

## Public Consultation document

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December 2021

### Consultation on revised *Guidelines for safe Chinese herbal medicine practice*

#### Summary

The Chinese Medicine Board of Australia (the Board) is opening public consultation on its recently revised *Guidelines for safe Chinese herbal medicine practice* (the guidelines) which first came into effect in 2017.

The guidelines were developed to address the absence of national Chinese herbal medicine guidelines. The guidelines:

- Provide clear guidance to practitioners on the consistent writing of prescriptions, labelling and dispensing of medicines.
- Enable practitioners to identify and correct any deficiencies in practice.
- Encourage consistency within the profession in the use of herbal names and patient record-keeping.

The guidelines were due for review three years after they came into effect. In preparing for the review the Board commissioned an independent survey of practitioners about the usefulness of the guidelines (the survey report). The survey report showed strong evidence of support for the guidelines and did not indicate major changes were required.

The changes in the proposed revised guidelines are mostly editorial and do not represent any significant change or impact for practitioners. The main changes are to:

- refer to 'medicinal ingredients' rather than just 'herbs', recognising that practitioners use other ingredients, such as minerals
- change a reference to 'individualised formulations', which is what practitioners prescribe to their patients, rather than 'raw herbs' and 'herbal extracts'
- remove the year of publication from some references, such as the Chinese Pharmacopoeia, as these references are regularly updated, and
- reorder and simplify some of the technical supporting information on nomenclature of ingredients.

More information about changes is included in this consultation paper. This consultation is open until **close of business Friday 4 March 2022**.

## Preliminary consultation

In September 2020, the Board undertook preliminary consultation with stakeholders on the draft revised *Guidelines for safe Chinese herbal medicine practice* (the guidelines). This allowed the Board to test and refine its proposals, before proceeding to public consultation. It also meant that the feedback improved the clarity of the consultation document.

Stakeholders, including professional associations, the Commonwealth, state and territory health departments and co-regulators, submitted written responses.

The Board is now releasing its consultation paper for public feedback.

## Providing feedback

Feedback can be provided by completing the online survey available on the Board's [website](#).

If you are unable to complete the online survey, please contact us at [chinesemedicineconsultation@ahpra.gov.au](mailto:chinesemedicineconsultation@ahpra.gov.au) and we can provide you with a Word document template to complete.

Feedback is required by close of business on **Friday 4 March 2022**.

## Publication of submissions

The Board publishes submissions at its discretion.

The Board generally publishes submissions on its website to encourage discussion and inform the community and stakeholders. Please advise us if you do not want your submission published.

We do not place on our websites, or make available to the public, submissions that contain offensive or defamatory comments or are outside the scope of the subject of the consultation. Before publication we will remove personally identifying information, including contact details.

The views expressed in the submissions are those of the individuals or organisations who submit them, and their publication does not imply any acceptance of, or agreement with, these views by the Board.

The Board accepts submissions made in confidence. These submissions will not be published on the website or elsewhere. Submissions may be confidential because they include personal experiences, or other sensitive information. Any request for access to a confidential submission will be determined in accordance with the *Freedom of Information Act 1982 (Cth)*, which has provisions designed to protect personal information and information given in confidence.

Please let the Board know if you do not want your submission published or if you want all or part of it treated as confidential.

**Published submissions will include the names of the individuals and/or organisations that made the submission unless confidentiality is requested.**

If you have any questions, you can contact the Board at [chinesemedicineconsultation@ahpra.gov.au](mailto:chinesemedicineconsultation@ahpra.gov.au)

## Next steps

After public consultation closes, the Board will review and consider all feedback from this consultation before making decisions about implementation and the supporting documents.

## Background

The role of the Chinese Medicine Board of Australia (the Board) is to work with the Australian Health Practitioner Regulation Agency (Ahpra) and the other National Boards to achieve the objectives of the National Registration and Accreditation Scheme (the National Scheme), which has public safety at its heart.

The Board develops registration standards, codes and guidelines under the Health Practitioner Regulation National Law, as in force in each state and territory (the National Law). These documents:

- set out the requirements for registration
- establish obligations for professional practice, and
- can be used as evidence in disciplinary proceedings of what constitutes appropriate professional conduct or practice for the profession.

The Board regularly reviews all its registration standards, codes, guidelines and other policies to ensure they remain relevant, contemporary and effective.

These guidelines are due for review and the Board has developed a proposal for consultation.

## Context

### Current guidelines

The current guidelines were published on 12 November 2015 and became effective (after a two-year transition period) on 12 November 2017. They were due for review three years after implementation or earlier if required and the review process was to start by November 2019.

Chinese medicine practitioners prescribe, compound and dispense medicines in accordance with their qualifications and registration status. The guidelines aim to:

- provide clear guidance to Chinese medicine practitioners on the consistent writing of prescriptions, labelling and dispensing of medicines to support safety and quality in Chinese medicine practice
- enable Chinese medicine practitioners to be aware of expected standards of practice and correct any deficiencies of practice
- encourage consistency within the profession in the use of ingredient names and patient record-keeping.

To support the professions and the community, the Board also published a [Nomenclature compendium of commonly used herbs and other ingredients of Chinese medicine](#) (the compendium). The compendium cross-references commonly used species by:

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

The compendium also provides relevant information about SUSMP<sup>1</sup> and CITES<sup>2</sup> restrictions.

In 2019, the Board commissioned an independent survey of Chinese medicine practitioners to test the usefulness of the guidelines and compendium to the profession (the survey report). The survey response rate of 29% of 3,106 Chinese herbal medicine practitioners and dispensers was exceptional and much higher than comparable benchmarks. The respondents were generally representative of the demographics (in gender, age and work location) of all Chinese herbal medicine practitioners and dispensers on the Chinese medicine register.

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<sup>1</sup> *Standard for the uniform scheduling of medicines and poisons*

<sup>2</sup> The Convention on International Trade in Endangered Species of Wild Fauna and Flora  
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The results indicated that:

- the purpose of the guidelines and compendium has been well accepted by most practitioners,
- most Chinese herbal medicine practitioners follow the guidelines and compendium in their practice and are therefore likely to provide consistent and high-quality prescribing and dispensing services to their patients.

The survey report showed evidence of strong support of the current guidelines and did not indicate that major changes are required.

The Board revised the guidelines and they are now ready for public consultation.

The revised guidelines:

- further standardise some of the terminology used
- simplify some of the background information about the nomenclature of medicinal ingredients
- refer to 'medicinal ingredients' rather than 'herbs' to reflect that the materials used by Chinese medicine practitioners are broader than herbs and include other matter such as minerals
- include supporting information about, and links to, the regulation of the supply of medicines, advertising of health services and professional insurance
- include information about sourcing herbs and other materials and maintaining their quality
- avoid referring to specific editions of references such as pharmacopoeias to avoid the need to update the guidelines as editions change
- make a clearer distinction between individualised formulations prepared from raw or prepared medicinal ingredients and those prepared from extracts such as granules.

## Proposal

### Risk-based approach

The Board considered specific risks:

- many Chinese herbal medicine practitioners work as sole practitioners who prescribe, compound and dispense prescriptions and need to be aware of and apply expected standards of health services
- many Chinese herbal medicine dispensers use unregistered dispensing assistants who need to be adequately supervised by the registered practitioner.

## Options

The Board considered two options in developing the revised guidelines.

### Option 1 – maintain the status quo

Option 1 is to continue with the existing guidelines.

The Board had identified a few issues with the current guidelines which would benefit from some restructuring, clarification or additional information.

This option would not enable these improvements to be made.

### Option 2 – adopt the revised guidelines

Option 2 involves the revision of the guidelines. It takes account of good practice, feedback received and the findings in the survey report.

The proposed revised guidelines aim to:

- improve the overall clarity and workability of the guidelines
- improve alignment with the guiding principles of the National Scheme and the Regulatory principles for the National Scheme, including for the protection of the public.

The proposed guidelines do not result in unnecessary restriction of competition among health practitioners.

### **Preferred option**

The Board prefers Option 2.

### **Issues for discussion**

#### **Potential benefits and costs of the proposed revision**

The benefits of the preferred option are that the proposed revised guidelines:

- are more user-friendly
- have been reworded to be simpler and clearer
- have additional useful guidance
- have clearer and more consistent terminology.

The costs of the preferred option are:

- registrants, applicants, other stakeholders, Ahpra and National Boards will need to become familiar with the revised guidelines, noting that the changes to the requirements are minor.

#### **Estimated impacts of the proposed revision**

Little impact is anticipated on Chinese medicine practitioners, businesses and other stakeholders arising from the revisions as they primarily reflect existing good practice within the profession and clarify some areas of uncertainty.

While there are changes in the revised guidelines, the changes are considered quite minor and most of the content in the current guidelines is present in the revision.

The guidelines support the credibility, defensibility and quality of services provided by Chinese medicine practitioners and to ensuring the quality of services provided to the public.

The Board will monitor the implementation of the revised guidelines to ensure their relevance and effectiveness over time.

### **Questions for consideration**

1. *Are there any specific issues or effects from applying the current guidelines? If so, what are they?*
2. *Is the content and structure of the draft revised guidelines helpful, clear and relevant? If not, please explain why.*
3. *Is there anything missing that needs to be added to the draft revised guidelines? If so, please provide details.*
4. *Are the guidelines practical to implement and sufficient for safe prescription writing, labelling and dispensing of Chinese herbal medicines?*
5. *The Board is proposing a five year review period of the guidelines., Do you agree?*
6. *Do you have any other comments?*

### **Relevant sections of the National Law**

Section 35, of the National Law