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)*
Mary-Jo Bevin

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, not botanical as in TGA nomenclature. This was already resolved by the Victorian guidelines for the previous CMRBVic.

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?

It is overkill to require the botanical name for every herb to be supplied to every patient. It is sufficient to have the botanical name available at the prescribing clinic where it may be accessed if needed.

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 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 stated in the full name in pinyin.

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 the important information is provided to the patient.

As most practitioners still write prescriptions out by hand, it would be too time-consuming to copy a complex prescription with 10-15 herbs onto each of 8 bags of herbs, as well as having time to design and write the prescription, and dispense the herbs.

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?

Yes, however it highlighted that having such a label for each pack of herbs dispensed as part of a single prescription is excessive and unnecessary, and negates the debate over use of pinyin or botanicals in prescription writing, since the 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, with 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?
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?
The proposed guidelines for labelling would require a separate computer system and new software for printing labels for individual bags, so this time period seems inadequate, and the software would likely be very costly. Please don’t implement this.
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?

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