

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

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22 July 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>
<b>Contact information</b> <i>(please include contact person's name and email address)</i>
Dr Angela Yang

#### 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>I prefer to adopt the Victorian guidelines.</p> <p>If the new guidelines have to be placed, I support the proposed guidelines subject to amendments outlined below.</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?</p>

If you disagree, what alternatives do you suggest?

The current clinical practice is to use Pin Yin names in writing up the Chinese herbal medicine prescriptions for individual patients, with the addition of Chinese characters where necessary. The requirements of using botanical names will have significantly negative impact on the current practice.

In the TGA's documents, Pin Yin names are listed under the column of Common Names in the existing TGA "Approved Terminology for Medicines" for Chinese herbal medicines. The TGA nomenclature guidelines are designed for manufactured herbal products registered with TGA therefore, they are not practical to be implemented for labelling the individualised raw herb formulae or herbal granules.

The current practice (ie. the use of Pinyin names in the prescription) is recommended to remain the same.

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, 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?

There is no concern about labelling for manufactured herbal products. However, I do not agree with labelling requirements for individualised herbal formulae listed in "2.2 Label content" with reasons as below:

- Registered Chinese herbal medicine practitioners in Australia are only allowed to prescribe non-scheduled substances listed in TGA's Poisons Standard 2013.
- The draft guidelines do not reflect the existing practice which is primarily using Chinese characters or Pin Yin names. Labelling as per the draft guidelines will significantly delay the clinical practice of Chinese medicine practitioners.
- The example using the same "Da Ji" for two different herbs is incorrect. *Euphorbiae pekinensis* is botanical name for Jing Da Ji (京大戟) not Da Ji as per the Chinese Pharmacopoeia. If the full Pin Yin name is used for each Chinese herb, no confusion will be caused as there are no same Pin Yin names across all the Chinese herbs.
- A degree in botany studies "plant ecology, mycology, the ecological physiology of plants, plant biochemistry, plant molecular biology, genetic engineering of plants, and the taxonomy, evolution and biogeography of flowering plants" (<http://www.latrobe.edu.au/botany/study-options/botany>, accessed 6 July 2014). However, study in Chinese herbal medicine focuses on the properties, actions and indications of processed substances. Therefore, the species and botanical names should be provided by botanists instead of the Chinese medicine practitioners.
- Not all the Chinese herbs can be identified by their botanical names. For example, Bai Shao and Chi Shao share the same botanical name as *Paeonia lactiflora* Pall. However, they are two different herbs with different actions.

4. Are the labelling requirements practical to implement?

No, labelling requirements are not practical to implement.

5. Is the required information for prescriptions appropriate?

### Re 3.1 Information required on prescriptions

"In the case of an individual herbal formulae (extemporaneously prepared medicine), the:

- name of each herb included in the prescription
- part of the herb (where relevant)
- form of processing (where relevant)
- quantity of each herb in grams
- preparation instructions, and

- *number of packets (for raw herbs), with each packet numbered sequentially.*”

It is unclear what “form of processing” refers to, individual herbs included in the formula or the formula itself? It is impossible to list the detailed information on the form of processing.

**Re 3.2 Providing instructions to the patient**

*“Clear instructions must be provided to the patient in writing, or the patient's parent or guardian, covering the following:*

- *at-home preparation of the herbal medicine where relevant*
- *the correct route for consuming or administering the medicine*
- *how often, when, and for how long the medicine should be taken, and*
- *information relevant to potential interactions with other concurrent medications (both Chinese and Western), where known and relevant.”*

“Information relevant to potential interactions with other concurrent medications” is normally verbally provided to the patients during the consultation. It is not feasible to include such information in the prescription. In addition, such information is not required to be included in the prescription from other professionals (such as general practitioners).

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

I do not agree with self-medication and urges patients to consult a registered Chinese medicine practitioner prior to taking any Chinese herbal medicines.

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

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

The draft guidelines indicate: *“when writing prescriptions, clear and accurate herbal nomenclature is used, and when dispensing herbs, clear identification on the label of the specific species used.”*(Appendix 5)

Chinese herbal medicine practitioners and dispensers are only the users of the processed Chinese herbs. The species of Chinese herbs can only be identified from the plants instead of the processed Chinese herbs. The species should be identified by experienced experts in Pharmacy of Chinese Medicine or botanists. Manufacturers and suppliers are expected to provide the appropriate species of Chinese herbs to the practitioners and dispensers.

According to the Chinese Pharmacopoeia, identification of individual herbs is sought from the physicochemical, microscopic, molecular biology, TLC and HPLC levels. However, with the training requirements, the Chinese herbal medicine practitioners are not able to perform all these laboratory experiments.

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

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

There is no evidence to show the close relationship between labelling each herb on a package and safe practice by a practitioner. Safe practice from practitioners’ perspective relies on the sufficient education and appropriate application of knowledge and skills (eg. proper combination and dosage of individual herbs) to the daily operation of the clinic. Unnecessary labelling will increase the workload of the practitioners and decrease the efficiency of clinical practice which will lead to delayed services to the public.

11. Is the content flow and structure of the guideline helpful, clear, relevant and workable?
12. Is there any content that needs to be changed or deleted?
13. Is there anything missing that needs to be added?
14. Do you agree with the proposed 12-month transition period and if so is this period adequate?
15. Should the review period for the guidelines be two, three or five years?
16. Do you have any other comments on the draft guideline?
<p>Chinese herbs are currently widely used by regulated or non-regulated health professions in Australia. It is currently illegal for a Chinese medicine practitioner and dispenser to “obtain, possess, use, sell or supply” those traditionally-used Chinese herbs included in the TGA’s Poisons Standard 2013. However, some toxic Chinese herbs such as Ma Huang (<i>Herba Ephedrae</i>), Fu Zi (<i>Radix Aconiti Lateralis Preparata</i>) and Ban Bian Lian (<i>Herba Lobeliae Chinensis</i>) etc. are legally accessible to medical practitioners, dentists, veterinary surgeons, pharmacists regardless of whether or not those professionals have proper training in the application of the Chinese herbs. As a profession regulated by the Australian Health Practitioner Regulation Agency, the Chinese medicine profession is supposed to have the same level access as other regulated professions to the existing resources, including scheduled herbal medicines.</p> <p>I concern about self-medication by the patients and use of Chinese herbs by other healthcare professions due to lack of proper training in Chinese herbal medicine. It is suggested that standardisation of education on Chinese herbal medicine be approached to other health professions. It is recommended that the registered Chinese medicine practitioners continue using the Victorian guidelines which will limit the impact of the new guidelines on the daily practice.</p>

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