

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 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
Australian Traditional Chinese Medicine Association
Contact information

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?
<i>Disagree.</i>
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?
<i>We do not agree with changing the current practice of using Chinese Characters or Pin Yin to Pin Yin or Pharmaceutical names as this is what will make it difficult for patients and other Chinese Herbal Medicine professionals to understand what medicine the patient is taking. A big percentage of patients taking Chinese Herbal Medicine are from Chinese backgrounds. Chinese Herbal Medicine is ingrained into the very foundation of Chinese culture. As such many patients have some basic knowledge of Chinese Herbal</i>

Medicine as it is part of daily life, if the medium is changed from Chinese Characters to alternative nomenclatures these patients will no longer be able to differentiate the herbs, thereby reducing their understanding of what they are taking as they may only recognise the herbs via Chinese Characters.

That is not to say that patients who would like the prescription in botanical name shouldn't be offered the choice. Of course there are patients that may not have a background knowledge of Chinese Herbal Medicine and they should be given the choice of having botanical names attached to their prescriptions (not the other way around, of optional Chinese Characters). How this will be provided is addressed below.

The formal practice of nomenclature in Chinese Herbal Medicine has always been with Chinese Characters, how is it inadequate now? Adding which part of the plant and how it was processed for each herb is redundant as the Chinese Characters already reveal both this. In addition there are some herbs written in Chinese Characters that are even more precise than botanical names as it states what region of China it is from (as this could also impact the property of the herbs).

There are many aspects of the this guideline that are very impractical. Clearly stated on the Draft guidelines for safe Chinese Herbal Medicine Practice is the little impact anticipated on practitioners. This will not be the case. There are two styles of practice when it comes to prescribing Chinese Herbal Medicine right now. One is from practitioners of Asian descent (who can read and write Chinese) and the other is practitioners of non-Asian descent (who cannot read or write Chinese). This guideline seems easier to implement for non-Asian practitioners as they primarily use Pin Yin (therefore can continue to use Pin Yin, (which is actually more ambiguous than Chinese Characters) should botanical names be rejected). They also primarily use granules making the labelling process a lot less labour intensive than packets of raw herbs.

Patient safety should be paramount so this guideline is a step in the right direction. It however needs to take into consideration who it is trying to protect. By changing the nomenclature from Chinese Character this board is preventing the very people they are trying to protect from understanding and recognising what they are taking. An alternative is to use the "Cross Referenced Nomenclature List of Commonly used Chinese Herbal Medicines" and add an index column. That way the practitioner can easily insert the index number behind the Chinese herb. Anyone that wants to know more about the herb can easily look it up on the excel. This is much more safer than trying to ensure a whole profession learns what will essentially be a new language and possibly making mistakes because it will not be a simple process. Don't forget some of the best practitioners are the ones that have been practicing for the longest. If this guideline in its current form goes ahead there will be a huge negative impact on the profession. Many of these sage practitioners may just leave the field all together, causing CMBA to deny the public access to these masters. Or mistakes in writing alternative nomenclatures will be made as the whole profession is forced to change the way it has practiced since it started (something it may not be equipped to do).

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?

Please refer to Question 2. Also is this the article? Zhao Z, Hu Y, Liang Z, Yuen J, Jiang Z, Leung KSY (2006) Authentication is fundamental for standardization of Chinese medicines. Planta Med 72:865–874? It was not listed in the referencing. Would have liked to read which herbs made the 27%. It may be easier to differentiate these 27% from each other than to enforce a whole new nomenclature.

4. Are the labelling requirements practical to implement?

Too cumbersome, not suitable in practice for dispensing of Raw Chinese Herbs. Labelling is something that should be implement in the future. However it is a complicated process as there are many factors to consider, it therefore needs more time for discussion. The processes suggested are also very time and

labour intensive. Without computers (which is the norm currently) to assist, many dispensers will not be able to follow the detailed labelling requirements suggested in the guidelines. This cumbersome addition to the labelling system could also mean that the additional labour costs will have to be passed onto the public. So not only will the public need to spend more time waiting for the medicine to be packed but they will be paying for the privilege of waiting. For now it would be best to require all practitioners to include the needed information in the prescription (eg patient information, cooking instructions, frequency and dosage to take, contraindications, warnings etc) and for the patient to be able to retain that prescription after it is packed. All containers of herbs should contain warnings to keep out of reach for children.

5. Is the required information for prescriptions appropriate?

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

We should be able to supply herbs for self-medication unless it is a listed restricted herbs until CMBA arrange to set up a guideline to identify non-prescription herbs and prescription herbs, similar practice in western pharmacy. Consumers can buy Panadol, Vitamins and etc even Panadine and some product include pseudoephedrine over counter without prescription. So if there is to be restriction on self-medication (Chinese Herbal Medicine) then some guideline of non-prescription and prescription herbs should be compiled.

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

To wash hands between every prescriptions is useless. In regards to granules the dispenser would not even touch the actual granules. In relation to the raw herbs, the herbs itself are not food grade clean, the herbs are not food that the patient consumes raw, it is cooked than consumed.

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

How long does the dispenser need to keep a record of the prescriptions? A suggestion that only prescriptions need to be recorded, non-prescription herbs bought should not need a record.

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

The samples actually missed components that were listed in the guideline, but as we disagree with the level of information needed on the labels and prescriptions this may be a mute point.

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

Public safety should always be paramount and processes transparent and easy to understand. Reiterating Questions 2, there are many aspects of the this guideline that are very impractical. Clearly stated on the Draft guidelines for safe Chinese Herbal Medicine Practice is the little impact anticipated on practitioners. This will not be the case. The guideline seems to be trying to structure Chinese Herbal Medicine into the parameters of Western Pharmaceutical Medicine. However because the two are very different it is not practical to push Chinese Herbal Medicine into this format. There are processes that should be adopted for public safety but also consideration should be made for practicality and a reminder that a percentage of patients are of Asian descent and these guidelines will actually put them at risk (eg unable to understand what they are taking anymore).

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

It is a very lengthy, verbose document for a profession where many do not have English as their first language. This makes it hard to understand and as most were not made aware of this guideline until the forum (23 June 2014) there wasn't sufficient time to thoroughly discuss this guideline with relevant stakeholders.

12. Is there any content that needs to be changed or deleted?
<i>Yes, refer to previous questions.</i>
13. Is there anything missing that needs to be added?
<i>Not at this point as there is already so much that needs to be reviewed and discussed already within this guideline.</i>
14. Do you agree with the proposed 12-month transition period and if so is this period adequate?
<i>No. Continuing with the view point discussed earlier there is much that needs to be revised first. When the guidelines are finalised we will have a clearer idea of what needs to be implemented and only then will we know what will be an adequate transition period.</i>
15. Should the review period for the guidelines be two, three or five years?
<i>Two years.</i>
16. Do you have any other comments on the draft guideline?
<p><i>We support CMBA's effort in producing a guideline for the safe practice of Chinese Herbal Medicine. It is essential that a clear and transparent guideline be produced to help ensure public safety. This guideline also needs to be practical to implement and not weigh down the TCM field with unrealistic theoretical best codes of practice. Having reviewed the guideline the following are points of consideration.</i></p> <ol style="list-style-type: none"> <i>1. A longer review period of the guideline would be appreciated. Even though 3 months was given for the review, it was only at the CMBA forum on the 23 June that we became aware of this proposed guideline. As mentioned before this document is lengthy and verbose. There could have been a better division of each category like labelling, dispensing etc and also clear key points at the end of each section. As CMBA is aware many of the practitioners have an English condition placed upon their registration. This means a Chinese version of the guideline (like other translated CMBA documents in the past) would have been appreciated should CMBA want a more thorough feedback. This document therefore is not easy to understand for practitioners/dispensers of Asian descent, whom we believe will be the most impacted stakeholder in this.</i> <i>2. The work involved in implementing some of the additional processes are not practical. It would not be the little impact envisioned by CMBA, there would be an increase in time, money and labour spent. From learning the new nomenclature, procuring additional resources like photocopiers and having to pass this increase in time, re-education, labour and costs to the public.</i> <i>3. The implementation of the guideline as is has caused a lot of stress for many stakeholders as they are not sure they will be able to comply with so many additional requirements. They worry it will either make them unable to practice or cause a bottleneck effect with workflow.</i> <i>4. Some thoughts from our members are:</i> <ol style="list-style-type: none"> <i>a. Chinese Herbal Medicine has a very long history and has proven to be relatively harmless in comparison to other medicines. The risk when it comes to Chinese Herbal Medicine is from practitioners who are inexperienced. That issue however is not part of this guideline, that is already dealt with via the CMBA registration process. CMBA already protects the public via its registration process and list of prohibited herbs published in 2012.</i> <i>b. Another aspect is that there is a big portion of herbs that are already currently consumed in daily life as food. As mentioned before Chinese Herbal Medicine is ingrained into the very foundations of Chinese culture and as such there is a portion of the public community who consume it like food like Lian Zi, Hong Zao, Gou Qi. As Chinese Herbal Medicine was initially food they are commonly stored in the house as items of food. The community gains its knowledge from cultural and familial information, newspapers, magazines, radios. For example they will know to make Ju Hua tea for dry eyes, dry bitter mouth or Jin Yin Hua for sore throat. This is similar to the public being able to buy panadol or cough syrup at any store without having to go through any processes. Where will self medication stand</i>

on this? The difference in processes required between retail and the practitioner/dispenser is commercially not balanced. As herbs are treated like a food by the Asian community they are sold as such in retail stores. Having one set of rules for one party and another set for the other means there is no consistency and this will end up confusing the public. By excluding retail from this guideline it defeats the purpose of what this guideline is trying to achieve.

- c. An unreasonable amount of resources is consumed making the labels instead of treating the patient. Most practitioners are sole traders and as such have a limit on how long they can spend with one patient. Within this time frame CMBA now has proposed a very time and labour intensive inclusion in the process. This situation could lead to:
 - i. Practitioners not being able to see their normal quota of patients due to the longer turn around it takes to see one patient
 - ii. Dispensers could lose business due to the longer turn around needed for each prescription as well as the added labour costs that could be passed onto the public
 - iii. Less consultation time with the patient, more time wasted on packaging, looking up the botanical/pharmaceutical/Pin Yin nomenclature of the herb (which could also lead to increase risks due to inadequate knowledge of new nomenclature).
 - d. Changes have been made to Acupuncture that are both practical and benefit the public like no longer having to wear gloves, or use alcoholic swab before insertion of needles. Can this guideline not be like that, benefit the public as well as being practical. The guideline needs to be less convoluted, more simple to implement.
5. To consider are
- a. The educational/experience level of the practitioner and dispenser heavily influences the safety of a prescription. It makes more sense to focus on that.
 - b. Many practitioners have English condition placed on their registration
 - c. Pin Yin is not a system that everyone knows, and as a nomenclature it is more ambiguous than Chinese Characters so should not be considered a preference above Chinese Characters.
 - d. Computer/photocopy use is not prevalent in many of the clinics in practice.
 - e. Many work as sole traders in small environments.
 - f. Many practitioners/dispensers do not know the pharmaceutical/botanical nomenclature of herbs.
6. Recommendations due to the above points
- a. Consideration needs to be made for practitioners that are registered via grandparenting and/or have English condition placed on them.
 - b. Pharmaceutical/botanical nomenclature is not an easy language to use without assistance (eg from Computers or re-education). Changing the nomenclature of herbs could actually cause more harm, contradicting what the guideline was hoping to prevent.
 - c. Victoria has already been registered for over 10 years. It should be stated that ONLY 15% of complaints concern Chinese Herbal Medicine. This should prove how safe it is in comparison as it only takes up a small percentage of complaints while it makes up a much larger part of the profession. Of interest is what was the division of the 15% of complaints? Where did the findings come from? How was it compiled? Did it have anything to do with what is being addressed in the guideline or were they more about wrong diagnosis made? Registration nationally has transpired for 2 years now. We propose following another 2 years a study be conducted on the complaints made in relation to Chinese Herbal Medicine so that we can see where actual problems may lie.
 - d. Labelling is something that should be implemented in the future. However it is very time and labour intensive so more consideration needs to be made on how to make a smooth transition to this new phase. Currently many practitioners/dispensers do not have technological resources like computers or photocopiers at hand to make this an easy process. We therefore for now propose that all the information that is needed in both the prescription and labelling be placed in just the prescription and that the patient be given a copy to keep. For now herbal containers/packages should hold information that can link it

back to the prescription it belongs to. There should always be a Child safety warning on all herbal packages.

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