for special medical purposes should be based on sound medical and nutritional principles. Their use should have been demonstrated, by scientific evidence, to be safe and beneficial in meeting the nutritional requirements of the persons for whom they are intended.' We would assume the 'beneficial' would naturally take into account efficacy.

Should FSMP be regulated as special purpose foods and why? (page 14)

Yes, simply because they are **not** foods intended for general use by the public, but are 'prescribed' for a specific medical purpose by a qualified practitioner.
If not issued through hospitals or by prescription, it would be possible for non-qualified people to prescribe or suggest use – this is recognised as a concern on page 15 of the Paper, final paragraph.

Should FSMP be required to conform to the existing Standards as listed above? Please explain.

In the main yes, but perhaps not all would be applicable. For example Standard 2.9.3, formulated meal replacements and supplementary foods or the addition of vitamin and minerals might not apply. It is possible that a category to cover FSMP would stand alone without these particular standards (or have specific requirements for them outside the present standard), whereas others mentioned, such as labelling would still apply.

Council would support the Codex Standard's definition of Foods for Special Medical Purpose, i.e.:-

A category of foods for special dietary uses which are specially processed or formulated for the dietary management of patients and may be used only under

medical supervision. They are intended for the exclusive or partial feeding of patients with limited or impaired capacity to take, digest, absorb or metabolise ordinary foodstuffs or certain nutrients contained therein, or who have other special medically-determined nutrient requirements, whose dietary management cannot be achieved only by modification or the normal diet, by other foods for special dietary uses, or by a combination of the two.

Questions, page 15:-
Whilst the New Zealand Dietary Supplementary Regulations create a separate category for dietary supplements in addition to those for foods and medicine/therapeutic goods, FSMP are not considered medicines in that country since they are not used for a therapeutic purpose. Therefore the most sensible approach would be to adopt the Codex Standard and definition. It should be noted that the Codex definition specifically refers to being used only under medical supervision and refers to 'patients', which is the line favoured by Council. In addition it also calls the standard 'Foods for special Medical Purposes' which Council also sees as being relevant and consistent internationally.

The defining components should be that such foods conform to the Codex definition, which is appropriate internationally and therefore should be domestically, that such foods are prescribed either by prescription or through hospitals, and are monitored for both compliance and efficacy upon the commencement of treatment. FSMP should be treated as a sub-classification to 'Foods for special dietary uses' and incorporated in Volume 2 of the Food Standards Code.

Composition of Foods for Special Medical Purposes:
It is expected that any food prescribed under this section would have the implications of its consumption thoroughly understood by the person responsible for prescribing it. Indeed the definition and the principles underlying the production of and prescribing of FSMP under Codex expect this too. Council sees no reason why, even though most of these formulations are produced overseas, their modus of operandi and the expected outcome of consumption should not be understood. If a particular product was not thought by the prescribing authority to be able to achieve the desired result, then surely the product would not be used, even if it was allowed to be imported into the country. If there were no sales, the product would most likely be withdrawn by the manufacturer. There is no 'trade barrier' on the product coming into the market if it meets all the regulatory requirements and is able to do the job it was designed to do.

Council appreciates there may be a need to vary the amount of nutrients from the general standards, e.g. vitamins etc.. Provided the use of such variants are safe and efficacious, then this is what the standard is set up to cater for.

Nutritive Substances:
Most of this section Council would agree with. However we do not support the Standard covering an 'extensive array of biological substances', if this refers to those that have been genetically engineered. We do not considered there has been sufficient

study done to show these substances to be safe in the long term. There have been no human studies conducted and so GM nutritive substances should not be prescribed for already severely compromised patients.

Council appreciates the difficulty in meeting the 'complete nutrition' needs of vulnerable individuals and recognises that complete nutrition changes in response to new medical discoveries and technological advances. Whilst Council welcomes the Authority's view, is it surprised that ANZFA is concerned here in 'maintaining quality' as quality is a parameter they have consistently maintained is not one that should be laid down in a standard.

Questions:-

Are there any health and safety risks to consumers associated with the composition of FSMP?

If adequately regulated, there shouldn't be.

Relative to risk should FSMP have compositional regulation?

Council sees that there would be a number of formulations which will come under this standard. It may not be feasible to have one compositional requirement, except perhaps where a product is used as a 'nutritionally complete' food and even this will alter as medical advances are made. It would appear to depend under what circumstances a particular product is prescribed. These will vary. A schedule, similar to that drawn up for vitamin and mineral additions, could be established for nutritive substances in FSMP. Such substances would need to have been shown as safe, and an upper limit established. It would also need to have efficacy established.

Does a public health and safety risk exist in the unrestricted access to FSMP?

Yes, through self diagnosis and treatment.

Are there any situations in which you believe ANZFA should restrict the sale of FSMP?

Yes – unless prescribed by hospital or medical practitioner or health professional as specifically authorised.

If so, then where should FSMP be available and in what manner should they be accessed? Should product labelling reflect any restriction on access, e.g. Pharmacy only product?'

A pharmacy would be the best outlet and the products should carry the 'Pharmacy Only Product' labelling.

Labelling of Foods for special Medical Purposes:

It is of concern to read that 'currently *most* FSMP labels include product identification, full ingredient listing, nutrition information panels, date marking and lot and batch numbers. Why are not all supplying this? The majority of these foods are coming from Europe and the USA, both these areas are familiar with international requirements and there is no excuse for them not labelling according to the Codex

Standard. If the majority of suppliers are supplying this information, then they all can. Requiring information specific to the country of export is not imposing an 'inappropriate regulatory constraint' (page 18) and it is difficult to see how ANZFA would equate insisting on this with forcing some suppliers out of the market and restricting access to the products. The majority of civilised countries have certain labelling requirements which must be complied with if another country wants to export to them.

However, if it is perceived that there may be difficulties arise with local labelling requirements, the only information which would now be required in addition to that which ANZFA says the majority are already supplying, is the local supplier/contact details and local reference values. 'Pharmacy Product Only' and/or some advisory warning such as 'Use under medical supervision' which is already being voluntarily placed on labels. However, most changes are usually gazetted with a suitable lead in time, and doing so in this case would certainly alleviate the problem.

Labels remains the single most effective manner in which to deliver information to consumers. Whilst an ill person may take no interest in these products whilst in hospital, it is a different matter when they are having to use FSMP at home under medical supervision. The point that 'most' local suppliers ensure accompanying product information contains local information including suppliers contact details and appropriate local reference values etc., is not good enough. The person consuming these products must have the right to this information too. Inserts are often lost whereas the label is usually there to refer to if need be.

ANZFA asks, 'If changes could not be made on product labels, what is the best way to ensure all necessary information is available to the end consumer? What information is considered necessary?' Council does not believe that changes could not be made. They obviously could, but at a cost. If these products are to be regulated under the Food Standards Code, then the same information that consumers currently receive under the Standards for other foods should be available for FSMP.

Warning and Advisory Statements:
FSMP should not be exempt from Standard 1.2.3 and warning statements should apply. Council agrees that the person recommending the product should take the responsibility for doing so and consider the appropriateness of the product. We maintain these foods should be taken only under medical supervision, and consequently it is that medical advisor who has this responsibility. He/she should ensure that regardless of the label and any accompanying information, the patient fully understands about the product. Council applauds those products voluntarily carrying the warning statement, but feel it should now be mandated. Label declaration is necessary regardless of what material is given the patient and what information the doctor chooses to give the patient. Labels ensure a point for future reference should the patient 'forget', or loose the insert.

Whilst Council would have no objection to other 'health professionals' being able to recommend and supervise the use of FSMP, there would need to be a very clear definition set out as to who would come under this term. In addition, such health

professionals should not be able to market (sell) FSMP. These products should still have to be obtained from a pharmacy, doctor or hospital, and not from a supermarket.

Health and Related Claims:
Council has previously advised it does not favour the introduction of health related claims. Those proposed are so varied and diffuse that consumers will have a difficult time understanding the difference between them. ANZFA's proposed substantiation for these claims is defined as having to be 'convincing'. Convincing to whom? To ANZFA?
Some studies that are presented in relation to other applications, particularly those dealing with genetic engineering applications, ANZFA has found 'convincing' enough to recommend approval of the application against the views of other scientists presented to them that are not so convinced! ANZFA's definition of 'convincing' is anything but conclusive and that is what is needed - conclusive proof for a health claim to be made.

The promotion of FSMP should be directed to the doctor/health professional, not the patient. These are not normal foods, but to be taken only under direction of someone qualified to treat a particular condition. There should not be advertising to the general public of FSMP.

Council is at this point undecided about whether permission to make reference to a particular disease state is wise. If all other precautions were taken, i.e. the warning statements on labels, FSMP being only obtainable from pharmacists or hospitals, prescribed only by those qualified to treat, and no marketing to the general public, it might be allowable However, marketing is always a problem and unless this was 'controlled' then the public may unwisely seek to 'treat' themselves without benefit of medical advice or supervision. This would not be desirable.

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