Consultation report: Guidelines for safe Chinese herbal medicine practice

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1. Executive Summary

Chinese medicine practitioners are currently prescribing, compounding and dispensing medicines in accordance with their qualifications and registration status, and most are doing so safely and ethically. However, in some clinics practice could be improved to meet generally accepted professional standards.

The Board issued draft *Guidelines on safe Chinese herbal medicine practice* for public consultation from 28 May to 23 July 2014. A key proposal in the public consultation guidelines was to use botanical (scientific) names on medicine labels. After considering all submissions from stakeholders, input from an expert advisory group, and further targeted consultation, the Board has reconsidered its proposal on nomenclature. While this is appropriate nomenclature for scientific publications, it is not practical in the context of clinical practice and Chinese medicine education.

The Board is now confident that the use of *pin yin*[1] on all prescriptions and labels:

- is the most suitable nomenclature to use in Chinese herbal medicine practice
- when adopted universally will provide greater consistency across the profession, and
- adequately protects public safety.

[1] A **system for transcribing the sounds of Chinese language into Roman script**.

Other changes have been made to make the requirements both simpler and clearer in response to useful feedback.

2. Background

Since the transition of Chinese medicine into the National Scheme, a national Chinese herbal medicine practice guideline has not been published[2]. Chinese medicine practitioners are already prescribing and dispensing medicines, however there are identified risks of harm associated with some Chinese herbs, and the knowledge of this was one of the drivers for registering Chinese herbal medicine practice.

Notifications from the previous Victorian registration scheme demonstrated that not all Chinese herbal medicine practice meets accepted standards. Evidence of this experience is included as Appendix 1.

Currently, 61% of Chinese medicine registrants are registered for Chinese herbal medicine (practitioners and dispensers). Most of these practitioners extemporaneously compound and/or dispense herbs, and one percent of all registrants are registered solely as dispensers. In addition, many acupuncturists prescribe Chinese herbs[3] as an adjunct to their acupuncture practice. This means that the majority of practitioners need this guideline.

Under the National Law, the Chinese Medicine Board of Australia (the Board) has a statutory responsibility to protect the public and a statutory function to develop guidelines for the profession where needed. This is particularly appropriate where there is an identifiable risk that could be addressed by providing appropriate guidance and clearly stating the Board's expectations about safe practice to registrants. These national guidelines therefore aim to address and reduce the risk of unsatisfactory practice.

3. Consultation and Revised Position on Nomenclature

The National Board issued draft *Guidelines on safe Chinese herbal medicine practice* for public consultation from 28 May to 23 July 2014.

A proposed requirement to use botanical names on medicine labels sparked a strong response from the profession. There were 232 submissions, although 202 of these were multiple copies of 8 versions of 'template' submissions, leaving approximately 30 substantive submissions in addition to the template submissions. The vast majority of the submissions objected to the recommendation to use botanical names for herbs in prescriptions and labels, and some provided useful explanations and suggestions. A number of submissions also objected to having prescriptions and labels written in English. The Board has decided this is essential to allow scrutiny and understanding of prescribed herbs by other health care professionals. The use of any foreign language makes it difficult for other health practitioners in Australia to understand the ingredients of a herbal medicine. There is no prospect that such a practice can be considered acceptable to the Australian community.

The submissions were, however, numerous and complex and the analysis and consideration of options for moving forward required expert input. The Board therefore sought the advice of a 'Technical Advisory Group' (TAG) – see www.chinesemedicineboard.gov.au/News/2014-09-11-update-on-consultation.aspx for details.

The TAG and the Board's 'Policy, Planning and Communications Committee' (PPCC) met on various occasions for over 12 months to consider the issues, options and to make final recommendations to the Board. The PPCC also consulted with various practitioners and the Therapeutic Goods Administration to clarify legal and regulatory aspects and implications of the guidelines.

Although there was some support for the original proposal to mandate use of botanical names in prescriptions and labels to identify the precise herbal species in use and to aid in pharmacovigilance, the Board has now decided to recommend *pin yin*.

When considering the form of nomenclature to use in the specific context of Chinese medicine practice in Australia, the Board has considered how the information will be interpreted in the event that the patient has a health problem that requires scrutiny of all their medications by the broader health team.

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[2] Previously such guidelines existed in Victoria only, for 6 years.

[3] Most commonly manufactured medicines

Pin yin naming of herbs is widely used in Chinese medicine textbooks, including the most widely accepted major reference[4]. *Pin yin* is:

- readable
- understandable by both English and non-English speakers
- able to be typed without special fonts
- searchable by both English and Chinese speakers, and
- taught in Board-approved Chinese herbal medicine courses in Australia.

In many examples, the required herb, expressed in *pin yin*, can be sourced from multiple species which all have the same medicinal effects.

Herb importers already are required to label raw herbs with botanical (scientific) names to fulfil the requirements imposed by the Australian Quarantine and Inspection Service (AQIS)[5]. However the use of scientific or pharmaceutical names alone would be problematic. The names are long, may be difficult to spell (as they use Latin botanical names), and the names do not necessarily contain all the herbal information included in the names in *pin yin* or Chinese characters.

To assist the professions and the community, the Board commissioned The National Institute of Complementary Medicine (NICM) to develop a nomenclature compendium of commonly used Chinese herbal medicines[6]. The compendium cross-references commonly used species by:

- *pin yin* name
- simplified and traditional Chinese characters
- common English name
- pharmaceutical/Latin name, and
- all the acceptable botanical/scientific (source species) names.

On the very rare occasions when there is a possibility that the use of *pin yin* alone may result in confusion, the *pin yin* should be used together with another name, such as the botanical (scientific) name or pharmaceutical name written in Roman script. Appendix 2 of the Guidelines includes information about some herbs which carry a risk of such confusion.

The Board is now confident that the revised guideline which requires use of *pin yin* on all prescriptions and labels:

- is the most suitable nomenclature to use in Chinese herbal medicine practice in Australia, and
- adequately protects public safety.

This is because of the previously mentioned points, and that it is a feasible and practical option with which the profession can comply.

An additional benefit of using *pin yin* is that it eliminates any confusion between Chinese herbal medicine and herbs used by naturopaths or other herbalists.

Another change of note in the guidelines is the use of the term ‘scientific’ instead of ‘botanical name’. This is in order to have consistency between the compendium and guidelines. The compendium also includes fungal, animal and mineral components, as well as plant herbs. Therefore, the use of ‘scientific name’ is more correct.

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[4] State Pharmacopoeia Commission of the PRC, *The Pharmacopoeia of the People's Republic of China* (English Edition 2010) Volume 1, People's Medical Publishing House

[5] AQIS uses botanical (scientific) names to search their own database to check for illegal imports

[6] The sources of the list include Chinese Pharmacopoeia (Chinese Pharmacopoeia Commission, 2010. Pharmacopoeia of the People’s Republic of China, 2010 edition. China Medical Science and Technology Press, Beijing, China.), Hong Kong Chinese Materia Medica Standards (Volume 1-6. Hong Kong Department of Health. 2005-2013. www.cmd.gov.hk/html/eng/health_info/publication.html) Encyclopedia of Medicinal Plants (ZZ Zhao, PG Xiao. Encyclopedia of Medicinal Plants, Volumes 1-4. Shanghai World Publishing Corporation.)

In July 2015, further targeted consultation was carried out with practitioner experts in Chinese medicine to test the revised position.

The group of practitioners who participated represented the following.

- registered Chinese herbal medicine practitioners
- registered Chinese herbal dispensers
- practitioners only registered as dispensers
- practitioners associated with tertiary education institutions
- practitioners from
  - Victoria
  - NSW
  - Queensland
  - at least one other jurisdiction
- practitioners in:
  - sole practice
  - group practice
- practitioners:
  - trained in Australia
  - trained in China
  - trained in 'other countries'

The feedback from this additional targeted consultation resulted in further minor changes being incorporated into the proposed guideline. This included rewording sections which were not clearly understood, and the removal of unnecessary repetition.

4. Other Changes

The document has been substantially edited to improve clarity and flow. Many of the very helpful comments and suggestions received from stakeholders have also been incorporated.

Initially, the Board was keen to limit the guideline to principles and desired outcomes, and avoid delving into 'how to do it'. Feedback from the targeted consultation, however, indicates that it is helpful to provide examples or suggestions about how some of the requirements can be implemented.

The table below summarises the most significant changes, and many of these are further explained in the following sections.

Summary of key changes to the *Guidelines for safe Chinese herbal medicine practice*

A summary of key changes to the *Guidelines for safe Chinese herbal medicine practice* since public consultation is provided below.

Previous proposal		CMBA final position in new Guideline since public consultation
1	Mandatory use of botanical name in labelling	Mandatory use of *pin yin* with additional nomenclature where there is any ambiguity.
2	Prescription may have botanical name, pharmaceutical name or *pin yin*	Mandatory use of *pin yin* with additional form where there is ambiguity.
3	Difference in recommended nomenclature between labelling and prescription	Consistency between these.

Previous proposal		CMBA final position in new Guideline since public consultation
4	No distinction between instructions for raw herbs and concentrates/extracts	Separately dealt with in specific sections now.
5	Labelling rules to follow SUSMP	Chinese medicine practitioners are currently unable to prescribe scheduled herbs. Manufactured medicines fall within the jurisdiction of the TGA which has very specific labelling requirements. For contemporaneously compounded and dispensed herbs, this guideline emphasises use of clear and consistent herbal nomenclature, the recording of adequate details of Chinese herbal medicines in patient health records, and accurate and informative labelling.
6	Prescriptions to expire after 1 month	Prescription expiry to be defined by prescriber according to individual patient needs.
7	Nomenclature discussion	Change in language to reflect subtlety: more respectful of all nomenclatures.
9	Botanical names	Change from use of term 'botanical' to 'scientific' name because the compendium includes fungal, animal and mineral components as well as plant herbs, and therefore 'scientific name' is more correct.
9	References	References added to support safety issues, illustrate risks and illustrate adverse event reporting.
10	Consistency with other guidelines	Consistency between these Guidelines and the *Health record keeping guidelines*[7] with regard to use of languages other than English.
11	Labelling feasibility	Reduction in the amount of information required on the label and prescription.
12	Consistency throughout chain of events	Ensuring the same minimum set of information is on the prescription and the label so that a copy of the prescription may be used as a label (especially relevant when prescribing raw herbs).
13	Feasibility and efficiency	Written prescription may not be required if the prescriber is the dispenser, and full details are on the label (size of font permitting).
		The removal of labelling of manufactured medicines, except where the dose required is different from that specified on the existing label.
14	Extemporaneous dispensing	TGA has clarified circumstances for exemption.
15	Dispensary assistants	Strengthened practitioners' responsibility to train and manage, and reduced some impractical requirements.
16	Dispenser knowledge and skills	Clarification of relative roles and limited responsibility of dispenser, consistent with professional prescriber competencies.
17	Self-medication	Clarified – i.e. no dispensing without a valid prescription.
18	Adverse event reporting	Section updated according to current information on TGA website.
19	Examples	More and better examples in appendices.

5. Prescriptions, Labels and Patient Information

These elements have been separated to distinguish more clearly between extemporaneous compounding, dispensing and compounding, and dispensing by third parties.

[7] Currently being consulted on as a review of the existing Patient Records Guidelines

There was much feedback about unnecessary duplication, lack of consistency and increased risk of error. Much effort has focussed on improving this aspect.

When a health problem occurs, the label or prescription is the immediate source of information for other health practitioners. This information must always be available and be in English and *pin yin* to enable ready access to databases of herbs and adverse event reports.

In circumstances where the patient record is required, this occurs at a later time and the *Health record keeping guidelines* address circumstances where translation may be required.

The nomenclature requirement for prescriptions and labels is now consistent.

The overall approach:

1. avoids unnecessary duplication of effort
2. reduces the risk of errors, which improves patient safety
3. ensures that both patients and other health care practitioners have access to useable information, and
4. respects patient rights to safety and quality of medication usage.

In the event of a health problem which necessitates the scrutiny of all medicines a patient is taking, the required information will always be available on the label or prescription in a language and nomenclature that can be easily cross checked using the compendium and searched on international databases.

Chinese characters alone are not permitted on labels, as this is a foreign language and cannot be understood by other practitioners in the Australian healthcare system. Chinese characters may be added where it is an accurate translation and enhances patient safety and compliance (e.g. for Chinese speaking patients).

It is not mandatory always to provide a copy of a prescription to a patient. There are times when this is clearly not necessary – e.g. when a medicine is administered at the clinic. In this case, the information is to be recorded in the patient record (a common example in Western medicine being vaccinations). Patients are always to be provided with information about a medicine, on either a prescription OR a label.

The requirement to state total weight of the dispensed medicine on the label has been removed because in Chinese herbal medicine practice, this information is not indicative of the content of the active ingredients. Hence, this the information does not enhance patient safety.

6. Expiry Dates for Prescriptions

Rather than specify an arbitrary expiration date, the Board has added an expectation that registered practitioners will specify the period during which a prescribed formula is suitable or valid for that specific patient. This is because Chinese medicine practitioners conduct differential diagnosis and identify underlying patterns of disharmony according to Chinese medicine theory. The patterns change with treatment, and practitioners modify the prescribed formula as they reassess the patient based on their response to the treatment. While some formulae for general tonification and health maintenance may have quite a lengthy period allowed by the practitioner, continuing to take a formula outside the recommended period is to be discouraged.

7. Dispensing

Training of Assistants
It has been suggested by some that the Board should develop guidelines for training or skill requirements for dispensary assistants. Presently, there are no formal training programs available for dispensary assistants. The Board notes the need for more formal guidance on the training requirements for any future course for dispensary assistants, and see this as the goal of a potential future project.

However, the Board has further revised the guidelines to include more detail regarding the role of dispensary assistants and the responsibilities of the registered practitioner supervising them.

8. Self-Medication

The Board has elected to take a risk-management approach and notes that:

- the Board has limited authority in this area, and
- members of the public have a right to self-medicate using non-prescription medicines.

However, it must be considered that:

- all medicines carry a risk of producing adverse reactions in some patients, and
- registered practitioners when supplying medicines have a higher duty of care than retailers.

Some key determinants of risk in medicines are:

1. therapeutic claims (indications) and known toxicity risk
2. accuracy of labels
3. the prospect of unintended effects of medicines (e.g. from interactions, wrong dose, inappropriate use, sensitivities and allergies, prolonged use)

Therapeutic claims: *Listed medicines*

Products such as vitamins, minerals, sunscreens and herbal complementary medicines are deemed by the TGA[8] to carry a lower risk, and receive a lesser degree of initial assessment by the TGA than higher risk medicines.

These products are listed on the ARTG[9] provided certain conditions are met. The listing process for complementary medicines is based on an applicant certifying that the claims made about the effectiveness of their product are accurate, that the relevant quality and labelling and packaging standards have been met that the medicine contains only approved ingredients, and that the manufacturing facilities and processes have been assessed for compliance with standards of Good Manufacturing Practice.

Unlike registered medicines, the TGA does not evaluate lower risk 'listed' medicines individually before they can be made available for use in Australia. However, listed medicines cannot claim to treat serious diseases, and can be removed from the market if the claims made for the products are inappropriate or any of those certifications are not correct.

Accuracy of labels and unintended effects of medicines

Of concern to the profession is the practice of marketing Chinese manufactured formulae by Western disease names. Practitioners report that some patients self-medicate on these products with either no effect or, despite the assessment of low risk, occasionally with ill effects. This is highly problematic but increases sales to those who are not able to differentially diagnose.

The Board is not able to address this issue, but the TGA is aware of this concern.

The Board has decided on the following:

Compounding medicines

In this situation, the guidelines apply.

Dispensing prescriptions

In this situation, the guidelines apply.

Supply of manufactured (listed) medicines

There appears to be a growing trend in Australia for consumers to self-medicate with non-prescription or non-registered medicines for common ailments. This is possibly due to a more general trend in consumer preferences towards self-care and self-responsibility for health.

This area is regulated by the TGA through the ARTG, and registered practitioners and retailers are generally free to supply the products. A registered practitioner is qualified and experienced to provide

[8] Therapeutic Goods Administration

[9] Australian Register of Therapeutic Goods

advice and counselling on herbal medicines, and has a professional responsibility to do so with the care of the patient as the primary concern.

Supplying Raw Herbs

It is also a known practice for some members of the public to seek to purchase a range of raw herbs from herbal retailers for health maintenance. Supply of these materials can be a retail task, and thus is unregulated.

A registered practitioner or dispenser, however, is expected to provide advice and counselling on herbal medicines in accordance with their qualifications and training. They have a professional responsibility to do so with the care of the patient as the primary concern.

9. Impact

The feedback from a further targeted consultation in 2015 indicates that the revised guidelines are practicable and reasonable. It also suggests that use of computers (or at least label printing machines) in Chinese medicine clinics will make implementation straightforward. This would improve efficiency, save costs and contribute to wider acceptance of Chinese medicine in mainstream healthcare.

It appears that many practitioners are already using computers in their clinics. Equally, the Board is aware that some practitioners may object to the prospect. Whilst use of computers will facilitate ease of compliance, it is not a requirement and prescriptions and labels may be hand written.

In some clinics, improving practice will require some adjustment and the Board has allowed for a two year transition period to achieve full compliance.

There is therefore minimal impact anticipated on the majority of practitioners, businesses and other stakeholders arising from the guidelines, as they primarily reflect existing good practice within the profession and clarify areas of uncertainty. A small number of practitioners may need to correct deficiencies in some areas to meet the minimum standards for public safety.

The decision to allow use of standardised *pin yin*[10] as the primary nomenclature is consistent with:

- the feedback from the public consultation
- the advice of the Technical Advisory Group appointed by the Board
- delivering patient safety by enhancing communication about medications with other health practitioners, and
- enabling herbs to be readily identified on international databases in relation to adverse reactions.

It is understood that a small number of Chinese medicine practitioners may currently not be familiar with *pin yin*, as they may be relying on the use of the language in which they have been trained outside Australia (often Chinese). The longer transition period will enable this group of practitioners to learn *pin yin* and the Board understands that this is a feasible option.

10. Overall benefits and costs

Chinese medicine practitioners are already prescribing, compounding and dispensing medicines in accordance with their qualifications and registration status, and most are doing so safely and ethically. These guidelines make no change to that. The guidelines aim to:

1. provide clear guidance to registered practitioners/dispensers on the consistent writing of prescriptions, labelling and dispensing of medicines to support safety and quality in Chinese medicine practice
2. enable practitioners to identify and correct any deficiencies of practice, and
3. encourage consistency within the profession in the use of herbal names and patient record keeping.

There will be a small cost to some practitioners to alter their practice (for example introducing printed labels or learning to write the names of herbs in *pin yin*) in order to meet these guidelines, which reflect accepted clinical practice within the profession and provide the level of safety and communication expected by the community.

[10] Provided that when there is a possibility for the use of *pin yin* alone to result in confusion, the *pin yin* must be used together with another name to remove ambiguity.

The feedback from the further targeted consultation has indicated that many practitioners are already in a position to comply, and that any necessary adjustment to achieve compliance is a reasonable expectation. Some experienced practitioners whose practice already meets the guidelines have offered to provide mentoring to older practitioners, who may not be native English speakers and may need some assistance in adopting the guidelines. Any initial costs, for example the purchase of computer-based printing systems, will be offset in the longer term by savings in practitioner time. Such costs are also warranted to deliver public protection.

11. APPENDIX 1

Under the Victorian registration scheme, a number of notifications revealed some poor herbal medicine practices, in particular related to labelling. In many examples, patients and other members of the healthcare team were unable to ascertain what herbs the patient was taking. Approximately 15 per cent of complaints received (211 in total) involved herbal practice issues. Of these:

- 72% involved improper labelling (i.e. lack of information or often, no labels)
- 47% involved failure/refusal to provide prescription details, instructions or advice when asked
- 16% involved failure to appropriately manage adverse medication reactions
- 9% involved failure to advise on (side) effects
- just over 6% involved using endangered species
- just over 6% involved using restricted herbs, and
- just over 6% involved poor or dishonest prescribing practices.

Other allegations (1 case only) involved:

- herbal overdose
- remote consultations & supply of herbs
- importing and prescribing illegal substances
- inappropriate manufacturing practices, and
- dispensing insect infested herbs.