Submission on the CMRB of Australia's *Draft Guidelines for safe Chinese herbal medicine practice*

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1. **Do you agree that these guidelines apply to all medicines prescribed and/or dispensed by Chinese medicine practitioners?**

Yes, I agree that these should apply to all medicines prescribed and/or dispensed by CM 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?**

2.1. For prescription writing, I agree that the pinyin or the pharmaceutical (Latin) name may be used as an alternative to the botanical name. However, the difficulty with the suggestion that Chinese characters are *an addition, where necessary*, is that for practitioners who are Chinese (English is not the first language) and who were trained in China or other parts of Asia, writing Chinese characters is the norm and they will simply not know the pinyin equivalent nor the pharmaceutical or botanical names.

2.2. It could be argued that this stipulation that the herb names must be in English in a prescription is at odds with the first part of the CMRB's Patient Record Guidelines, bolded below, which state that:

"It is the Board's preference that records be kept in English. Given the primary purpose of the record to create a comprehensive and accurate record, the Board accepts, however, that in some circumstances it may be preferable to use a different language. This will only apply to practitioners registered per grandparenting provisions. *This will also be an important professional judgment made by the practitioner and the Board notes that if a practitioner has submitted evidence or a statement that they meet the CMBA*

English Language Standard, there is an expectation that their patient records will be in English" (CMRB [2012] Patient Record Guidelines, p. 4, available at URL: http://http://www.chinesemedicineboard.gov.au/Codes-Guidelines.aspx)

However, it is acknowledged that the above guidelines sit on the fence somewhat and do not give a clear instruction one way or the other on the use of English or not- the last part contradicts the first part.

2.3. *'**The use of Chinese characters alone makes it difficult for patients and other health practitioners to understand what medicine the patient is taking'.*** I am not sure which 'other' healthcare practitioners are being referred to here, however, it is unlikely that other healthcare practitioners will know what a particular herb is even if it is written as the botanical name or pharmaceutical name (unless perhaps they are a western herbalist).

2.4. My suggestion is that for prescriptions, it should be acceptable to write the herb names as characters when the patient can also read Chinese characters and where the practitioner is Chinese speaking and has been grand-parented with respect to registration, in line with the first part of the CMRB's Guidelines for Patient Records. It should also be acceptable to write the herb names in pinyin gives an accurate description of the herb. Where practitioners also know the botanical and/or pharmaceutical names, these may be added or used instead (but should not be mandated).

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 labeling?**

I have a number of comments in relation to the statements and questions posed above.

3.1 There is an inconsistency in the draft Guidelines. If, as it says in section *1.2 Herbal nomenclature for labels,* the botanical name should be used when labeling medicines, why is it that in writing prescriptions, it is acceptable that the pinyin name or pharmaceutical name may be used as an alternative to the botanical name?

3.2 *'**Best practice is to label herbs supplied to a patient by the botanical name to allow for ..... the informed use of evidence from pharmacological research'.*** I am not sure what labeling of herbal medicines using botanical names in clinical practice has got to do with the informed use of evidence from pharmaceutical

research. How is the labeling of herbal medicines in a clinical practice going to *allow for* the informed use of evidence from pharmaceutical research? I cannot see the logic behind this statement. In addition, there is an assumption that pharmaceutical research papers report only the botanical names of Chinese herbs- that is not the case- the pinyin names of the herbs are also generally included, particularly in research conducted in China where the majority of Chinese herbal medicine research has been conducted.

3.3 The past and possibly current Chinese medicine education system in Australia is likely to be deficient with respect to any requirement for practitioners to know the botanical name of Chinese herbs. Certainly, from my own experience when Chinese medicine education was introduced into Australian universities in the early to mid 1990's, there was a requirement to know the pinyin names but not the botanical names.

So for this reason I doubt that the requirement to label herbs with the botanical name will be practical to implement, simply because this has not been a requirement in the Australian Chinese medicine education (students have typically learned names of herbs in pinyin as the priority), and there is a cohort of practitioners originally trained in China and other parts of Asia who were not taught the botanical name (written in English)- they are likely to only know the Chinese characters.

3.4 I am not sure which drug-herb interaction data-bases are being referred. Nonetheless, if an adverse event is reported in relation to a Chinese herb, written in pinyin and/or characters, a simple cross-referencing would sort out the botanical name to be entered onto any data-base if this data-base did not include pinyin or characters and only included botanical names. However I would expect a data-base designed for Chinese herbal medicine to include characters, pinyin and botanical names for cross-referencing purposes. Again, the amount of effort to translate the pinyin or character into the botanical name in the relatively uncommon case of adverse event reporting and subsequent entry on an adverse event database would seem relatively small in comparison to the amount of effort required for what is likely to be a very large number of Chinese medicine practitioners to write botanical names on herb labels when a) their education emphasised the pinyin above the botanical and pharmaceuticals names (in the case of practitioners educated in Australia) or b) they only learned the Chinese characters (in the case of Chinese practitioners trained in Asia who immigrated to Australia).

4. Are the labeling requirements practical to implement?

4.1. There seems to be a doubling up of information in what is required on labels and in the written prescription for individual herbal formulae. Is this necessary?

4.2. The guidelines are not clear on whether it is best practice to provide the patient with a copy of the herbal medicine prescription or not. Section 3 simply states: *'A copy of the prescription in English must still be provided to the patient on request'.* This makes it optional unless a patient asks. The fact that the labeling requirements are so detailed in some ways may negate the need to give the patient a copy of the

prescription, unless they ask, as most of the information set out in a prescription is included on the label. However, I would think it best practice to provide a patient with a copy of the prescription as a matter of course. If this were the case, would it then be necessary to repeat the herbal ingredients on the labels?

4.3. I am not sure why the total weight of the dispensed prescription needs to be included on the label.

4.4 The Draft guidelines need to be clearer in section 2.2 about whether all bags of (raw) herbs must be labeled or not.

In **section 3.1 Information required on prescriptions** (page 12), the sixth point (reproduced below) states: *'.....with each packet numbered sequentially'*

'In the case of an individual herbal formulae (extemporaneously prepared medicine), the:

1. name of each herb included in the prescription
2. part of the herb (where relevant)
3. form of processing (where relevant)
4. quantity of each herb in grams
5. preparation instructions, and
6. number of packets (for raw herbs), **with each packet numbered sequentially'**

If each packet is required to be numbered sequentially, then this information needs to go into the section on labeling (**section 2**) as this requirement may not be easily picked up here in the section on prescriptions.

5. Is the required information for prescriptions appropriate?

5.1 I do not think it necessary to add the patient's date of birth on the prescription.

5.2 I think it needs to be made clear within the section on prescriptions what is meant by the term 'Other warnings'. I note a sample warning is provided in the sample prescription in Appendix 3 ('***If unexpected symptoms occur stop taking the herbs and contact your practitioner.'***) however suggest it is explained within the section on prescriptions and not left to the appendices (many people will not look carefully at these). You may want to consider whether the sample warning directs patients to contact their practitioner and/or in more severe cases, a medical practitioner.

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

If Chinese herbal medicine is considered unsafe enough in the hands of unskilled practitioners as to warrant statutory regulation, then by definition it should not be supplied to patients for self-medication. I therefore do not agree with either the first part of section 4.8 (in relation to proprietary forms of medicine) or second part of section 4.8 (in relation to the supply of an extemporaneously prepared medicine). Dot point 2 suggests the dispenser must determine that the medicine is indicated for the condition that the consumer requests it for, however this assumes the consumer is going to divulge this. Even if the consumer *does* divulge the condition, it is unlikely they will know what underlying pattern of disharmony (Chinese medicine syndrome). And diagnosis of the underlying pattern of disharmony tends to be what guides the choice of medicinal formula. In other words, the dispenser is not going to be able to establish if the medicine is indicated for the condition without conducting a Chinese medicine consultation.

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

Yes, I agree with these.

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

In section **4.11 Expired and undated prescriptions**, it states that:

'When no expiry date is recorded, the prescription must expire one month after the day upon which the prescription was written'.

Why is the expiry date suggested in the guidelines one month after the date of prescription? That is, on what basis was the time of one month chosen? Perhaps that needs clarification.

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

I think that the provision of samples in the appendices is an excellent addition to any guidelines.

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

There are some fundamental problems with the requirements in the guidelines that will make them impractical to implement, in particular the stipulations around prescription writing and labeling including the requirement for use of botanical names.

Consideration will need to be given to what information is set out in Course Approval Guidelines for courses of study that lead to registration of graduates with respect to herb nomenclature *if* the guidelines do end up stipulating that in the labeling of herbs practitioners must use botanical names.

However, in general the intent, structure and much of the content of the guidelines is relevant and provides good, common sense guidance, which if adhered to, should allow for safe practice.

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

The structure of the guidelines is reasonably clear and very relevant.

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

I suggest that the guidelines be amended to stipulate that Chinese characters are acceptable for prescriptions and labeling where the Chinese medicine practitioner has been grand-parented and where they have been trained to use Chinese characters for herbal nomenclature, in particular when the patients can also read Chinese characters. I also suggest that the guidelines be amended to stipulate that pinyin is acceptable for prescriptions and labeling.

I further suggest that in the case where a prescription *is* provided, the requirements for labeling of extemporaneously prepared herbal medicines be reduced to avoid doubling up of information.

13. Is there anything missing that needs to be added?

I suggest that the guidelines give clear guidance about whether a prescription should be given to the patient as a matter of good practice *or not*. Currently the guidelines only stipulate it is necessary should a patient ask for it and that directive is lost within the text. It should be made more clear. I suggest that it is good practice to always provide it.

14. Do you agree with the proposed 12-month transition period and if so is this period adequate?

No, I don't, not if they remain as they are. You have some fundamental issues to deal with before you can effectively implement the guidelines in their current form: in particular the issue of what Australian higher education institutions have been and are delivering and requiring of students in terms of herb nomenclature.

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

I suggest a period of three years to allow them to be actually implemented and used.

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

In general, the guidelines are well written and sufficiently detailed.

Typographical error
Page 7: Capitalise the Standard for the Uniform Prescribing of Medicines and Poisons (SUSMP)