

CMEC 5

**Complementary Medicines
Evaluation Committee**

Extracted Ratified Minutes

Fifth Meeting

Thursday, 14 May 1998

Complementary Medicines Evaluation Committee

Item 1 Procedural matters

Item 1.1 Opening of Meeting

The fifth meeting of the Complementary Medicines Evaluation Committee was held at the Ansett Golden Wing Lounge, Sydney airport on Thursday, 14 May 1998.

Members of the committee present were:

Professor David Roberts, Chairperson
Professor Jorma Ahokas
Dr Roberta Chow
Dr Colin Duke
Ms Val Johanson
Professor Chiang Lin
Dr Stephen Myers
Dr Anne Tonkin
Mr Allan Ware

Also present from TGA were:

Mr Terry Slater
Dr Helen Cameron
Ms Pat Brown

Professor Roberts opened the meeting at 10.05 am and welcomed members.

Item 1.2 Apologies

Apologies were received from Dr Joachim Fluhrer.

Professor Roberts noted that Ms Gwenda Cannard had resigned from the committee. He thanked Ms Cannard for her contribution to the committee.

Item 1.3 Conflict of Interest

Conflict of interest forms were completed by the members and handed to the chairperson.

Item 2 Confirmation of Minutes

Item 2.1 Confirmation

The minutes were confirmed.

Item 3 Action Arising from Previous Meetings

Item 3.1 CMEC 4 Meeting

Item 3.1.1 Shark Cartilage

Item 3.1.1.1 Potential Conflict of Interest

A member advised that they may have a possible conflict of interest in relation to this item. Professor Roberts ruled that there was no conflict of interest.

Item 3.1.1.2 Shark Cartilage - item 4.1 of CMEC4 refers

Dr Cameron introduced the item and members noted the following information contained in the agenda paper;

- In December 1997, following advice from the External Reference Panel on Interface Matters (ERPIM), public comment was sought on a proposal to declare goods containing isolated shark cartilage, or labelled or promoted as containing shark cartilage, to be therapeutic goods. Such a declaration is possible under section 7 of the *Therapeutic Goods Act 1989* (the Act). Under this section, the Secretary of the Department may declare certain goods to be, or not be, therapeutic goods when used, advertised, or presented for supply in a particular way. Public comment closed in late March 1998.
- The proposal for a declaration arose out of concern that many shark cartilage products are promoted for therapeutic use but are being sold as foods. In some cases the promotion for therapeutic use occurs in point-of-sale promotional material or on the Internet, rather than on the product label. Therapeutic uses for which shark cartilage is promoted include cancer inhibition, arthritis and psoriasis treatment, and healing of sporting injuries.
- The rationale provided for the proposal was as follows:
 - Shark cartilage has no principal food use since its value as a source of nutrients is low. It may contain protein but not of quality compared to other foods. Shark cartilage is perceived to be a therapeutic good

because of the widespread promotion as an immunostimulant, for use in treating arthritis and cancer.

- Shark cartilage is not currently in any products on the Australian Register of Therapeutic Goods. Shark cartilage would be treated as registrable unless accepted as listable. Products containing shark cartilage may only be listable on the Register if they were generally regarded as safe, and were associated with claims for only minor, self-limiting conditions. Applications for inclusion of shark cartilage products on the Register would have to include data to support a safety evaluation.
- Section 7 declarations do not change the requirements of the legislation. They are intended to provide greater clarity and certainty for sponsors and regulators by resolving the status of certain products at the food/drug interface. Legitimate food use of shark cartilage, such as in soups and Chinese cooking, would not be prohibited if the proposal were to go ahead.

Summary of public submissions

- In general there was less support expressed in public submissions, for declaring shark cartilage to be a therapeutic good than there was for either declaring it not to be a therapeutic good, or retaining the status quo of case-by-case assessment. In part, this lack of support arises from a misunderstanding of the implications relating to the declaration. Many respondents thought that declaration as a therapeutic good would prohibit all food use of shark cartilage. Several respondents supported the proposal only if shark cartilage were to be permitted in listable products, where the cost of applications for inclusion on the ARTG is lower and the data requirements less stringent. Issues raised fell into five major categories.

Shark Cartilage as a recognised food use

- Particularly among Asian communities, shark cartilage has a long-standing use as a food. As a non-Asian food, shark cartilage is sometimes consumed in soups or in flavoured drink bases. One respondent likened shark cartilage powder to gelatine, which has an established use as a food but is extracted from the bones and cartilage of calves.
- Many respondents claim their product is sold only for legitimate food use. For example, one respondent claimed to market its shark cartilage as a food supplement with no associated therapeutic claims. However its Internet site contains dosage recommendations, instructions for rectal use and reference to the TGA. Some Australian producers export most of their product in the form of powder, to Asia and the US. For example, Lane Labs in Brisbane produces, as a food, a product known as BeneFin; this is then exported to the US where it is sold for therapeutic use in the form of powder, capsules and caplets.

- Shark cartilage contributes a range of nutrients, particularly energy, protein, calcium and phosphorus. No data are available concerning the amino acid composition of shark cartilage protein, so it is difficult to reach a conclusion as to the value of its protein compared to other foods. Even small doses of cartilage (eg 5 g per day) would contribute significant levels of calcium as shark cartilage contains up to 20% calcium.
- The levels of shark cartilage consumed vary depending on whether or not the cartilage is being used as a food or to gain a therapeutic effect. For food use, intakes may range from approximately 10 to 250 g per serve. In the case of therapeutic use, the conditions being treated affect the recommended dosage. Recommended daily doses range from around 1 - 5 g for maintenance doses for arthritis and psoriasis, to up to 90 g for cancer treatment.
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If shark cartilage is to be declared a therapeutic good, it should be able to be used in listable products

- Some respondents recognised the value in declaring shark cartilage to be a therapeutic good, particularly in relation to the restriction this would place on the type of claims that can be made for the product. However they indicated that the high cost and stricter data requirements of Registration would restrict the ability of many smaller companies to submit applications. CMEC has already recommended that shark cartilage is suitable for use in listable products, given the absence of major safety concerns.
- One respondent noted that regulatory authorities already have the power to act against non-conforming shark cartilage products, and that enforcement of existing regulations could address problem products.
- The NFAA indicated that it would support a modified declaration that shark cartilage products presented in the form of a capsule, tablet, powder or pill be considered to be therapeutic goods, subject to shark cartilage being able to be used in listable products. It should be noted that some of the products claiming principal use as a food are sold in the form of a powder.

Absence of public health problems arising from current use

- Some respondents cited the absence of any safety concerns as indicating that the current regulatory system is operating effectively. At its last meeting, CMEC did not identify any major health risks associated with shark cartilage use, although it was agreed that warning statements should be required in regard to the potential for suppression of angiogenesis.
- According to the Australian Quarantine Inspection Service (AQIS), there may be problems of microbiological contamination of shark cartilage, based on the

observed use of irradiation and ethylene oxide sterilisation by the Australian industry. Irradiation is not permitted for food products although it is not specifically prohibited for therapeutic goods. No data are available concerning the microbial flora of shark cartilage, nor on the levels of organisms in products for sale.

Stricter production requirements for therapeutic goods than for foods

- Therapeutic goods must be manufactured in premises licensed by the TGA, to pharmaceutical level Good Manufacturing Practice. These GMP standards are stricter than those applying to food manufacture. Therefore declaring shark cartilage to be a therapeutic good will require many manufacturers to upgrade plant and equipment, which would entail considerable cost.

Potential for disruption to markets and for economic loss

- Some respondents expressed the concern that changes to the regulatory status of a product can result in market uncertainty and the potential loss of sales. In particular, companies with established Asian export markets were worried that any change to regulatory status in Australia may impact negatively on sales of their products, with consequent financial and employment loss.

CMEC was requested to consider:

- the appropriate regulatory status of shark cartilage;
- a proposed label warning statement for therapeutic goods containing shark cartilage; and
- a proposed monograph for shark cartilage.

Recommendation to TGA:

- **that a proposal that shark cartilage in forms such as powder (subject to evidence of use as a food), capsules, tablets, and pills, be declared to be therapeutic goods, under section 7 of the Act, be circulated for a second round of public comment.**

The reasons for this recommendation were:

- There is widespread promotion of shark cartilage for its therapeutic uses.
- Legitimate food use (eg in soups) would not be prohibited.
- Sponsors of products included on the ARTG would then be able to make legal therapeutic claims on their product's label.
- CMEC has already recommended that shark cartilage is of sufficiently low risk to permit its use in listable therapeutic goods.
- CMEC could also consider amending the wording of the declaration, for example to indicate that shark cartilage products presented in the form of a

capsule, caplet or tablet are therapeutic goods.

The following warning statements were considered by CMEC: (Different point sizes were presented for illustration):

Not suitable for use by children, pregnant or breastfeeding women, or those who have recently had a heart attack, surgery or a major accident, unless recommended by a health practitioner. (1.5 mm type)

Children, pregnant or breastfeeding women, and those who have recently had a heart attack, surgery or a major accident should not consume this product unless recommended by a health practitioner. (2 mm type)

Don't consume this product if you are pregnant, breastfeeding or have recently had a heart attack, surgery or a major accident, unless recommended by your health practitioner. This product is not suitable for use by children without medical advice. (3 mm type)

Recommendation to TGA:

The following warning statement be included for discussion in the proposal:

Children, pregnant or breastfeeding women, and those who have recently had a heart attack, surgery or a major accident should not consume this product without medical advice. (1.5 mm type with consideration of larger type for larger containers)

This recommendation was made subject to more information being received about the use of shark cartilage powder.

At CMEC4, concern was expressed at possible heavy metal contamination of shark cartilage when sharks have been living in contaminated waters. The TGA was asked to provide information on the possibility of incorporating the Food Standards Code limits for heavy metal contamination into a standard for therapeutic goods containing shark cartilage.

Members noted the information from the Food Standards Code (Standard A12) relating to relevant limits for heavy metal contamination. Limits specified are either those applying to fish or seafoods, or general food limits where these are given.

The limited data available suggest that lead contamination may be a problem with shark cartilage and that some products now available as foods would be illegal on the basis of contamination. If the Food Standards Code limits were to be adopted, existing products would not be disadvantaged, although enforcement of these limits could require removal of some products from the market.

As noted at CMEC4, the Bureau of Resource Science's National Residue Survey will in future examine heavy metal levels in shark cartilage, as well as other seafood products, but at present no comprehensive survey has been conducted.

At present there are no pharmaceutical monographs for shark cartilage. Under TGA procedures, approved names must be allocated to all substances used in therapeutic goods. These names must be referenced to a monograph, although this monograph may be one produced by the TGA in the absence of any other published monographs.

Recommendation to TGA:

A proposed monograph for shark cartilage be circulated for comment as follows:

Definition

Shark cartilage is the cartilaginous material derived from species of the class *Chondrichthyes*, sub-class *Elasmobranchii*. It has been cleaned of adhering flesh and blood and may or may not be dried and milled.

Contaminants

Shark cartilage shall not contain more than the maximum permitted concentrations of the following metals:

Metal	Maximum permitted concentration
Lead	0.5 mg/kg
Copper	10.0 mg/kg
Mercury	1.0 mg/kg
Arsenic	1.0 mg/kg as inorganic arsenic
Antimony	1.5 mg/kg
Selenium	1.0 mg/kg
Zinc	150 mg/kg

Methods of analysis

As specified in the US Pharmacopoeia.

This monograph would be included for comment in the proposal for a section 7 declaration for shark cartilage when it is circulated for a second round of public comment.

Recommendation to TGA:

- **that TGA laboratories assay the heavy metal levels in shark cartilage products currently available on the market.**

Item 3.1.2 Kava - Submission to NDPSC - item 5.1.2 of CMEC3 and item 3.1.4 of CMEC4 refers

Members noted the submission prepared by CMS on kava for the National Drugs and Poisons Schedule Committee. CMS was complimented on the preparation of the paper.

Item 3.1.3 Report from the Working Party on Priorities for the Review of Herbs - Item 3.1.1 of CMEC4 refers

Dr Myers tabled a report of three meetings of the Working Party held by teleconference on Friday 17 April with members of the TGA (Laurayne Bowler and Helen Cameron) and on Friday 8 May and Wednesday 13 May.

Dr Myers addressed the four matters in his report as follows:

- Review of ADRAC Reports
- Development of a List of Herbs on the Australian Market
- Literature Review
- International Resources

Recommendation to TGA:

that Kerry Bone and Steven Clavey be co-opted as members of the Working Party on Priorities for the Review of Herbs for the meeting on 10 June 1998 in order to expedite the Working party's deliberations.

Item 3.2 CMEC 3 Meeting

Item 3.2.1 Royal Jelly - item 3.1.4 refers

Professor Roberts provided a verbal report of a conference held on 28 April 1998 in Sydney.

between representatives of industry organisations, health authorities and CMEC from Australia and New Zealand to discuss royal jelly.

Details of representatives attending were:

Ms Gill Shaddick, member of NFAA royal jelly task force;
Mr David Bell, Super Bee Honey Company;
Mr Ron Law, NFAA New Zealand;
Mr Cliff Van Eaton, Comvita, New Zealand;

Mr Paul Bryden, NFAA;
 Mr Michael Apollonov, NSW Health;
 Mr Basil Evans, consultant;
 Ms Angela O'Sullivan, ANZFA (by teleconference);
 Mr Chris Preston, ANZFA (by teleconference);
 Professor Roberts, CMEC; and
 Dr Helen Cameron, TGA.

There was no conclusion at the meeting but rather an exchange of information on royal jelly and its regulation as a food and as a therapeutic good.

A standard for royal jelly may be developed as a result of the meeting. ANZFA will now hold an inquiry into the proposal for a warning statement for royal jelly which had been prepared and agreed to as a matter of urgency last year. It was noted that New Zealand had still not agreed to the warning statement.

Members noted this item.

Item 3.2.2 Proposed Schedule 14 - item of CMEC2 and item 3.1.2 CMEC3

Members considered the proposed Schedule 14.

It was suggested that an explanatory memorandum on the purpose of the schedule be included with the schedule even if it could not be included in the gazette notice.

Recommendation to TGA:

1 Schedule 14 be amended as follows:

- **bioflavonoids in item 2 of Schedule 14 could be deleted because they were covered by item 6 (plant and herbal materials etc);**
- **item 6 of Schedule 14 be amended to include fungi after algae;**
- **item 6 of Schedule 1, include a comma after the word 'chlorophyll'; and**
- **item 8 of Schedule 14 -amend the entry to state 'microorganisms, whole or extracted, except vaccines'.**

2 that an explanatory memorandum on the purpose of the Schedule be included with the Schedule.

Item 3.3 CMEC 2 Meeting

Item 3.3.1 Safety of Ginger - Item 5.1.2 of CMEC2 refers

Members discussed further the concerns associated with concentrated ginger extracts.

Item 3.3.2 Kombucha tea- item 3.1.3 of CMEC3

At CMEC3 it was agreed that CMS would provide advice soon as possible as on the current regulation of kombucha tea in foods and in therapeutic goods.

Recommendation to TGA;

- **that the safety concerns of kombucha be discussed at the next foods/drugs interface meeting with a view to discussing education of consumers to address the safety issues.**

Item 4 Evaluation of new substances

Item 4.1 Conflict of Interest on Zinc Ascorbate

A member declared a possible conflict of interest in relation to this item.

The Chairperson ruled that her potential conflict of interest be noted and they be allowed to take part in the discussion and vote on the matter.

The Chairperson reminded all members again of the confidentiality of committee matters.

Item 4.1 Zinc Ascorbate

Members considered an applicaiton for permission to use zinc ascorbate as an active ingredient in listable therapeutic goods.

Members noted the following:

- Zinc ascorbate is not a permitted active ingredient in listable therapeutic goods. Part 3 of schedule 4 of the Therapeutic Goods Regulations ('the Regulations') permits the following zinc salts to be used as actives in listable products, up to a maximum daily dose of 50 mg for each product: zinc amino acid chelate as a source of zinc, zinc chloride, zinc citrate, zinc gluconate, zinc oxide, zinc succinate, zinc sulfate. Part 2 of schedule 4 permits the following sources of vitamin C to be used in listable goods without restriction: ascorbic acid, calcium ascorbate, magnesium ascorbate, nicotinamide ascorbate, potassium ascorbate and sodium ascorbate. Ascorbyl palmitate is also a permitted source of vitamin C, but when used in oral preparations, the goods must be labelled with a recommended daily dose that is equivalent to 100 mg or less of ascorbyl palmitate.

- Under the *Uniform Standard for the Scheduling of Drugs and Poisons* (SUSDP), zinc compounds for human internal use are classified as schedule 4 (prescription only) poisons except:
 - (a) in preparations with a recommended daily dose of 25 mg or less of zinc; or
 - (b) in preparations with a recommended daily dose of more than 25 mg but not more than 50 mg zinc when labelled with the statement:

WARNING - May be dangerous if taken in large amounts or for a long period; or

WARNING - Contains zinc, which may be dangerous if taken in large amounts or for a long period.

- Thus, zinc-containing products with less than 25 mg per daily dose do not require any label warning statements.
- Zinc ascorbate is not used, either as an active or excipient, in any products Registered on the Australian Register of Therapeutic Goods (ARTG). Zinc ascorbate is not a permitted food additive in Australia.
- TGA have not identified, through searching of Medline and Toxline over the last 10 years, any papers that have considered the safety of zinc ascorbate. Zinc ascorbate would rapidly dissociate in the body to zinc and ascorbate. Zinc has a potential for toxicity, both acute and chronic, which is recognised in the SUSDP requirements noted above. The WHO has allocated it a provisional maximum acceptable intake of 1 mg/kg/day (Mills 1988), equivalent to a daily intake of 55 mg for an “average” woman. Current food-derived zinc intakes at the 95th percentile, for Australian women, are estimated to be 21 mg per day.’
- The proposed use of zinc ascorbate, contributing doses of 12 mg zinc and 70 mg ascorbate per day in the strongest adult formulation, and 0.8 mg zinc together with 5 mg ascorbate per day in the children's formulation, is unlikely to present a safety risk unless concurrent consumption of other significant zinc sources occurred. In any case, there is no evidence available to suggest that zinc ascorbate poses any risks additional to those posed by other sources of zinc and vitamin C that are already permitted in listable therapeutic goods.
- Nevertheless, problems of excessive zinc consumption may arise in consumers taking several zinc-containing supplements concurrently, each one with a zinc content below that at which warning statements may be necessary. This may be of particular relevance to those individuals already consuming high food-derived intakes.
- Both zinc and ascorbate are essential human nutrients. Clinical deficiencies are recognised for both nutrients, but sub-clinical deficiencies are harder to recognise and to define. There is little or no evidence of clinical deficiency of either nutrient in

Australia, and in the case of zinc there is evidence of high food-derived consumption. Nevertheless there are some population groups, such as the elderly, who are likely to have intakes below the RDIs. In the case of zinc, there are also recognised deficiencies resulting from the impaired absorption present in acrodermatitis enteropathica and sickle cell anaemia (Solomon 1988).

- A number of studies have shown moderate zinc supplementation, at approximately one to two times the RDI, of zinc-deficient population groups (malnourished children, institutionalised elderly) to result in significant reductions in the incidence of infections (eg Girodon et al 1997, Rosado et al 1997). By virtue of its involvement in a large number of biochemical functions, zinc may be useful in the treatment of a number of other conditions although evidence in this regard is inconclusive.
- Vitamin C compounds also are involved in a range of biochemical functions and have been associated with the amelioration of a number of conditions. Overt deficiency of vitamin C results in scurvy, but there is also growing, but inconclusive, evidence that the anti-oxidant properties of vitamin C may have a role in the prevention of some cancers and in the enhancement of the immune response.
- In addition, vitamin and mineral preparations are required under the Regulations to carry the label statement “Vitamins can only be of assistance if the dietary vitamin intake is inadequate”.

Recommendation to TGA:

- **that zinc ascorbate is suitable for use in listable therapeutic goods and that Schedule 4 of the Regulations should be amended to permit this.**

The reasons for this recommendation are as follows:

- Both zinc and vitamin C are already permitted in listable therapeutic goods in other forms.
- There are adequate warning and availability requirements in place under the SUSDP to ensure that dangerous levels of zinc are not made available in listable goods.
- There do not appear to be any additional safety concerns posed by zinc ascorbate above those that may be posed by other, currently permitted, forms of zinc and vitamin C.
- There is evidence to suggest that zinc ascorbate is of comparable bioavailability to other sources of vitamin C.

Item 4.2 New substances in fat storage reduction and muscle building products

Dr Cameron introduced this item and members noted that:

- There is a huge interest in the importation of sports performance enhancing therapeutic goods or goods that influence body fat storage and affect body shape or obesity. A

number of these products contain several substances currently not permitted in listed therapeutic goods. Application for acceptance of such substances is usually substance by substance, as if each were mutually exclusive in terms of assessing the impacts on the body. Importers are anxious that we have a mechanism to allow such products for supply in Australia.

- Some of the substances not permitted in Listed products have recently been accepted, to certain limits, in sports foods. (Attachment 1, Standard R10, Formulated Supplementary Sports Foods, of the Food Standards Code to the agenda paper refers).
- The TGA agreed to permit five substances to the daily limit provided for in the Standard R10:
 - creatine
 - creatine monohydrate
 - chromium picolinate
 - mixed tocopherols
 - cupric citrate
 - and a sixth substance
 - creatine phosphate

CMEC advice was sought as follows:

- should there be public consultation on these products and their substances?
- Should the TGA prepare risk assessment principles by which substances and products are determined to be, or not to be, with or without limits, low risk; and
- the best approach to evaluation of the substances frequently used in products linked to reducing fat stores and building muscle tissue.

Members also noted that:

- the words in the introduction of Standard R10 - Formulated Supplement Sports Foods as published in the Commonwealth Gazette on 13 March 1998, states that the Standard defines and regulates the composition and labelling of foods specially formulated to assist sports people in achieving specific nutritional or performance goals. Such foods are intended as supplements to a diet rather than for use as the sole or principal source of nutrition.
- clause 3 of the standard states that:

(1) the label on a formulated supplementary sports food must include statements to the effect that:

(a) the food is not a sole source of nutrition and should be consumed in

conjunction with a nutritious diet; and

(b) the food should be used in conjunction with an appropriate physical training or exercise program.

- page 10 of the full assessment report, third paragraph under the heading 'vitamins and minerals, includes a sentence 'Fortification of sports foods with vitamins and minerals to the level where they might function as ergogenic aids was considered to be outside the boundaries of food regulation.' This statement impinges on CMEC deliberations because as soon as sports foods are fortified above the levels specified in the Food Standards Code, they become products to be considered by CMEC; and
- Standard A12 - Metals and Contaminants in Food of the Food Standards Code relating to prohibited botanicals (Members would be provided with a copy for information);

It was agreed that CMS in consultation with NFAA, would prepare a list of substances that could be evaluated as a package as potential ingredients in fat storage reduction and muscle building products that would be listable subject to review, for consideration at CMEC6.

Recommendation to TGA:

1. in consultation with NFAA, TGA would establish a list of substances for consideration at CMEC6 that could be reviewed as a package as potential ingredients in fat storage reduction and muscle building products that would be listable subject to review; and
2. CMEC would subsequently undertake safety evaluations of these substances, individually and when used in combination.

Item 5 Safety review

Item 5.1 Guarana

Dr Cameron introduced the item and members noted that:

- In July 1997, a reader wrote to the Editor of Australian Prescriber concerned about the lack of acknowledgement of the presence of caffeine in guarana products.
- The *Food Standards Code* does not permit the addition of caffeine to foods except as flavouring in kola syrup and kola soft drinks to the limit of 145 mg/kg in the final product but permits the addition of tea, coffee and guarana as foods.
- The issues to be considered were:
 - identification of the problem as a safety issue or a consumer information issue or both
 - the need for further research into the pharmacology of guarana which is variously

described as containing caffeine or guaranine or caffeine and guaranine

- the appropriateness of standardisation to caffeine, which could involve addition of caffeine and such caffeine could come from other sources
- the need to inform non-herbalist practitioners of such pharmacology
- the priority to be placed on any safety issues

CMEC was requested to recommend a course of action to respond to the issues.

Members noted that because caffeine has many different effects it was important for consumers that products containing caffeine are labelled with the caffeine content. It could be a safety issue if people are not aware that products contain caffeine.

It was agreed that TGA would obtain more information on the caffeine content of guarana products and that the matter be considered at a future CMEC meeting.

Recommendation to TGA:

- 1 that the chemistry and pharmacology of guarana be researched; and**
- 2 depending on the information from TGA, CMEC would consider appropriate action on providing information to consumers about the caffeine content of these products**

Item 6 Action List

See item 3.

Item 7 Information

Item 7.1 ADEC Conflict of Interest Guidelines - Draft 5

Members noted that the CMEC Guidelines on Conflict of Interest were working well. However it would be useful if the formats between of the ADEC and CMEC guidelines were similar. When the ADEC guidelines were formalised, CMS would examine the CMEC guidelines to see if any changes were necessary.

Item 7.2 Extract of Minutes of 226th ADRAC Meeting, 13 February 1998

Members noted the Extract of the Minutes of 226th ADRAC Meeting held on 13 February 1998

Item 8 Other Business

Item 8.1 Pharmaceutical Society of Australia

Professor Roberts reported that the Pharmaceutical Society of Australia had written to him

about the membership of CMEC.

Members noted this item.

Item 8.2 CMEC meetings

Members agreed that future meetings be held every six weeks.

Recommendation to TGA:

- **after the meeting on 10 June future meetings of CMEC be held approximately every six weeks.**

Item 9 Decision Record

CMEC made decisions on the following items:

- Item 3.1.1.2 Shark Cartilage
- Item 3.1.3 Working Party on Priorities for the Review of Herbs
- Item 3.3 Kombucha
- Item 4.1 Zinc Ascorbate
- Item 4.2 Products for fat storage reduction and muscle building
- Item 5.1 Guarana
- Item 8.2 CMEC meetings

The meeting closed at 3.30pm.