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
Safflower Chinese Medicine Clinic
Contact information *(please include contact person's name and email address)*

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?
Yes, should apply to all medicines. The guidelines need to be an integrated part of a practitioner's daily routine in prescribing, labeling and dispensing.
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?
Listed medicines are OTC medicines and are sold in health food shops or any practitioner and

not exclusively by Chinese medicine practitioners. We believe that OTC products need to have different treatment as they are widely distributed to unspecified individuals.
If a Chinese herbalist prescribes individually customised formulas for a patient, he/she would use Pinyin as a preference as undergraduate training is based on pinyin. Furthermore, All Chinese medicine literature and standard Chinese reference books use pinyin and the pharmaceutical names to identify a specific herb. Pharmaceutical names are relevant to pharmacists; botanical names are relevant to botanists.

The Swiss model where a TAS list (traditional Asian substances list is compiled for the save access, used, prescribing by Chinese medicine practitioners), pharma and Pinyin names are used. Therefore, pinyin should be used as an alternative to the *pharmaceutical name*.

We don't think that Chinese characters should be used alone as herbs can't be identified by individuals who are not familiar with the Chinese language.

We have pointed this out before, only pharmaceutical names are relevant to identify a correct Chinese herb. Sometimes one Chinese herb can be sourced from several different botanical species (Qin Pi: Fraxinus rhynchophylla HANCE, F. chinensis ROXB., F. szaboana LINGELSH.) The pharmacopoeia indicates which botanical species can be used for a particular herb and furthermore it indicates the part of the plant/animal.

We believe that the guideline is practical and necessary to implement. Costs for the initial set up of a database with relevant names plus the relevant hardware, label and printers might arise. Also, the work flow might have to be adjusted in order to comply with the guideline. However, these costs are expected to be minimal.

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?

We are unable to locate the Zhao et al (2006) paper in order to establish what bases the research was conducted on, what motive the research had and how this research was payed for. If 'research' and crosschecks are conducted by the prescribing/dispensing practitioner prior to prescribing/dispensing, the botanical name can be included to assist in assessing interaction database or ruling out of potential adverse effects, but botanical names don't have to be an integral part of labelling.

No, we don't agree that labelling should be according to botanical names (see our comments in 2) and above.
Pinyin and pharma as established under 2).

Your sample for Pharmaceutical name: Page 26 of proposed guidelines

All three species of Lilii bulbus (Bai He) are acceptable for use.

It might be noted at this stage that 'harmonising' two entirely different systems (Eastern and Western herbal medicine) might be difficult as the bases are so diverse. We are talking flavours and actions in Chinese herbal medicine and active ingredients/compounds in Western medicine. To push the labelling of customised dispensing of Chinese herbal to use botanical names is a cut back and disregards the origins of Chinese herbal medicine.

4. Are the labelling requirements practical to implement?

The labeling requirements are practical to implement and are an integral part to professional dispensing, expect the nomenclature.

5. Is the required information for prescriptions appropriate?

The information required for prescriptions is relevant.

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

We agree with the circumstances that self-medication can be supplied – only TGA listed medicines are appropriate for self-medicating.

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

No. The practitioner is responsible for the appropriateness of the medicines in relation the full medication history and for any counseling of the patient. A trained dispensing assistant should be able to conduct a final check of dispensed medicines according to the prescription provided. If a dispensing assistant dispenses medicines only, the assistant might have a lot more experience in doing that and this should be recognized by the board.

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

A dispensary should list batches received for individual herbs. Further on, these batch numbers should be listed for each herb used in a particular prescription. This is the only way that products can be recalled, if at any time, the batch number could be recalled by the supplier/manufacturer/wholesaler or if there are severe adverse effects in a patient.

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

The sample label is clear but in order to prevent mixing up the patient address and Date of Birth could be helpful.

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

Safe dispensing in itself requires noting of batch numbers to backtrack any substances dispensed for immediate recalling if necessary. In our opinion this aspect is missing. Another important area that these guidelines do not include is the quality of herbs. If order to safeguard the public, any raw materials need to be tested an analysed.

11. Is the content flow and structure of the guideline helpful, clear, relevant and workable?
Yes.
12. Is there any content that needs to be changed or deleted?
No.
13. Is there anything missing that needs to be added?
See point 10.
14. Do you agree with the proposed 12-month transition period and if so is this period adequate?
Yes, we think it's an appropriate timeframe.
15. Should the review period for the guidelines be two, three or five years?
3 years.
16. Do you have any other comments on the draft guideline?
No thank you for the opportunity to comment on these guidelines. We hope that some of our comments will be taken on board.

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