

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
Federation of Chinese Medicine & Acupuncture Societies of Australia Ltd (FCMA)
Contact information <i>(please include contact person's name and email address)</i>
Professor Tzi Chiang Lin PhD National President, FCMA

Your responses to consultation questions

Guidelines for safe Chinese herbal medicine practice <i>Please provide your responses to any or all questions in the blank boxes below</i>
1. Do you agree that these guidelines apply to all medicines prescribed and/or dispensed by Chinese medicine practitioners?
Yes, the FCMA agrees with this statement.

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?

No, this guideline is not practical to implement.

The FCMA agrees for Chinese herbal medicine prescription writing, pinyin or the pharmaceutical name should be used as an alternative to the botanical name of herbal substance. However, the FCMA believes that Chinese characters should also be included as one of the alternatives to the botanical name of herbal substance for prescription writing and not 'only an addition where necessary'. Inclusion of Chinese characters as one of the accepted nomenclatures of Chinese herbal substance in prescription writing will not only be consistent with the nomenclature list of commonly used Chinese herbal medicines endorsed by Chinese Medicine Board of Australia (CMBA), but also consistent with the requirements of the Guidelines for Patient Records issued by the 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."

It is not logical or reasonable or practical that only the pinyin, pharmaceutical or botanical name should be mandatory for prescription writing where all parties including the patient, the Chinese herbal medicine practitioner and/or the herbal dispenser can understand Chinese language. Australia is a multicultural society and many patients who seek Chinese herbal medicine service are of Chinese ethnicity. The CMBA should have an obligation to protect the public as a whole including those Australian residents who speak Chinese language. There is a significant cohort of Chinese medicine practitioners who were trained in China and other countries in Asia where Chinese characters were the only form of written nomenclature for Chinese herbs. Therefore it would be unreasonably disadvantaging a large cohort of Australian practitioners who have not learned the botanical names nor pharmaceutical names nor the Romanization that is pinyin.

The FCMA believes that pinyin and Chinese characters should be the key language used for prescription writing. The botanical names of Chinese herbal medicines were not initially created within the Chinese medicine system; those botanical names are not practical in everyday prescription writing.

Firstly, the botanical names do not always fully reflect every single herbal species, for instance, Chinese herbs Bai Shao and Chi Shao are both named as *Paeonia lactiflora* Pall in botanical naming system but they are two different herbs with different functions.

Secondly, it is not efficient and effective to write botanical names in prescriptions for Chinese herbal medicine practitioners and herbal dispensers as well as herbal medicine shop assistants. Chinese characters and Pinyin names are the most widely acknowledged and accepted reflection of Chinese herbal medicines in practice. The use of Chinese characters and Pinyin names in the prescription and labelling can avoid confusion and unnecessary mistakes in the herbal dispensing process. Chinese characters and pinyin are still the most efficient and effective ways to prescribe and supply Chinese herbal medicines in Chinese herbal medicine practice in Australia.

In addition, the Chinese characters and Pinyin names of the herbal medicine are a crucial component of the Chinese herbal medicine system. The Chinese herbal names contain the place of origin, its process and part of plant used and are the best reflection of the herbal species (e.g. Bei Qi, Huai Niu Xi) and flavour (e.g. Gan Cao, Suan Zao Ren). The system of Chinese herbal nomenclature has been in place for thousands of years- it is irreplaceable. We cannot rewrite "Compendium of Materia Medica", 本草纲目, we should treat ancient Chinese wisdom with respect. In Chinese herbal nomenclature, the Chinese character itself contains all the information about the herb, eg 川牛七, Chuan Niuxi, it comes from Shi Chuan province where 淮牛七 Huai Niuxi, comes from Jiangshu and Anhui provinces; 生地黄 Sheng Dihuang and 熟地黄 ShuDi Huang indicate its process.

Thus, it is recommended that for accurate communication and recording of herbal medicine, prescriptions and labelling should be written in either Chinese characters or Pin Yin at all times. For those Chinese medicine herbal practitioners who do not speak Chinese or who cannot write Chinese characters, Pin Yin should be used. For those who are Chinese speaking and are not familiar with Pin Yin, Chinese characters should be used.

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?

The FCMA opposes the proposal of labelling requirements on “2.2 Label content”, in particular listing all botanical names and dosage of each herb on the label for an extemporaneously compounded medicines based on the following reasons:

1. FCMA respects patients’ rights to have full and accurate information on Chinese herbs they are prescribed however the issue of safety is addressed by the standard of care and expertise of the herbalist first and foremost in prescribing the appropriate combination of herbs to be used in a formula.
2. Most of the Chinese herbs prescribed or supplied by registered Chinese herbal practitioners in Australia are non-scheduled substances in the *POISONS STANDARD 2013*, published by the Therapeutic Goods Administration (TGA). The FCMA believes that it is inappropriate to apply the same requirements and restrictions on labelling for both non-scheduled and scheduled substances. Requirements for labelling of Chinese herbs in the proposed guidelines are identical and on some case even more rigid than those for the scheduled medicines (e.g. Australian approved names are allowed to use for scheduled medicines whilst the botanical name of species is required by the proposed guidelines).
3. There will be significantly negative impact on Chinese medicine practitioners as the proposed guidelines do not reflect the existing practice which is primarily using Chinese characters or Pin Yin names. In addition, it is likely that the majority of higher education institutions teaching undergraduate programs in Chinese medicine are primarily requiring students to know the pinyin names (rather than the botanical names).
4. It is also unlikely that patients, practitioners, herbal dispensers and other health care providers including medical practitioners will understand the botanical names anyway.
5. Currently there is no comprehensive database or reference to check herbal interactions or interactions between Chinese herbs and drugs. The issue of allowing referencing to drug-herb interaction databases is not hindered by the use of Pin Yin or characters on labels nor particularly enabled more by using botanical names on labels. The main enabling factor is that adverse events are reported in the first place. Chinese characters and Pin Yin are readily translated in the case where an adverse event is reported. We acknowledge that in long term the profession will need such database or reference to assist the regulation of Chinese herbal medicine.

The FCMA suggests that, as an alternative to requiring that names and dosages of herbs are included on labels, this information is simply included in the prescription and given to the patient.

4. Are the labelling requirements practical to implement?

No, the FCMA does not believe that the labelling requirements for extemporaneously compounded medicines e.g. raw herb formulae or herbal granules are practical to implement. There is a doubling up of information of what is required on a prescription and on a label.

Translation of the Chinese herbs from Pin Yin or characters to botanical names could be only achieved by computer software or employment of person with special training in both Chinese herbal medicine and phytology, which may increase costs to the practitioner and could indirectly translate into increased costs born by the patient.

5. Is the required information for prescriptions appropriate?

<p>The required information for prescriptions would be appropriate <i>if</i> the Chinese characters are able to be used for Chinese herbs where all parties including the patient, the Chinese herbal medicine practitioner and herbal dispenser understand Chinese language.</p>
<p>6. Do you agree with the circumstances in which a medicine may be supplied for self-medication?</p>
<p>The FCMA encourages patients to consult a registered Chinese medicine practitioner before taking any Chinese medicines. However exceptions could include some traditionally used herbal formulas used for health maintenance purposes.</p>
<p>7. Do you agree with the limited role of dispensary assistants as outlined in section 5 of the guidelines?</p>
<p>No further comment.</p>
<p>8. Are there any additional requirements which should apply to the management of a Chinese herbal dispensary?</p>
<p>No further comment.</p>
<p>9. Does the sample label and prescription assist in understanding the requirements set out in the guidelines? Should any other examples be used?</p>
<p>In general, it is very useful for guidelines to provide samples- in this case a sample label and prescription- though as stated previously, the FCMA does not agree with the content of labels (too much information when the same information is provided on a prescription) nor on the mandatory requirement for herbs to be written as botanical names.</p>
<p>10. Taken as a whole, are the guidelines practical to implement and sufficient for safe practice?</p>
<p>Exclusion of Chinese characters in prescription writing does not make the public safer. This requirement does not respect the informed right of a patient who speaks Chinese.</p> <p>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 could raise unnecessary error and confusion within the profession.</p>
<p>11. Is the content flow and structure of the guideline helpful, clear, relevant and workable?</p>
<p>The content and structure of the guidelines is clear and relevant. The main issue with the guidelines is the stipulation that botanical names should be written on labels and in prescriptions and that Chinese characters are not acceptable alone.</p>
<p>12. Is there any content that needs to be changed or deleted?</p>
<p>The FCMA suggests that Chinese characters or Pin Yin be acceptable for prescriptions. It is suggested that prescriptions be given to patients as a matter of course and that these contain the full details (including herbal ingredients and dosage), and that consequently labels do not require herbal ingredients and dosage to be listed (in other words, these can be simplified).</p> <p>See previous sections.</p>
<p>13. Is there anything missing that needs to be added?</p>
<p>No further comment.</p>
<p>14. Do you agree with the proposed 12-month transition period and if so is this period adequate?</p>

The FCMA believes 12 months transition period will be adequate, provided Chinese characters and pinyin are acceptable for prescription writing (and labelling if the requirements for labelling can't be changed). If however, it became mandatory that prescriptions and labels must include botanical names, then a much longer transition period would be required in order for education institutions to change their practices and for practitioners to obtain software that could assist them in translation of Chinese characters to botanical names.

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

Three years should be fine.

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

The FCMA is concerned that the scope of proposed guidelines will only be limited to registered Chinese herbal medicine practitioners and dispensers whereas anyone can sell or authorise the supply of Chinese herbal medicines to patients as Chinese herbal medicines are not prescribed medicines (except those listed in Poisons Standard 2013). Ironically, Hong Qu (red yeast rice, a controlled Chinese medicinal substance in Schedule 4 in Poisons Standard 2013) can be bought from most Asian grocery shops for cooking but not for therapeutic use prescribed by Chinese medicine practitioners. If the FCMA really believes that the requirements of prescription and labeling of Chinese herbal medicines are critical to patient safety, then applying such restrictions to registered Chinese herbal medicine practitioners and dispensers but not the others will not address the problem.

The FCMA is also concerned about the safety in relation to self-medication by the patients and the use of Chinese herbs by other regulated or non-regulated health professions in Australia. It is currently illegal for Chinese medicine practitioners and dispensers to 'obtain, possess, use, sell or supply' those traditionally-used Chinese herbs that have been included in the Poisons Standard 2013 regardless of qualifications/training and notwithstanding the fact that these Chinese herbs have been in traditional use in China and other parts of Asia for a long period of history. Yet at the same time, some Chinese herbs such as Ma Huang (*Ephedra spp.*), Fu Zi (*Aconitum Spp.*) and Ban Bian lian (*Lobelia*) etc. are legally accessible to medical practitioners, dentists, veterinary surgeons, pharmacists regardless of whether or not those professionals have proper training in the usage of the Chinese herbs, and access is denied to those who do have the appropriate training: registered Chinese herbal medicine practitioners and dispensers. Where is the benefit to the Australian public if qualified Chinese medicine practitioners registered by legislation cannot access certain potent scheduled herbal medicines. Therefore, the FCMA suggests the scheduling of Chinese herbs should be on the agenda of CMBA as a matter of urgency to ensure the safe usage of Chinese herbal medicine.

The FCMA further suggests that the Therapeutic Goods Act 1989 and its Amendment 1990 should be amended again so that registered Chinese herbal medicine practitioners can have the same access to Scheduled herbs as other registered health practitioners (who are not being trained in Chinese herbal medicine) do.

Finally, the FCMA is concerned that some registered Chinese herbal medicine practitioners and herbal dispensers may not renew their registration in the Chinese herbal medicine division due to the unnecessary burden which may result from the implementation of the proposed guidelines in their current form which precludes the use of Chinese characters.

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