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
Contact information *(please include contact person's name and email address)*
Steven Clavey

Your responses to consultation questions

Guidelines for safe Chinese herbal medicine practice *Please provide your responses to any or all questions in the blank boxes below*
1. Do you agree that these guidelines apply to all medicines prescribed and/or dispensed by Chinese medicine practitioners?
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?
Yes, pinyin should be used in Chinese herbal prescription writing. The Victorian guidelines were sufficient in this regard. As an aside, I would be very cautious about adopting TGA guidelines for traditional medicines. Their

purview applies to manufactured medicines ONLY, and primarily over-the-counter (OTC) medicines at that, they are not concerned with individual practice, and their management of the complementary medicine and in particular the Chinese medicine area has been ill-thought-out.
Even in the limited arena of OTC medicines the TGA approach has resulted in complete chaos for the Chinese medicine practitioner trying to use patent medicines. Eg the indications the TGA requires the label to carry are all based around Western bio-medical practice and are completely inappropriate for Chinese medicine. This in fact results not only in confusion but dangerous disruption of practice. For example, it is very common for a male patient to refuse to take the appropriately prescribed patent medicine Xiao Yao San (Wandering Powder) because it is labelled "for the treatment of PMS" (one of the few appropriate indications allowed by the TGA for this formulation). There is no recognition of or allowance for the fact that a Chinese herbal formula has multiple uses, and the result of this is that a patient will often fail to comply with a prescribed treatment because "the label said it was for something else." This state of affairs has gone on for 20 years and is a disgrace.
We need to design our own way forward in terms of patent medicine indications that work for Chinese medicine, and hopefully present a better proposal to the TGA, not the other way around.

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?

While "multiple species" may sound disturbing to the layman, the fact is that these species are for all functional purposes medically-equivalent. This means that you will get a clinically-similar therapeutic effect on humans (which, after all, is the "testing site" where the effects of Chinese herbs have been observed for all these centuries) from different species of plant. In most cases these "different species" are really very close botanically, such as in the Lilium species proposed as an example.
Where there *are* significant differences in effect, this is for the most part accounted for in the additional designations used traditionally, eg Bei Sha Shen (for Glehnia littoralis root) or Nan Sha Shen (for Adenophora tetraphylla). All this is of course part of the training of a competent Chinese herbalist.

These facts reduce the significance of the "impossible to accurately identify the species" to the very few instances in which there may have been an adverse event.
It is overkill to require the botanical name for every herb to be supplied to every patient, 99.9% of whom will never need it. It is sufficient to have the botanical name available at the prescribing clinic where it may be accessed if needed.

4. Are the labelling requirements practical to implement?

The labelling requirement that each daily dose (eg, one bag of raw herbs) be labelled with all the information stated is impractical and excessive.

As long as a clear written prescription is provided to the patient with all the information required (as stated in the guidelines for individualised herbal formulae, the name of each herb IN PINYIN), each bag can then be safely labelled with the prescription number, the name of the patient, the date, and crucial warnings in red (eg "External Use Only").

This way all important information is provided to the patient.

"Impractical" because it would involve either a very time-consuming copying of a complex prescription with 12-15 herbs, written out eight or nine times (or however many bags are prescribed), or a change in technology so that prescriptions must be computer-generated and labels printed out. It may be that the latter is seen as preferable by the Board, but most practitioners at present write out prescriptions by hand, and the demanded change would result in very widespread disruption of daily practice and significant outlay of capital for new technology.

There are factors here, too, that go beyond what the Board may have considered.
In my traditional teacher's opinion, for example, a well-written prescription, its choice of language and its very structure, was considered an art form that itself had a therapeutic function: a patient would observe the elegant presentation of the handwritten prescription and realise he had found a trustworthy physician. At the very least (leaving aside the effects of trust on a treatment) it would ensure compliance with the protocol set out for him.

5. Is the required information for prescriptions appropriate?

Yes, except that not every individual prescription is based on a standard formula. This should not be required to be part of the prescription unless the practitioner wishes to state it.

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

Yes

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

Yes

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

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

This sample should have been provided at the relevant section. I only found it after quite a while of looking.
When I did find it, it made it clear that having such a label for each pack of herbs dispensed as part of a single prescription is excessive and unnecessary, and makes a mockery of saying "You can use pinyin for your prescriptions" (since your package labelling would require the botanical name anyway).

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

Impractical. It would be sufficient to have a clear written prescription provided to the patient with all the information required (as stated in the guidelines for individualised herbal formulae, the name of each herb IN PINYIN), after which each bag can be safely labelled with the prescription number, the name of the patient, the date, and crucial warnings in red (eg "External Use Only").
This would satisfy the need for safety and clarity. In those extremely rare instances where the precise botanical name of the species used is required for some reason, eg an adverse event, it can be supplied by the practitioner upon demand.

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

Section 2: "Labelling" it was unclear at first whether "dispensed medicines" referred to individually prescribed raw herbs; this only became clear toward the end of the section.

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

As per these comments.

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?
If it requires a separate computer system and new software for printing labels for individual bags, probably the time is inadequate. I am not even aware of the availability of such software, its cost nor how much training may be involved in its use. And this is in a practice (ie, mine) where the rest of the guidelines as specified are already in place, albeit in a handwritten form. The impact on other practices, those newly registered for example, may well be much more onerous.
15. Should the review period for the guidelines be two, three or five years?
Three years.
16. Do you have any other comments on the draft guideline?
Thank you for the opportunity to comment.

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