

# **CMEC 11**

**Complementary Medicines Evaluation Committee**

**Extracted Ratified Minutes**

**Eleventh Meeting**

**24 February 1999**

**Item 1.1 Opening of meeting**

The eleventh meeting was held at the Ansett Golden Wing Lounge, Sydney Airport, between 10.00 am and 4.00pm on Wednesday 24 February 1999.

Members present were:

Professor David Roberts (Chair)  
Ms Jocelyn Bennet  
Dr Roberta Chow  
Dr Colin Duke  
Dr Joachim Flurher  
Ms Val Johanson  
Mr Allan Ware  
Professor Chiang Lin  
Dr Stephen Myers

Present from the TGA were:

Dr Fiona Cumming  
Mr Graham Peachey  
Mr Robert Spence  
Dr Helen Cameron  
Dr Judith Cunningham  
Dr Barry Fankhauser

Professor Roberts (Chairman) opened the meeting and welcomed members.

The Chairman and members congratulated Dr Fiona Cumming on her appointment as Manager of the Office of Complementary Medicines. The Chairman reminded CMEC members that all comment offered by Dr Cumming prior to CMEC 11 reflected those of a CMEC member, while comments offered in the current and future CMEC meetings are those of the Manager of the Office of Complementary Medicines, TGA.

(Please note: These minutes will refer, as in the past, to the work and staff in the TGA Complementary Medicines Section (CMS) as the work undertaken for this meeting occurred prior to the establishment of the Office of Complementary Medicines (OCM)). Dr Cumming's title has been established as Director of the Office of Complementary Medicines.

**Item 1.2 Apologies**

Apologies were received from Professor Jorma Ahokas who was unable to attend the meeting due to illness.

**Item 1.3 Conflict of Interest**

Conflict of Interest forms were completed by the members and handed to the Chairman.

**Item 2 Confirmation of Minutes****Item 2.1 CMEC10 (9 December 1998)**

The minutes of CMEC10 were confirmed.

**Item 3 Action Arising from Previous Meetings****3.1 CMEC10 Meeting****3.1.1 Working Party on Priorities for the Review of Herbs - item 3.1.1 CMEC10 refers (Dr Myers)**

The Chairman requested a verbal report from the Chairperson of the Working Party on Priorities for the Review of Herbs on the progress of this matter.

The Chairman of the Working Party reported to members that the Working Party had made progress but recently he had been unavailable and that the Working Party had not met formally since CMEC10.

The Chairman recounted how the Working Party had consulted with two former TMEC members to develop an understanding of the strategy, structure and difficulties encountered in the previous TMEC review of herbs. Additionally, the Working Party had reviewed the major herbs indicated on the ADRAC database and prioritized these with a view to future literature searches and evaluation.

The Chairman reminded the committee that the current Working Party was to be dissolved with the dissolution of the present CMEC and the continuation and direction of the Working Party would be the prerogative of the reformed CMEC. The Chairman of the Working Party suggested that he produce a final report on the Priorities for the Review of Herbs to assist any future CMEC decision making process.

**Recommendation 1**

**The present CMEC recommends that the Chairman of the Working Party, on behalf of the Working Party, submits a final report for review by a future (reconstituted) CMEC.**

Reason for recommendation:

- Under the reformation of CMEC, the present Working Party is dissolved.
- The reformed CMEC will consider future directions on the matter.

### **3.1.2 Harmala Alkaloids – request by NDPSC – item 3.1.2 of CMEC10 refers (report)**

A member reminded CMEC that the NDPSC scheduling changes for Harmala alkaloids would become law on the 19 March 1999 and noted the gratitude of the NDPSC, for the expert advice offered by CMEC.

A TGA officer indicated that, in light of the descheduling, the TGA would be reviewing the status of harmala alkaloid containing herbs covered by Customs prohibition.

### **3.1.3 Submission to NDPSC on Selenium- item 3.1.3 of CMEC10 refers (report)**

A member stated that NDPSC has reconsidered its position on selenium and has decided to align with the limits held in the *Food Standards Code* (NDPSC, February meeting). This will allow for open sale in listable goods, a maximum daily dosage of 26 µg of organic selenium and 52 µg of inorganic selenium. This decision is expected to take effect from 19 September 1999. Members also noted that, as at 18 June 1999, selenium present in goods for oral human therapeutic use at no more than 26 µg per daily dose (organic and inorganic form) is to be descheduled, and amounts up to 100 µg per daily dose are to become poisons under Schedule 3 of the Standard for the uniform scheduling of drugs and poisons.

## **Item 4 Evaluation of new substances**

### **Item 4.1 Coenzyme Q10**

The TGA evaluator opened this item with a detailed summation of the evaluation and possible CMEC options. The evaluator presented the following key points:

- While the application contained no reference to available toxicological data, a CMS review of databases had identified brief abstracts of previously unreviewed toxicological research on Coenzyme Q10 (CoQ10), of Japanese origin. This item was postponed from CMEC10 while CMS attempted to obtain the full English text of this information. However it had not been possible to obtain English translations of the information.
- Few adverse reactions, and of these only minor reactions, were reported in chronic studies using 100 mg/day up to 12 months duration. Reports of longer term studies were not found.
- There were no data on the use of CoQ10 usage in infants or during pregnancy and lactation.
- No acute animal toxicity studies on CoQ10 were found. However CMS was able to review chronic animal (rats and mice) toxicological data. The data on reproductive toxicity were conflicting.
- Much of the research reviewed was of a poor quality. However, Co Q10 may be of benefit as an adjunctive treatment in a range of cardiovascular diseases, particularly in building exercise tolerance. Therapeutic claims of antioxidant activity are unsubstantiated by research cited in the application.
- Grandfathered CoQ10 products have been available for at least 10 years, in up to 30 mg dosage vehicles. Since 1993, the ADRAC database has compiled only 5 adverse reactions with no direct causality established.

- Two overseas reports suggest a blocking effect of CoQ10 on warfarin therapy. No reports of this type have been compiled, to date, in Australia. CoQ10 and warfarin interaction is possible since CoQ10's chemical structure has close similarity to that of vitamin K, a known warfarin antagonist.
- Concerns are held that one target group, patients suffering from impaired cardiac function, may use both CoQ10 and warfarin simultaneously, and warning statements against concurrent use may be advisable.
- There is the possibility that individuals using anabolic steroids may have elevated serum levels of CoQ10 and additional CoQ10 supplementation could further increase serum levels, with unknown outcomes.

The Chairman thanked the evaluator, noting the thoroughness of the evaluation, and invited members to discuss the item.

A member reminded the committee of the previous CMEC10 discussion when it was requested that the TGA contact an Australian based researcher in CoQ10, to seek expert toxicology advice and possibly obtain the full English text of the Japanese toxicology research. The evaluator informed the committee that it had not been possible to contact the researcher. A member stressed the importance of the Japanese toxicology research, given the long history of CoQ10 in Japan, and emphasized the view that a future CMEC should review these data. The evaluator replied that an American patent application for CoQ10, summarized in the evaluation, cites the Japanese research as supporting evidence although, citation of the research did not allow for the analysis of the raw data.

A member searching for CoQ10 information identified citations of the November 1998 *Annals of the New York Academy of Science* which gives a substantial profile of information on CoQ10, including physiology, biochemistry, clinical trials and toxicity studies. The member suggested the breadth of research appears to be indicative of a new interest in CoQ10, particularly as a marker of the progression of disease states, such as cancer. Details of the citation were provided to the evaluator.

Two members gave positive account of approximately 10 years of general experience (respectively) in prescribing daily doses of 100 mg – 150 mg of CoQ10 to patients suffering from cardiac dysfunction and fatigue, especially that associated with cholesterol reduction therapy. One member recounted that a patient, on warfarin therapy, had displayed a significant reduction in blood clotting time (increased International Normalised Ratio (INR)) while taking 600 mg daily dosage of CoQ10. A member stated that he would undertake an independent literature review of possible CoQ10 warfarin interaction, and if warranted, raise further issues on the matter with a future CMEC. The member also suggested that the TGA explore the possibility of CoQ10 interaction with the Statin class of cholesterol lowering drugs. They suggested that serum CoQ10 levels were dramatically depressed in patients undergoing Statin based cholesterol-lowering therapy. CoQ10 is frequently prescribed to offset the fatigue associated with this type of treatment. The Chairman questioned whether reduced CoQ10 serum levels in patients undergoing cholesterol lowering treatment are an artefact of reduced serum Low Density Lipoproteins (LDL) in which the fat soluble CoQ10 is transported. The example of vitamin E was given, where the plasma content of vitamin E is expressed against lipoprotein levels. The evaluator acknowledged that relevant studies in the evaluation were unlikely to have corrected serum CoQ10 levels against lipid content.

The committee briefly deliberated on the research articles used in the evaluation process. A member inquired whether the committee felt there is a need to review research data, additional to that of the evaluation, to establish the safety of CoQ10, given its 10 year history of use in Australia in grandfathered therapeutic goods. The member recommended that, in the absence of safety concerns by the committee, listing of CoQ10 should be approved with a maximum daily dosage in the range of the Grandfathered products.

The Chairman confirmed that, through analysis of the evaluation data, the members had no unresolved safety concerns regarding CoQ10 usage based on the dosages available in the grandfathered products. A member suggested that 150 mg maximum daily dosage is reflective of current prescribing practices and the upper limit of therapeutic dosages used in most clinical research. A member suggested that the actual dosage unit might be limited to 50 mg to avoid consumers exceeding the recommended dosage. A TGA officer noted that limiting the dosage unit size could not be justified unless there were strong safety concerns. Members agreed that this was not apparent in this case.

The committee discussed the need for label warning statements. Members agreed that a statement on the product label and product information was required in regard to concurrent use of CoQ10 during warfarin therapy. Members discussed the possibility of seeking Industry advice on the exact wording of the warning statement. A TGA officer pointed out that the discussion would delay the listing of CoQ10, since it would be impractical to impose warning statement requirements post approval. Following discussions by the members on the wording, the warning statement “do not take while on warfarin therapy without medical advice” was recommended.

Further discussions focused on the need, if any, for a warning statement against use of CoQ10 during pregnancy and lactation. The evaluator had previously advised that reproductive toxicity data for CoQ10 were conflicting and did not enable a conclusion to be drawn regarding its safety. A member noted that without evidence of safe usage, CoQ10 should have a classification equivalent to the “B” grouping used in the system to classify the safety of prescription medicines in pregnancy. Therefore it could be argued that a label warning against use during pregnancy was required. Against this was noted that a high degree of consumer awareness exists regarding the use of any medicines during pregnancy. A member questioned whether the inclusion of a cautionary statement in this case, would set a precedent affecting the label requirements for all complementary medicines for which reproductive toxicity data could not be obtained. A member noted that CoQ10 was not a therapeutic drug, in the sense that it is ubiquitous in the human body and supplemental CoQ10 was only intended to boost endogenous levels. The committee concluded that a label warning statement cautioning against use during pregnancy is not required.

During discussions on the implications of the warfarin warning statement, a member emphasised concern regarding the potential interaction of warfarin with a wide range of complementary medicines, including CoQ10. The member recommended that CMEC advise ADEC to consider mandatory label and Product Information requirements on all warfarin products warning against concurrent usage with complementary medicines. The Chairman charged a member with producing, and providing for review at CMEC12, brief documentation to formalise CMEC’s intended request for ADEC action on the matter.

## **Recommendation 2**

**CMEC recommends that coenzyme Q10 is suitable for use in listable therapeutic goods with the following requirements:**

- (a) A maximum daily recommended dosage of 150 mg; and**
- (b) Coenzyme Q10 products to carry the warning statement “do not take while on warfarin therapy without medical advice”.**
- (c) A member will prepare a Position Paper, for CMEC12, on the justification for the inclusion of warning statements that medical advice should be sought before taking any complementary medicine in conjunction with warfarin therapy for ADEC’s consideration.**

### **Reasons for the recommendation:**

- Coenzyme Q10 products have a history of safe use as grandfathered therapeutic goods with a dosage up to 30 mg per unit. There have been only 5 adverse reactions reported to ADRAC over 6 years, which have been largely of a minor nature with no firm causality established.
- Current usage patterns for available Coenzyme Q10 products deliver dosages of 100 mg to 150 mg per day.
- Clinical trials have used Coenzyme Q10 dosages up to 600 mg/day in adults in short term studies, with only minor adverse reactions, if any.
- There are reports of interaction between coenzyme Q10 and warfarin in humans. Therefore consumers on warfarin (anticoagulation) therapy need to be advised to seek medical advice before consuming coenzyme Q10.
- CMEC holds concerns that the efficacy of warfarin therapy may be compromised through possible interactions with a broad range of complementary medicines. Further CMEC12 discussion is warranted, with a view to possibly advising ADEC to consider appropriate warning statements on warfarin products.

## **Item 5                      Safety review**

### **Item 5.1                    Echinacea**

One member declared a conflict of interest in relation to this matter but the Chairman ruled, with Committee support, that this conflict did not prevent the member participating and voting on this item.

CMEC was requested to evaluate the safety of echinacea and to provide advice on echinacea products.

The TGA evaluator introduced this item, outlining the history of use of echinacea worldwide, the range of Australian products in which echinacea is found and the rationale for reviewing the safety of this herb. The considerable number of submissions received in response to a call for comments was highlighted, with a general consensus of these submissions being that echinacea was a safe and efficacious herb and did not require any additional restrictions relating to its use. The survey of clinical experiences with echinacea, compiled by the Australian Natural Therapists Association (ANTA) was also brought to the Committee’s attention.

Members brought the following documents to the attention of the TGA:

- on page 19 of the scientific evaluation, the letter by Myers & Wohlmuth (1998) should be referred to within the text in relation to the discussion of Dr Mullins' letter;
- an article from the *Australian Journal of Pharmacy* (vol 80, Feb 1999) entitled "Doubt over echinacea's effect";
- an abstract of an article by Melchart et al (1998), "Echinacea root extracts for the prevention of upper respiratory tract infections: a double-blind, placebo-controlled randomised trial", published in *Archives of Family Medicine* (vol 7, no 6, pp 541-545);
- an abstract of an article by Miller (1998), "Herbal medicinals: selected clinical consideration focusing on known or potential drug-herb interactions", published in *Archives of Internal Medicine* (vol 158, no 20, pp 2200-2211), and a brief report of this article. This article raised issues of echinacea interaction with hepatotoxic and immunosuppressant drugs.

There was considerable discussion by the Committee on the importance of the recorded adverse reactions, including both the number and type of reactions. In relation to the number of doses of echinacea believed to be taken annually by Australians (estimated to be between 50 and 200 million doses in 1998), the number of adverse reactions is believed to be low (36 reports to the Adverse Drug Reactions Committee since 1996). Each individual may take many doses and the rate of adverse reactions per individual taking echinacea is unknown, although one estimate places it at 1-3 events per 100,000 consumers. However it was noted that any reporting rate for adverse reactions is imprecise and may not have a direct relationship to the number of reactions occurring. The increased interest and media attention to echinacea may have encouraged reporting of adverse events associated with it. There remains a need for a stronger system for reporting adverse events in complementary medicines.

It was noted that approximately half of the ADRAC reports relate to allergic-like effects (such as bronchospasm) that had the potential to be severe. Five of the reports had been assigned a causality rating of "certain" by ADRAC, although the limitations of reporting to ADRAC were acknowledged. There was extensive debate about the nature of the adverse events and the immunological mechanisms that may be their possible causes. Some members doubted that there is a causal relationship between echinacea and allergic reactions. While asthmatics may be at risk of allergic reaction from echinacea (and indeed from a large number of allergens), echinacea may be particularly valuable for this group in terms of preventing respiratory infections or in minimising the harm caused by infections.

The benefit of echinacea to asthmatics was briefly discussed, particularly in relation to the prevention of respiratory tract infections, a major trigger of asthma attacks. Respiratory infections are themselves known to cause a heightened immune response for several weeks in atopic individuals. During such a heightened response it can be difficult to ascribe an allergic reaction to an individual environmental trigger. However atopic consumers may therefore be at heightened risk of allergy from echinacea products consumed during this time and the Committee noted that much uncertainty remains in this area.

The TGA evaluator pointed out that the mouth-tingling experienced after consumption of some products containing echinacea is not an allergic response but may be interpreted and reported as such by consumers and practitioners.

The wealth of practitioner experience captured by the ANTA survey was recognised by the Committee. However, it was noted that echinacea products supplied to practitioners are often different from those available to members of the public. This may have implications for the type and number of adverse events reported. Some practitioners had reported adverse reactions experienced by some of their patients and these reactions included allergic reactions such as skin rash. Nevertheless the overall response of those surveyed by ANTA was that echinacea was a safe herb.

The need for label warning statements for echinacea products was debated. While such statements may alert at-risk consumers to a potential for harm, the degree of risk associated with therapeutic goods containing echinacea is likely to be low based on an extrapolation of the number of adverse events. The risk potential may be no greater than for other complementary medicines for which no label warnings are required. Further, there is a possibility that by requiring a warning about allergic potential, the group most likely to benefit from echinacea, asthmatics, is the very group who may be discouraged from taking it. The public health implications of this are unclear. Label warnings for echinacea products for oral use are not believed to be required in other countries.

While the Committee considered that there is insufficient evidence at this time to warrant any changes to the regulation of echinacea in therapeutic goods, it is important that the safety of echinacea continues to be monitored by the TGA. Relevant information should be referred to CMEC for consideration.

Members adopted the following recommendation, with one abstention from the vote:

### **Recommendation 3**

**CMEC recommends that Echinacea be maintained as a listable substance with no additional conditions.**

CMEC requests that the CMS maintain vigilance on reports involving Echinacea, and table for CMEC discussion any developments regarding adverse reactions to Echinacea products.

Reasons for the recommendation:

- There is insufficient evidence at this time to require a warning statement.
- The efficacy of Echinacea is supported by traditional use and clinical trials.
- Echinacea is of low toxicity as shown by *in vitro* and *in vivo* studies.
- Echinacea is the most widely used herbal medicine in Australia and the prevalence of reported adverse reactions is extrapolated to be extremely low compared to the doses consumed.

**Item 6 Registration Applications****Item 6.1****Recommendation 4**

**CMEC recommends that the registration application be rejected due to insufficient efficacy data to support product claims.**

**Item 6.2****Recommendation 5**

**CMEC recommends that the registration application be rejected due to insufficient efficacy data to support the product claims.**

**Item 7 Responses papers circulated for comment****Item 7.1 Guidelines for Stability of Herbal Products**

The TGA officer introduced this item with a brief outline of the history behind the CMEC1 endorsement of the Draft Guidelines for the Stability Testing of Herbal Products. It was explained that TGA had created a Working Party in December 1998 to review public comments on the draft guidelines. The Working Party concluded (on the basis of the comments received) that the draft guidelines were not accepted by Industry and stakeholders and should be abandoned in favour of a less prescriptive model with clearer communication of the principles of stability testing. As such, the Working Party considered that the 1998 draft European Community (EC) herbal stability guidelines represented a model on which to redevelop workable Guidelines. Following comments by a CMEC member on the brevity of the EC Guidelines and the apparent prescriptive nature of stability testing, the TGA officer emphasized that the EC guidelines would require some modification and or augmentation to meet specific needs of the TGA and stakeholders. This matter was to be discussed in the March meeting of the Working Party. Any remodeled guidelines would ultimately be forwarded to CMEC for endorsement.

**Item 8 Policy Matters****Item 8.1 Regulatory status of Herbal Component Names**

Prior to commencement of this item a member acknowledged a conflict of interest in the matter. Following a brief review of the rationale for the Conflict of Interest, the Chairman ruled that there was no encumbrance on discussion and voting by the member.

A TGA officer introduced the background to this item and discussed the scientific rationale and regulatory principles behind the use of Australian Approved Herbal Component Names (HCN). However, the requirement for TGA to assign HCNs is considered an unnecessary onerous burden by Industry. Staff have encountered problems in resolving misunderstandings about the process of determining HCNs and their application.

The TGA officer read to the Committee, a relevant extract on the issue of HCNs from the unrated minutes of the Herbal Taskforce meeting of 19 February 1999. The extract read:

“Industry position is that manufacturers should have the right to decide how standardised statements are expressed. It is a matter for industry and the marketplace to decide rather than having a system imposed which is not suitable. There is no safety issue involved and the current system allows no flexibility. If it could be shown from an authoritative source that a herb contains a constituent – that should be accepted.

TGAL appeared to require HCNs for standardisation purposes which would assist when products were being scrutinised in the field. It was noted that nomenclature is always linked to methodology. The methodology applied to one company’s product may not apply to the product of another company. Industry was not against HCN *per se*, but is against the evaluation and determination as part of the pre-market process. Evaluation can be done post market in the field if required. Standardised methodology or a dictionary of terms may be options. There is no reason for TGA to continue with determining nomenclature. There are

enough authoritative references for nomenclature which can be used. Herbals are sufficiently different from pharmaceuticals not to need standardised names. A compromise position would be the adoption of specified references. If TGA were prepared to streamline the process, industry would be prepared to consider it. How standardisation is expressed is really the issue. Final decisions were required to be made in order for the ELF redevelopment to proceed.”

The Chairman requested confirmation from the Committee about the need for HCN, relative to public safety and consumer confidence. The Chairman also sought a judgment as to the appropriateness of either Industry or the TGA being responsible for setting HCN. Members offered contrasting views on the issues surrounding TGA’s use of HCN. A member suggested that the regulation of HCN by the TGA was not necessary from a safety perspective. Other members were of the opinion that the sponsor, on an individual basis, should justify the principle of standardisation claims on herbal products by supply to the TGA of an appropriate monograph. In contrast, other members stated the view that incorrect or unsubstantiated claims of standardisation could generate broad and indirect safety concerns and therefore the TGA control of HCN should not be abandoned. Further, HCN should not be sorted out in the market place since consumers have (generally) little understanding of the terminology of the HCN and are unlikely to be able to make a comparison between herbs and between parts of herbal chemical profile.

A member reported a case of an apparent quality survey involving 50 unstandardised Ginseng products. The resultant ginsenoside levels found in the surveyed products ranged between 0.9% and 9%, and 6 products showed a complete absence of ginsenosides. A member speculated that the survey uncovered a practice of marketing product manufactured from both the extract, and the residual ginseng material, under the general label of “ginseng”. Members suggested that the interpretation of efficacy and safety data derived from unstandardised herbal products could be of questionable integrity, and by extrapolation, may adversely influence the CMEC evaluation process. A member reflected that, for this reason, the journal *Phytomedicine* reviewed herbal standardization details before publishing research in the area. The Committee agreed that, from a research and evaluation perspective, standardization of herbal material including a HCN process would be advantageous.

A member offered an example of St Johns Wort (*Hypericum perforatum*), where the antidepressant properties of its preparation are not necessarily linked to the hypericin content by which the herb is standardised. The TGA representative confirmed that the HCN applies to the quantified component irrespective of the active ingredient. The member noted that any standardization system must be sufficiently flexible to accept improvements in the resolution of chemical components.

Discussions clarified several issues:

1. HCN are only necessary where quantification of herbal components is placed on the label, including the claim of standardisation.
2. Standardisation of a herb may not be to an active component, or could be standardised to alternative components to achieve different activities.
3. Herbal components can be multi-component and some names are very broad, which may be refined once more knowledge is obtained about the specific chemical profile.
4. HCN assignment by the TGA was not seen as a direct safety issue but part of a system of consistent and meaningful record keeping. One member queried the meaning of the HCN derived using the current process and whether consumers use HCNs when choosing a product. Industry does not want HCN if the process amounts to over-regulation.

A member moved that TGA seek further dialogue, be recommended by CMEC. The motion was seconded.

The Chairman requested members to vote on the recommendation. The motion was carried, with 1 vote against the motion, and 1 member absent during voting.

## **Recommendation 6**

**CMEC recommends that Industry and the TGA work together to produce a workable mechanism that addresses both Industry and TGA concerns.**

### **Reasons for the recommendation:**

- Public safety and consumer confidence will benefit through the formulation of a workable model of herbal component nomenclature, which is agreeable to all stakeholders.
- Definition of actives through standardized herbal component nomenclature will benefit the CMEC, which may have to rely on published research in a safety review.

## **Item 8.2 Identifying Low Risk Herbal Ingredients**

This item was introduced by a TGA officer who gave a brief background to the issues and drew the committee's attention to the submissions received from Industry and stakeholders.

The Chairman requested comments from the members. A member questioned whether the basis of the review was regulatory, and the agenda item did not carry direct implications on the safety and quality of herbal products. Against this, a TGA officer requested the committee to consider the safety implications when contemporary extraction techniques with possibly varied selectivity, are applied to a

herb that may have been considered safe on the basis of its traditional preparation process. The TGA officer emphasised that the aim of the review is to define what circumstances required evaluation (with respect to safety) of the herbal preparation. A member noted that herbal component selectivity through extraction and refinement techniques, could ultimately lead to purified compound(s), and a definition was needed to define herbal preparations from purified chemicals. A member suggested that all herbalists would distinguish the fundamental differences arising from alternative preparation techniques and identify this as an issue worthy of discussion. The member moved that the principles, implications and practicalities of identifying, both low risk herbal ingredients and herbal preparations which require safety evaluations, should be discussed (with robust dialog) in broad forum involving industry, stakeholders and input from eminent experts in the area. The forum should be coordinated by the TGA. The Committee approved that the motion be a CMEC recommendation.

### **Recommendation 7**

**CMEC recommends that the TGA coordinate a consultative forum with Industry and Stakeholders to discuss the issue of Low Risk Herbal Substances.**

#### **Reason for the recommendation:**

- Broad ranging and constructive dialog with stakeholders and Industry is required to clarify the fundamental basis and regulatory ramifications surrounding the issue of identifying which herbal substances cannot be regarded as automatically safe for listing, but need to undergo an individual safety evaluation.

### **Item 9                      Decision Record**

Decisions were made in relation to:

Item 3.1.1	Working Party on Priorities for the Review of Herbs
Item 4.1	Coenzyme Q10
Item 5.1	Echinacea - Safety review
Item 6.1	Registration application
Item 6.2	Registration application
Item 8.1	Regulatory status of Herbal Component Names
Item 8.2	Identifying Low Risk Herbal Ingredients

### **Item 10                      For Information**

#### **Item 10.5      Information from a member titled Pyrrolizidine alkaloids: some aspects of the Australian involvement**

A CMEC member briefly addressed the committee on Item 10. 3, the NDPSC Essential Oils Working Party Final Report, and noted that the final report of the Working Party has been deferred to allow time for further Industry submissions in relation to the matter. The member indicated that the Working Party had discussed generally principles covering restricted flow inserts, container sizes and Child Resistant

Closures (CRC). While no information was given, it was suggested that the outcome of these discussions would be reflected in the NDPSC scheduling process for May 1999.

### **11. Other Business**

The Chairman introduced Mr Graham Peachey, Director of Chemicals and Non-Prescription Drug Branch of TGA, to address members on the progress of the proposed package of regulatory reforms in the complementary medicine arena.

Members noted the information provided by Mr Peachey.

The meeting ended at 4.00pm.