

Consultation on draft guidelines for safe Chinese herbal medicine practice

21 July 2014

Responses to consultation questions

(Please provide your feedback as a Word document (not PDF) by email to 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).

Organisation name
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Contact information (please include contact person's name and email address)

Your responses to consultation questions

<p>Guidelines for safe Chinese herbal medicine practice</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>We accept the <i>Draft guidelines for safe Chinese herbal medicine practice</i> (draft guidelines) apply to all Chinese herbal substances prescribed and/or dispensed by registered Chinese herbal practitioners and dispensers subject to amendments outlined below in particular the inclusion of Chinese characters in prescription writing and remove the requirement of listing all medicines on label of practitioner's extemporaneously prepared medicine, e.g. raw herb formula or herbal granules.</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</p>

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?

We do not agree with the above claim that “the use of Chinese characters alone makes it difficult for patients and other health practitioners to understand what medicine the patient is taking.” At least those patients Chinese ethnic groups understand what medicines they taking by reading the prescription written in Chinese. The primary purpose of a Chinese herbal medicine prescription is to authorise supply of Chinese herbal medicines by a registered Chinese herbal medicine practitioner to his/her patient regardless what other health practitioners understand Chinese herbal medicine or not. Other health practitioners who have no proper training in Chinese herbal medicine would not understand Chinese herbal medicines even the medicines are written in English on a prescription. In the case of a serious adverse event associated with taking the Chinese herbal medicines occurs; the medicines taken could be tracked by contact the Chinese medicine practitioner via many ways, for instance, direct contact the practitioner or via register held in AHPRA.

We believe Chinese characters should also be used as one of the alternative ways to the botanical name of herbal substance for prescription writing and oppose the draft guidelines that Chinese characters are only an addition where necessary.

Inclusion of Chinese characters as one the of accepted nomenclatures of Chinese herbal substance in prescription writing will not only be consistent with the nomenclature list in commonly used Chinese herbal medicines endorsed by Chinese Medicine Board of Australia (CMBA), but also coherent the requirements of the *Guidelines for Patient Records* issued by CMBA in which it states that “*Information critical to patient safety, such as herbal names should be recorded in the most competent language e.g. English, Chinese, Latin, other.*”

The draft guidelines would not be practical to implement for those registered Chinese medicine practitioners who received their Chinese medicine education in Chinese or other Asian languages if Chinese characters are excluded in prescription writing. In the worst scenario, it would deprive of prescription right from the Chinese medicine practitioners who speak English as a second language from outside of Mainland of China as well as those Chinese herbal medicine practitioners who have been imposed English condition on their general registration as English is the only language allowed to use by the draft guidelines (although Pinyin is one the accepted herbal name nomenclatures, Pinyin is Romanization of Chinese and not all Chinese practitioners know Pinyin as Pinyin is only popular in Mainland of China).

It is unnecessary that Pinyin, pharmaceutical or botanical name are mandatory used for prescription writing where all parties including the patient, the Chinese herbal medicine practitioner or herbal dispenser can understand Chinese. Therefore, we suggest that Chinese characters for herbal name should be included in line with the other three forms of herbal nomenclature in section 1.1 Herbal nomenclature for prescriptions of the draft guidelines.

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?

TGA nomenclature guidelines are particular designed for the herbal products in **manufactured medicines**. TGA nomenclature guidelines are only practical to implement for herbal products in manufactured medicines registered with TGA but not for purpose of labelling the Chinese medicine practitioner’s extemporaneously prepared medicine, e.g. raw herb formula or herbal granules.

We suggest that a prescription or an information sheet contained the name and dosage of each herb

prescribed and other required information such as instruction of herbal usage could be provided to the patient as an alternative way to replace the content of name and dosage of each herb on a label. A similar arrangement has shown its success in Victorian Chinese medicine practice since 2011 when consensus has been reached between the Chinese Medicine Registration Board of Victoria and representatives from the profession.

4. Are the labelling requirements practical to implement?

Labelling requirements in particular list the name and dosage of each herb for the Chinese medicine practitioner's extemporaneously compounded medicine, e.g. raw herb formula or herbal granules are not practical to implement. Translation the Chinese herbs from their common name to botanical name could be only achieved by computer software or a personal with special training in both Chinese herbal medicine and phytology. This will inevitably increase the burden of the patients who receive Chinese herbal medicine treatment.

5. Is the required information for prescriptions appropriate?

The required information for prescriptions could be appropriate if the Chinese characters alone are allowed to use for Chinese medicinal substances where all parties including the patient, the Chinese herbal medicine practitioner or herbal dispenser understand Chinese.

In 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.

Not sure why and "*number of packets (for raw herbs), with each packet numbered sequentially*" should be included in a prescription.

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

We don't support self-medication. We encourage patients to consult a registered Chinese medicine practitioner before taking any Chinese medicines.

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

No further comment.

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

The guidelines draft as "*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)

We believe that Chinese 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 processed Chinese herbs. The identification of species should be performed by experienced experts in Pharmacy of Chinese Medicine or a botanist with supply of plants of herbs. Please be informed that although an herb is from a plant, the same plant is not necessary has the function of an herb as the function of an herb depends upon to the harvest time or process of a plant.

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

Listing each name and dosage of herbs botanical name on extemporaneously compounded medicines is inviable and costly.

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

Exclusion of Chinese characters in prescription writing does not make the public safer, In fact, this requirement (only use of pharmaceutical, botanical or Pinyin name of medicines) does not respect the informed right of a patient who speaks Chinese.

Labelling each herb on a package of extemporaneously prepared medicines does not increase or lower the degree of safety in Chinese herbal medicine practice. In fact, it will raise unnecessary error and confusions in the profession and increase burden of the public.

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

No further comment.

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

We suggest the following contents highlighted should be deleted or amended:

1.2 Herbal nomenclature for labels

We suggest rephrase the sentence as “The botanical name is the only name which clearly indicates the actual species used, therefore in the interest of patient safety the botanical name must be used when labelling manufactured medicines”.

2.1 Labels

We suggest rephrase the sentence as:

“Herbal names must be labelled using the botanical name of the species of herb supplied in accordance with the herbal nomenclature section of these guidelines for herbal products in manufactured medicines.”

2.2 Label content

For an individualised herbal formulae (extemporaneously prepared medicine, e.g. raw herb formula)

The label is to include the:

- specific directions for use, including route of administration, frequency and dose
- patient's name
- date of dispensing or supply
- name, address and telephone number of the dispensary
- name of the prescriber if different to the dispenser
- required storage directions and expiry date to promote the safe and effective use of the medication
- name and dose of each herb (measured in grams)
- total weight of the dispensed prescription (measured in grams), and
- name of the formula dispensed as described in a standard reference book, where applicable (see: 'nomenclature resources' in section of these guidelines 7 for examples of standard reference sources).

We suggest that to delete “ name and dose of each herb (measured in grams)” and replaced with “please refer to the prescription provided for name and dosage of each medicines”

3. Writing prescriptions

Prescriptions must be in English, apart from herbal names which are to be written according to the herbal nomenclature guidelines in this document.

We suggest to rephrase the sentence as:

“Prescriptions must be in English, apart from herbal names which are to be written according to the herbal nomenclature guidelines in this document (any one of the following nomenclatures for Chinese herbal medicines including Chinese characters, *pinyin* name, common English name, pharmaceutical/Latin name, and botanical name are accepted).”

We suggest to add the sentence as:

“If the herbal names were written in Chinese characters, should a copy of the prescription be requested by

the patient, or required by the CMBA or an authorised third party, it is the responsibility of the Chinese herbal medicine practitioner to provide at their own expense a translation of the herbal names into one of the following nomenclatures including Pinyin name, common English name, pharmaceutical/Latin name, and botanical name or cover the cost of this service.”

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.

We suggest to delete number of packets (for raw herbs), with each packet numbered sequentially.

13. Is there anything missing that needs to be added?

Non-herbal substances such as Mu Li (oyster shell), Shi Jue Ming (abalone shell) etc. should be included in a cross referenced nomenclature list developed or endorsed by CMBA.

14. Do you agree with the draft 12-month transition period and if so is this period adequate?

No further comment.

15. Should the review period for the guidelines be two, three or five years?

No further comment.

16. Do you have any other comments on the draft guideline?

We suggest CMBA considering the need and balance among those English and non-English speaking patients, English speaking and English as second language Chinese herbal medicine practitioners when it revises the draft guidelines. We also believe that both scientific and cultural perspectives of Chinese medicine system should be respected as Chinese herbal medicine origins from Chinese culture.

Public could only be protected if the guidelines are implemented in the way that all practitioners observe. If the guidelines are not practical to implement, there will be a lot of breaches of the guidelines and consequently forcing out the Chinese herbal medicine practitioners and dispensers from the registration as everyone in Australia can sell Chinese herbs without proper regulation.

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