03/02/2003

SUBMISSION

DRAFT ASSESSMENT REPORT

PROPOSAL P242

FOODS FOR SPECIAL MEDICAL

PURPOSES

The Stakeholders in this submission are:-

- Dr. Tim Orchard – Medical Practitioner and Managing Director of
- ORFAM PTY LTD

The content of this submission relates to sections of proposal P242, which refer to foods for special medical purposes (FSMP) – Very Low Energy Diets (VLED's) for obesity management.

This is the only area of this proposal in which the stakeholders currently have a vested interest.

BACKGROUND:-

Dr. Tim Orchard is a medical graduate of Monash University (1970). After 20 years of general medical practice he decided in 1990 to limit his practice to the special interest area of the management of overweight and obesity and co-morbidities.

It is generally recognized by his peer group that he has had more experience and treated more patients using VLED's than any other practitioner in Australia.

He has held a Clinical Teaching Fellowship at Queensland University of Technology, School of Human Movement Studies for 5 years until 1999, is a foundation member of ASSO (Australasian Society for the Study of Obesity) also serving on ASSO Council for 2 terms and is currently a member of the Obesity Advisory Panel of Abbott Australasia.

Together with Prof. Tim Welborn (Perth) and Prof. Mark Wahlquist (Melbourne) he wrote a submission on behalf of ASSO relating to the old proposal P49, abandoned in favour of P242.

ORFAM PTY LTD is a 100% Australian owned company, which over the past 10 years has developed and distributes a range of nutritional products including a VLED.

Originally developed for use in Dr. Orchard's practice and intended to offer consumers (patients) a wider variety of choice in a locally manufactured and more cost effective product than otherwise available, ORFAM's VLED is, as a result of approaches by other medical practitioners, now used in private general and specialist medical practices around Australia.

Before commenting on the specifics of the Draft Assessment Report of Proposal P242 it is noted that on page 26, 8.3 that FSANZ is seeking expressions of interest from Stakeholder groups in participating in an External Advisory Group.

Dr. Orchard would like to volunteer his services to be involved with this Group.

As to Proposal P242 we are delighted to see this proposal taking shape and are generally supportive of the spirit and the detail of the Draft Assessment. However, there are some areas on which we would like to comment.

OPTIONS:-

Not having had an opportunity to comment on the Initial Assessment of 10/10/01 and the 5 regulatory options proposed, we are pleased to see that the Draft Assessment has not only narrowed the regulatory options down to the 2 most workable, but is recommending Option 2 as the preferred choice to become the Code Standard.

We support this for all of the reasons outlined in paragraph 2 on page 7 but there will be a cost to industry to comply with the provisions of Option 2. Inevitably the extra cost will have to be past on to consumers. More on this directly.

DISTRIBUTION AND ACCESS:- 5.3.1

We agree that the current arrangements do not need change and that mandatory labeling for "use under medical supervision" should be sufficient safeguard.

ADVERTISING:- 5.3.2

While we can see that there would be little point in the general advertising of the majority of FSMP except in professional journals, we feel that the restriction should not apply to VLED's.

We do not advertise our VLED so the proposed ban on general advertising would have no effect on us but here is the problem:-

Formulated Meal Replacements (Standard 2.9.3) are advertised widely particularly on television often being recommend by high profile personalities. They have brand names that leave no doubt as to their intended purpose – SURESLIM,

SLIMFAST etc. These products are used by the general public as 'defacto' VLEDs. We are constantly seeing patients who self treat with these products inappropriately.

The consumer doesn't understand the difference, they just see a powder in a packet or a drink with the word "slim" incorporated somehow in the brand name and assume all products are the same.

We contend that the potential for inappropriate use/abuse is much greater with these freely available and nutritionally inferior products than for VLEDs.

Why would you therefore restrict advertising of the properly formulated and responsibly used products?

Surely the consumer needs to know and be given an opportunity to understand the difference and possibly make a more appropriate and safer choice.

It's all very well to restrict to advertising to professional or "trade" publications but the consumer/patient doesn't have access to these. They get their information from television, magazines, slips of paper under windscreen wipers, letterbox drops, roadside signs etc.

This is a major problem in clinical practice and FSANZ really needs to consider revisiting controls in Standard 2.9.3. But this is outside the scope of this submission.

HEALTH PROFESSIONAL PUBLICATIONS 5.3.3

Should the decision be made to restrict the advertising of FSMP including VLEDs, we would suggest that a little more latitude be given than just "health professional publications" and what is the definition of a health professional anyway? Does it include any body or individual who simply by deciding to dabble in health related areas regards themselves as a health professional but may have had no formal training and never had to submit their theories or therapies to scrutiny by the accepted medical standards.

Would you preclude the newsletter of a private health fund eg MBF, Medibank Private, from advertising to its members that a treatment method was available and how to access it?

COMPOSITION 5.4

Our formulation will need some rework to comply with the proposed Standard. Currently using the reference standard of 3 serves per day, we provided 45.6 grams of protein, 57.6 grams of carbohydrate and 1920 kilojoules. Modest changes in reformulating to comply will be required which present no technical difficulty but when added to the extra cost of repackaging and re-labeling our estimates are that there will be a cost increase of approximately 20% ex factory.

LABELING 5.5

Again we have no objection in complying with the provisions of paragraphs 5.5.1 and 5.5.2 but do have some concerns about 5.5.4.

We cannot see the need for a statement on VLEDs saying "for the dietary management of obesity". We would have thought that this was self evident but at the same time have no objection to including this statement should this be the decision.

We do feel however that it is quite unnecessary to include statements regarding fluid intake, unsuitability for pregnant, nursing, lactating women, infants, children, adolescents and the elderly.

As VLEDs are to be used and should be used under medical supervision this information and assessment of suitability should be given and made by the prescribing practitioner.

If warning statements like this are to be made then also included on the list should be type 1 diabetes, recent stroke and heart attack patients, renal disease, patients on certain drugs, patients with a history of certain mental illnesses etc.

As to recommend daily quantity this also should be a decision for the supervising practitioner as this could vary considerably from one patient to another.

OTHER COMMENTS

Finally the 2 year transition period is quite reasonable.