

Australian Medical Association Limited

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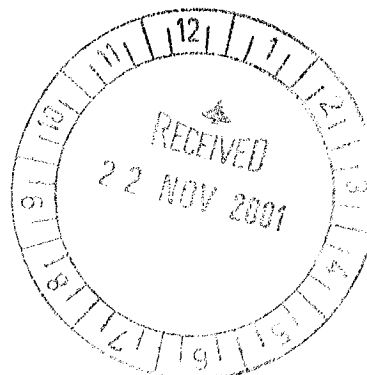
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DOI/5414

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ANZFA
PO Box 7186
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22 November 2001

ENTERED IN DATABASE
22.11.2001**Re Submission re Proposal p242 - Foods for Special Medical Purposes**

The AMA would like to thank ANZFA for asking the AMA to provide a submission to ANZFA in response to your Initial Assessment Report. It is understood that a draft assessment report will be prepared as a result of this round of consultation and that further input will be sought at that stage. The AMA would welcome the opportunity for further comment on your draft assessment report once produced.

The Initial Assessment report does not make it clear who is being asked for submissions at this point in the consultation. It is suggested that the Royal Australian College of Physicians (including Paediatricians and Public Health Physicians) and Royal Australian College of Surgeons also be consulted for comment.

The AMA would like to make the following comments:

1. A range of different definitions of foods for special medical purposes (FSMP) is cited in your paper from varying international sources. The Codex Standard definition appearing on page 5 of your paper is most acceptable to the AMA as it acknowledges that these foods should be used only under medical supervision. The definition reads:

"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 of the normal diet, by other foods for special dietary uses, or by a combination of the two"

2. The AMA is of the view that FSMP should be used under medical supervision and treated in the same manner as pharmaceutical products. As such FSMP such be treated in the same way as therapeutic products.

The AMA endorses the following principles in its policy statements in relation to therapeutic products:

- "Therapeutic goods should be of high quality, effective and safe.
- The interests of patients should be paramount in deciding whether these criteria are met. In coming to this decision, benefits and risks should be assessed against each other.
- Regulation by the proper medical body should be sufficient to achieve the first two principles and should facilitate early marketing in Australia of therapeutic goods that are assessed as meeting the criteria. Over-regulation in this area is undesirable"

3. Specific provision should also be made for labelling and composition of FSMP. Providing both provider and consumer product information should be part of this process

4. The AMA view would be that Option 4 as outlined in your paper, as the full regulation option is the preferred option.

5. The AMA believes that some special mention should be made of infant formulae. The AMA notes that in Australia's revised infant feeding policy the dietary guidelines for children and adolescents promotes exclusive breastfeeding for the first six months of life. Alternatives therefore require tight regulation. The AMA believes that because of their content, infant formulae and similar products should be treated as pharmaceuticals. The regulation of infant formula for very young infants is not like regulating foods for adults with a varied diet, who have mature immune system and gastrointestinal systems, food choices and a variety of food sources. This nutritionally vulnerable group needs some protection. Tighter regulation, better labelling and appropriate pricing is required to assist with appropriate choices being made in the best interests of the infant.

I am happy to discuss these issues with you further.

Yours sincerely

A/C Director
Health Services Department

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