Consultation on draft guidelines for safe Chinese herbal medicine practice

20 July 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).

Practitioner's name

Richard Liu

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

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

> No, I do not agree with the draft guideline. I strongly suggest to use with Pinyin and Chinese characters, and with the pharmaceutical name or botanical name in addition only under the circumstances of different herbs with same pinyin, but different Chinese characters.

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 agree that pinyin with the addition of Chinese characters should be used at all times as an alternative to or the pharmaceutical name and the botanical name. With the convenience of communicating technology, it is very easy for patients and other health practitioners if the labelling and prescription are in consistence ie with Pinyin and Chinese characters, and with botanical name in addition only under the circumstances of herbs with same pinyin, and different Chinese characters.

Prescriptions and labelling should be in consistence with Pinyin and Chinese characters at all times, and with the pharmaceutical name or botanical name in addition only under the circumstances of different herbs with same pinyin, and different Chinese characters.

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?

No, I do not agree in using botanical names in labelling all herbs as it is not a practical practice and does not make sense. Any draft guidelines should have a wide related variety and extended academic references to avoid tunnel-vision decisions.

According to the question, 27% of Chinese herbs are sourced from multiple species, instead of finding ways to overcome the possible ambiguity of the 27%, the guideline is expanding the issue three folds (to 73%) which cause more confusions and chaos.

The examples stated in appendix 5 table 1 is incorrect. If a competent Chinese medicine practitioner prescribes (2)卷丹 Juan Dan， he/she is not going to write 百合(Bai He), but 卷丹 Juan Dan ; same goes to (2) 细叶百合 XiYe Baihe.

Chinese name

Pinyin name

Common Name

Pharmaceutical (Latinised) name

Genus

Botanical name (Genus and species)

Source species in Chinese

百合 (1)

Baihe

Lily Bulb

Lilii Bulbus

Lilium

Lilium brownii var. viridulum

百合

~~百合~~ (2) 卷丹

~~Baihe~~ Juan Dan

Lily Bulb

Lilii Bulbus

Lilium

Lilium lancifolium

卷丹

~~百合~~ (3) 细叶百合

~~Baihe~~ XiYe Baihe.

Lily Bulb

Lilii Bulbus

Lilium

Lilium pumilum

细叶百合

For Chinese herbal Nomenclature, it is a system which has been in place for thousands of years, it is irreplaceable. We cannot rewrite “Compendium of Materia Medica”, 本草纲目， we should treat the ancient Chinese wisdom with respect. In the Chinese herbal nomenclature, the chinese character itself contains all the information about the herb, eg 川牛七,Chuan Niuxi, it comes from Shi Chuan province where 淮牛七 Huai Niuxi , comes from Jiangshu and Anhui provinces; 生地黄 Sheng Dihuang and 熟地黄 ShuDi Huang indicate its process. The chinese herbal names contain the place of origin, its process and part of plant use.

Prescriptions and labelling should be in consistence with Pinyin and Chinese characters at all times, and with the pharmaceutical name or botanical name in addition only under the circumstances of different herbs with same pinyin, and different Chinese characters.

It is proposed that an authority on the authentication of CMM be established, as a physical institution and/or as an electronic database.

Are the labelling requirements practical to implement?

The draft, as it is, is not practical. It will cause more confusions at clinical practice and distract practitioners’ attention and time from patients.

Is the required information for prescriptions appropriate?

In appendix 3, sample prescription given by the board, is appropriate for raw herbs.

Yes

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

Yes

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

Yes, below are a few points, to my own personal point of view.

It is unreasonable to ask dispensers to take.

1/ In 4.2 Checking prescriptions – the dispensers can only scrutinise obvious issue such as dosage of certain herbs, and will not have enough training or information in hand “to ensure there are no

errors in the names of herbs, dosages or preparation instructions", unless the dispenser is the prescriber him/herself.

2/ In 4.8 Self-medication – 1 & 2 for dispensers is obligated "to determine that the consumer does not have a known allergy to a component of the medicine." & "to determine that the medicine is indicated for the condition the consumer requests it for".

Up to date there is no data base of the "components" of raw herbs globally for herbs as commonly used as 当归 Danggui, as all herbs are natural products which include TGS listed complementary medicine with labels of ingredients only. Under the circumstances, how is any dispenser able to comply with these 2 points?

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

The sample is a good way to help in understanding the requirements. (Yes,) The Board should give as many samples as possible for all other guideline to avoid any misunderstanding and misinterpreting of the worded guidelines. A good example is CPD guideline with a very clear CPD portfolio sample.

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

No, the draft guideline is not practical to implement.

In the consultation document, under "Issues for consultation", the potential benefits were overstatement while the potential costs and the estimated impacts were understatement from the view of clinical practitioners. Taken as a whole, the draft guideline, if unamended, is impractical and is irrelevant to public safety. In contrary, it will throw the Chinese medicine industry in turmoil, which not only cause unnecessary hike in cost for both practicing practitioners and patients, but also cutting the umbilical cord of Chinese medicine industry in Australia as at present stage. China is still the world leading country in research and education for Chinese medicine industry.

The Board is proposing an "over" regulatory burdens that would create unjustified costs for the profession or the community., which at the same time contradictory to COAG principles of the proposal of the best option for achieving the stated purpose and protection of the public.

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

No, the content of the draft guideline is not helpful and unclear due to following:

1/ The example used in in appendix 5 is inappropriate (please refer to question 3)

2/ In question 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." The reference should be attached for submission reference, as it is very hard to get the full version of the article online.

3/ In option 3, the draft stated "The experience of the CMBRV was that approximately 15 per cent of complaints involved herbal practice issues." The original of the data should be attached and made easier for practitioners and public to assess for general justification.

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

Yes, as stated per above questions.

Is there anything missing that needs to be added?

Yes, as stated per above questions.

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

Before asking individual practitioner if the proposed 12-month transition period is adequate, Chinese Medicine Board of Australia should ask all Australian Chinese Medicine universities and Schools with approved course if 12 month transition is adequate for them to abolish the use of Pinyin in all the herbal related courses, as all sound and logical minds would agree that it is of course inadequate.

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

All reviews should be in consistence with other guideline review, ie 3 years.

Do you have any other comments on the draft guideline?

Whilst the draft may have been made with good intentions, it would be similar to asking a general practitioner doctor to state every single brand and generic name and possibly every latin name of a medication which would be an unrealistic and does not improve treatment outcome, only potentially confusing the pharmacist.

This draft proposes unrealistic guidelines without improving public safety.

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