Consultation report

September 2023

Guidelines for safe Chinese herbal medicine practice

Who we are

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.

Background

The *Guidelines for safe Chinese herbal medicine practice* (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, and
- encourage consistency within the profession in the use of herbal names and patient record-keeping.

The guidelines were first 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 they came into effect. In preparing for the review, the Board commissioned an independent survey of practitioners about the usefulness of the guidelines, which showed strong evidence of support for the guidelines and did not indicate major changes were required.

How we consulted

The revised guidelines were initially circulated to main stakeholders for preliminary consultation in July to October 2020, with 14 responses received. The feedback from this preliminary consultation allowed the Board to test and refine its proposals and improve the clarity of the consultation document.

The revised guidelines were published on the Board's website for public consultation from January to March 2022.

Proposed changes to the current guidelines

The main changes in the proposed revised guidelines for consultation were to:

- refer to 'medicinal ingredients' rather than '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
- re-order and simplify content.

Who we heard from

A total of 109 responses were received during the consultation: 101 responses from individual practitioners, four from professional associations and two from jurisdictions.

What we heard and how we responded

The response to the revised guidelines was mostly positive. The revised guidelines were not found to be missing anything in terms of content, and were regarded by all respondents to be practical and safe to implement. The majority of respondents agreed with the Board proposal to implement a five-year review period for the guidelines.

There was a large amount of feedback suggesting how the Board might change the revised guidelines. The Board considered every piece of feedback and every suggestion that it received, with many of these suggestions being considered ahead of publishing the updated guidelines (the revised guidelines). The major changes that have been made following the consultation process are outlined below.

The use of the term ‘medicinal ingredients’

The primary feedback that we heard was concerning changing language in the revised guidelines from ‘Chinese herbal medicine’ to ‘medicinal ingredients’, considering this change to have a large impact on the practice of Chinese medicine. Stakeholders highlighted the potential for confusion and adverse effects due to the change away from the term ‘herbal’, that the new language does not reflect traditional Chinese herbal medicine, and that the current language complimented the Therapeutic Goods Administration (TGA) framework and, therefore, should be maintained.

After careful consideration and deliberation of the change in language and, while noting that the revised guidelines explained the nuance in the change, the Board decided that the terminology should revert back to ‘Chinese herbal medicine’ in the revised guidelines.

Schedules of the Standard for the Uniform Scheduling of Medicines and Poisons (SUSMP)

Several comments were made regarding the clarity of the revised guidelines when referring to the SUSMP. Of particular concern was the language used when reflecting the relationship between the SUSMP and state and territory legislation.

The Board considered this feedback and agreed to adopt the suggestions made by stakeholders to tighten and improve the language referring to the SUSMP and its implications in the revised guidelines.

Structure

Feedback received from the consultation indicated that while the content of the revised guidelines was generally helpful and relevant, the structure of the revised guidelines was cumbersome to read and potentially confusing to practitioners whose first language was not English, or who were new to the profession. It was also highlighted that there was a lot of repetition in the revised guidelines, which did not aid clarity when reading.

The Board considered this feedback and agreed that a significant review and restructure of the revised guidelines was necessary to improve the clarity and readability of the document. The subsequent review, to be published as the revised guidelines that will take effect on 1 December 2023, produced a more succinct document that the Board considers to be clearer and easier to understand.

Changes made include:

- removing duplicated information
- reformatting prose into table format
- moving sections within the document to improve flow
- removing some appendices due to information appearing elsewhere, either within the guidelines or other Board or Ahpra resources, and
- combining appendices.

Other minor changes included corrections of typographical errors and language updates.

Prescription examples

Inconsistency was noted in consultation feedback between sections 3.1 and 3.2 on information required on prescriptions for individualised formulations and manufactured medicines respectively, and the prescription examples given in Appendix 3 (now Appendix 2 in the revised guidelines).

Specifically, it was noted that sections 3.1 and 3.2 did not list the address of the prescriber as required for prescriptions, while the examples given in the appendix included the address of the prescriber.

The Board considered this feedback and agreed that sections 3.1 and 3.2 should be updated to include the address of the prescriber as information required on both prescriptions for individualised formulations and manufactured medicines.

Other changes

The Board also received feedback and suggested changes on the following areas, which were updated in the revised guidelines:

- Consistent information on expiry dates and batch numbers.
- Adding 'Keep out of reach of children' to labelling of dispensed medicines.
- Updating the reference to TGA Order no.69 to TGO 92, which had superseded the earlier order.
- Replacing 'goods' with 'substances' in the definition of 'medicines' in the glossary.

Other feedback

The consultation process resulted in a significant amount of feedback. Although much of this was able to be considered when preparing the revised guidelines, some feedback, while noted and considered by the Board, was ultimately not able to be included in the revised guidelines. This included:

- A suggestion for the revised guidelines to include guidance on retention of patient health records.
- Changing examples of *pin yin* given in the revised guidelines.
- A request to remove requirements for Chinese herbal medicine practitioners to ensure the quality of the active ingredients by adhering to labelled expiration dates (when provided).

What we do next

The Board is grateful to all stakeholders and individuals that responded to the consultation on the *Guidelines for safe Chinese herbal medicine practice*. These contributions have helped improve the quality of the revised guidelines and will help ensure public safety. The revised guidelines will be reviewed in 2028. Until then, the Board will continue to update the *Nomenclature compendium of commonly used Chinese herbal medicines* on its website on an annual basis.