Mr J Carapiet
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20 11 01

Dear Anzfa,

Submission on Proposal P242

This submission opposes the proposal for Anzfa to consider and recommend regulation of FSMPs because FSMP's are characterised by Codex, (and other international standards), as associated with professional medical supervision, and as such should be dealt with as medicines, in the interest of public health.

Despite the name, FSMP'ss are not foods. The current absence of " prescribed standards and regulations of FSMP's under Anzfa's auspices is not in itself a problem as long as they continue to be regulated (ie the status quo option?), as goods with a therapeutic aim, effect and public health impact.

The crucial requirement for medical supervision is a defining aspect of FSMP's an should not be downgraded to allowing "other " medically-trained professionals to oiversse use without that medical oversight. This is because of the potential for complex interactions and effects on the body of any therepeutic and active substance that falls outside of " normal balanced eating".

There are serious public-health negatives from moving towards minimum effective regulation and voluntary industry codes which will run counter to current efforts to promote amongst the population balanced eating of ever-day foods including campaigns for "five-a day" for fruit and vegetables.

In support of this submission, the following points are noteworthy:

1)The Codex standards specifically refer to " dietary management of **patients"** where a normal diet or special-food diets cannot achieve the medical result desired**.**

2)EU guides also specifically mention "medical supervision". Any legislation or regulatory change that seeks to reduce this defining-criteria for FSMP regulation is not in the interest of ongoing management of Public Health issues. This is important as the priority given to public health in Anzfa's responsibilities should not be forgotten in this current process in favour of industry or trade benefits.

3)The Australian Therapeutic Goods Act 1989 is described by Anzfa as placing
" a number of products in the position of being clasified as either a food or a therapeutic good."

This is not a flaw. Clear definitions between food and medicine are a necessary aspect of regulation and have significant cultural aspect, especially for Maori. It is a vital requirement for adequate protection and management of public health. Being able to define may not always be easy but in doubt the precautionary principle should apply and all FSMP should be recognised as medically-active agents.
4) Maintaining regulation of FSMP's as therapeutic goods will make it easier for industry and other stakeholders to deliver against reqiured supporting information for claims, clinical testing, efficacy etc. Side-efffects could be advised to the medical supervisor and labelling issues raised as a concern by Anzfa would also be addressed and harmonised by requiring comprehensive detailing as ordinarily required for other medicines.

5) It is noted that the advice from the Australian Competition and Consumer Commission on the propsal P49 warned of difficulty in " a code that sought to restrict the sale and advertising of a food".
The inability to regulate potentially powerful effects achieved via FSMP's should ring alarm bells at Anzfa, in regard to the protection of public health.
Importantly, as FSMP's are not foods and for public health reasons should not be assessed as foods, such concerns will not be warranted on regulation of FSMP's as medicine.

6) Compositional regulation of FSMPs is best managed by medical protocols and testing which befits the nature of the substances, potential impacts from use, and the need to recognise that self-medication by people is not appropriate without medical supervision of a therapeutic effect, ie " preventing, diagnosing, influencing, susceptibility, testing for pregnancy " etc.

I urge the Anzfa to recognisethe serious threat to Public health management from deregulation and a shift in definition of food to accept this new category of medicines.

Yours sincerely

Mr J Carapiet