

## Consultation on draft guidelines for safe Chinese herbal medicine practice

28 May 2014

### Responses to consultation questions

Please provide your feedback as a Word document (not PDF) by email to [chinesemedicineconsultation@ahpra.gov.au](mailto:chinesemedicineconsultation@ahpra.gov.au) by close of business on Wednesday, 23 July 2014.

#### Stakeholder Details

If you wish to include background information about your organisation please provide this as a separate word document (not PDF).

<b>Organisation name</b>
Sydney Institute of Traditional Chinese Medicine (SITCM)
<b>Contact information</b> (please include contact person's name and email address)

#### Your responses to consultation questions

<p><b>Guidelines for safe Chinese herbal medicine practice</b></p> <p><i>Please provide your responses to any or all questions in the blank boxes below</i></p>
<p>1. Do you agree that these guidelines apply to all medicines prescribed and/or dispensed by Chinese medicine practitioners?</p>
<p>Yes. We agree.</p>
<p>2. TGA nomenclature guidelines require the botanical name to be used for herbal products in manufactured medicines. Pinyin and/or Chinese characters are more commonly used for Chinese herbal medicine prescription writing and dispensing. The use of Chinese characters alone makes it difficult for patients and other health practitioners to understand what medicine the patient is taking. For Chinese herbal medicine prescription writing, do you agree that pinyin or the pharmaceutical name should be used as an alternative to the botanical name, with the addition of Chinese characters where necessary? Is this guideline practical to implement? If you disagree, what alternatives do you suggest?</p>
<p>We agree that for Chinese herbal medicine prescription writing, any one of the botanical name, pinyin name or pharmaceutical name can be used.</p>
<p>3. Zhao et al (2006) identified that up to 27 per cent of Chinese herbs are sourced from multiple species, making it impossible to accurately identify the species used if the herb is identified only by pinyin,</p>

Chinese characters or pharmaceutical name. Best practice is to label herbs supplied to a patient by the botanical name to allow for accurate reference to drug-herb interaction databases, accurate tracking of potential adverse events and the informed use of evidence from pharmacological research.

Do you agree that herbs should be labelled according to their botanical name?

If not what alternative do you recommend to address these safety issues and remove ambiguity in labelling?

Like CMBA, we realise the importance of having a national guideline for the safe practice of Chinese herbal medicine in Australia. However, we disagree that herbs should be labelled according to their botanical name based on the following reasons.

1. The use of Pinyin (or Chinese character name) should remain an integral part of labelling for Chinese herbs in Australia, which has also been accepted internationally, e.g. in China, Japan, South Korea, USA, UK and Singapore. Pinyin (and/or Chinese characters name) has been proven (e.g. through Chinese medicine practice in China) to be able to accurately reflect the main therapeutic and/or prophylactic effects, and in some cases the adverse reactions, of a Chinese herb.

The concept of labelling Chinese herbs with botanical names might be appealing. However, solutions to better safety monitoring of Chinese herbs and subsequent signal management must rest on strong justification from clinical and pragmatic perspectives, underscored by quality evidence. The value of using botanical names in this regard remains unproven and controversial, partly because botanical names may not fully reflect the characteristics of a Chinese herb. For example, Zhi Gan Cao means honey-fried *Radix Glycyrrhizae* with sweet taste (tonifying and neutralising therapeutic effects).

Pinyin (and/or Chinese character name), reflecting the uniqueness of the Chinese culture, may greatly assist Western communities, TCM practitioners, students, and even patients to better understand and interpret the meaning and characteristics of a Chinese herb/medicine.

2. The accurate identification of the species is of limited value to individual TCM practitioners and patients, but it would be important for regulatory authorities, the herbal manufacturers and product importers. For TCM practitioners, the herbal functions and phytochemical contents of herbs are affected not only by different species, but also by various factors around the growth of the herbs, e.g. the location, the season, the number of growth years, and manufacturing methods etc. The Chinese government (see Version 1, 2010 Chinese Pharmacopoeia) has allowed the use of a Chinese herb sourced from multiple species based not only on thousands of years of clinical practice but also on modern evidence-based research. This regulation is consistent with TCM theory. The manufacturers and importers of herbs, but not only TCM practitioners, should be regulated by the government to supply Chinese herbs with species that are clearly indicated.
3. We also assert that more published and quality evidence is needed to allow for a thorough assessment to better justify this national guideline. The paper by Zhao et al. apparently is the only available data in this regard, the policy implications of which are still under debate. Most of current research findings in pharmacology including drug-herb interaction have been obtained from animal studies, with a limited number of randomised controlled trials in humans available. If a causality association between a certain Chinese herb and an adverse reaction is proven based on a proper safety signal evaluation, TCM practitioners will certainly treat it on

individual ground rather than through a blanket regulation.

The findings of previous scientific research (including Zhao's), are part of the beginning of a series of future efforts, not the end. Continued work on understanding the association between the safety profile of Chinese herbs and labelling methods is required to develop an evidence-based national guideline.

4. The practical and logistic challenges to use botanic name to label Chinese herbs should be considered. Many TCM practitioners and patients have not yet had adequate knowledge about botanic name and would have difficulties in finding the accurate botanic name for the herbs. As mentioned previously, we suggest that the use of botanical name may be more appropriately regulated at the level of the producers and/or importers.

In summary, we strongly recommend that Pinyin should be used as an alternative to the botanical name for labelling purposes, with the addition of Chinese character where necessary. The pharmaceutical and botanical names should be provided on patients' requests.

4. Are the labelling requirements practical to implement?

No comment

5. Is the required information for prescriptions appropriate?

No comment

6. Do you agree with the circumstances in which a medicine may be supplied for self-medication?

No comment

7. Do you agree with the limited role of dispensary assistants as outlined in section 5 of the guidelines?

No comment

8. Are there any additional requirements which should apply to the management of a Chinese herbal dispensary?

No comment

9. Does the sample label and prescription assist in understanding the requirements set out in the guidelines? Should any other examples be used?

No comment

10. Taken as a whole, are the guidelines practical to implement and sufficient for safe practice?

No comment

11. Is the content flow and structure of the guideline helpful, clear, relevant and workable?

No comment

12. Is there any content that needs to be changed or deleted?

No comment
13. Is there anything missing that needs to be added?
No comment
14. Do you agree with the proposed 12-month transition period and if so is this period adequate?
No comment
15. Should the review period for the guidelines be two, three or five years?
No comment
16. Do you have any other comments on the draft guideline?
No comment