



Australian Government
Department of Health
Therapeutic Goods Administration

Advisory Committee on Complementary Medicines

Minutes of Meeting 18 (DRAFT)

8 December 2017

TGA Health Safety
Regulation

Abbreviations

ACCM	Advisory Committee on Complementary Medicines
ARTG	Australian Register of Therapeutic Goods
CMES	Complementary Medicines Evaluation Section (of COMB)
CMRS	Complementary Medicines Reform Section (of COMB)
COMB	Complementary and OTC Medicines Branch (of TGA)
HCNs	Herbal Component Names
LCS	Listing Compliance Section (of COMB)
TGA	Therapeutic Goods Administration

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The Advisory Committee on Complementary Medicines (ACCM) held its eighteenth meeting at the TGA Conference Room 1, from 9:30 am to 3:30 pm on 8 December 2017.

Members of ACCM present

Prof Peter Howe (ACCM Chair) *via* teleconference
Dr. Alison Haywood (Acting Chair)
Dr. Di Wen Lai
Dr. Simon Spedding
Ms. Jebby Philips

Staff from the Therapeutic Goods Administration present

Adj. Prof. John Skerritt (Deputy Secretary)[morning attendance]
Dr. Cheryl McRae (Assistant Secretary, COMB)
s22(1) [REDACTED]

1. Procedural matters

1.1 Opening of meeting

The Acting Chair opened the meeting at 9:30am, welcoming ACCM members and TGA staff.

1.2 Apologies

Dr. Henry Ko
Assoc. Prof. Marie Pirotta
Prof. David Sibbritt
Assoc. Prof. Evelin Tiralongo

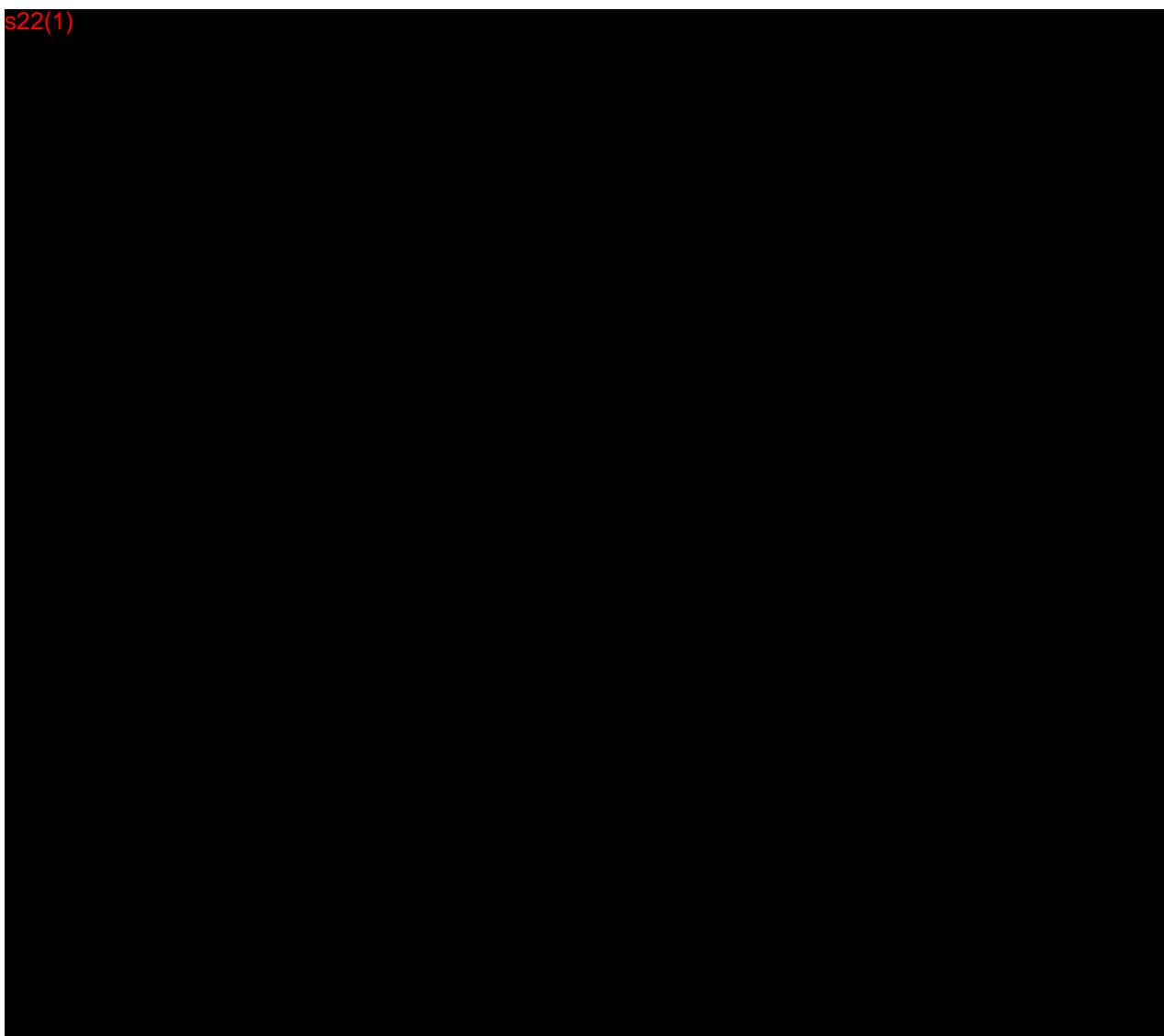
1.3 Meeting declarations of interest

Members declared no conflicts of interest.

2. Minutes of previous meetings

Accepted.

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5.1 Issues arising from Permitted indications consultation

The CMRS Director provided background information on TGA's finalisation of the list of permitted indications from which sponsors must select when listing a medicine in the Australian Register of Therapeutic Goods (ARTG). A number of issues relating to the inclusion of certain indications on the list had been highlighted during the TGA's public consultation on the list. ACCM's comment and advice on these issues were sought.

5.1.1 Traditional Chinese Medicine Indications not being understood by general consumers

A background was provided by CMRS Director:

Following the publication of a draft list of permitted indications, a number of stakeholders expressed concern in relation to the inclusion of paradigm specific terminology for Traditional Chinese Medicine (TCM) indications, stating that these are not understood by the general consumer and may therefore inappropriate to be included in the list.

TCM specific indications have been included in the list in recognition that traditional terminology is required for persons familiar with the TCM paradigm to use the medicines appropriately.

TGA proposed to include a general requirement that medicines using indications with paradigm specific terminology (e.g. TCM and Ayurvedic medicine indications) include an advisory statement on their label with words to the effect of:

'Please seek the advice of a traditional [insert paradigm] practitioner to ensure this medicine is right for you'

In addition, TGA proposed that Guidance material include a recommendation that TCM sponsors include a general plain English indication along with the traditional terminology on the medicine's label.

ACCM Discussion:

- TCM is a paradigm that is concerned with disease prevention rather than cure. While, TCM products are considered low risk listed medicines in Australia, they have been considered differently in China and Singapore where they can only be supplied after consultation with a trained personnel or a qualified TCM practitioner.
- Traditionally, TCM products are recommended to consumers by a TCM practitioner who usually prescribes a particular therapy for a specific condition/period. Some consumers may, however, continue using their TCM product without further consultation with a TCM practitioner which might not be appropriate with certain conditions/products.
- While TCM practitioners are regulated, wholesalers are not. In Australia, TCM products may be available to consumers (such as from sale online) without a prescription from a TCM practitioner. This poses risk to those who are not familiar with the paradigm and TCM-specific terminology.
- The terminology used in TCM does not necessarily have a directly comparable plain English equivalent that describes the identical condition that the medicine is intended to help manage. Having the terminology in English might therefore be misleading to the average consumer.
- The lack of comparable English terminology may potentially restrict the availability of TCMs to consumers in Australia.
- Given these considerations, the use of the advisory statement '*Please seek the advice of a traditional Chinese medicine practitioner to ensure this medicine is right for you*' would be beneficial to encourage consumers to seek advice from a TCM practitioner prior to initial/continuous usage.

ACCM advice and resolutions

ACCM recommended to the TGA Delegate of the Minister and Secretary that:

- Including the advisory label statement '*Please seek the advice of a registered traditional Chinese medicine practitioner to ensure this medicine is right for you*' would be appropriate considering that average consumers are not familiar with TCM paradigm.
- Using TCM specific terminology on medicines' labels is appropriate and consistent with the traditional paradigm. The use of English indications may mislead consumers to self-select products that might not be appropriate for their condition without advice from a TCM practitioner.

Chair's certification

I certify that this is an accurate record of proceedings of the meeting.

Dr Alison Haywood

ACCM Acting Chair

January 2018

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