Chinese Medicine Board of Australia

Public consultation

28 May 2014

You are invited to provide feedback on this public consultation

Draft *Guidelines for safe Chinese herbal medicine practice*

The Chinese Medicine Board of Australia (the National Board) is releasing the attached consultation paper.

The proposed guidelines are found at **Attachment A.**

Please provide written submissions by email, marked 'Consultation – *Draft guidelines for safe Chinese herbal medicine practice* to chinesemedicineconsultation@ahpra.gov.au by close of business on 23 July 2014.

Submissions for publication on the Board's website should be sent in a Word document (or equivalent)[1]. A word template is also provided to assist with this.

Submissions by post should be addressed to the Executive Officer, Chinese Medicine, AHPRA, GPO Box 9958, Melbourne 3001.

[1] You are welcome to supply a PDF file of your feedback in addition to the word (or equivalent) file, however we request that you do supply a text or Word file. As part of an effort to meet international website accessibility guidelines, AHPRA and National Boards are striving to publish documents in accessible formats (such as Word), in addition to PDFs. More information about this is available at www.ahpra.gov.au/About-AHPRA/Accessibility.aspx.

Public consultation

The Chinese Medicine Board of Australia (the Board) is releasing the attached consultation paper on Draft *Guidelines for Safe Chinese Herbal Medicine Practice*. You are invited to provide your comments on the consultation paper, including the questions in the paper, by 23 July 2014.

How your submission will be treated

Submissions will generally be published unless you request otherwise. The Board publishes submissions on its website to encourage discussion and inform the community and stakeholders. However, the Board retains the right to not publish submissions at its discretion, and will not place on its website, or make available to the public, submissions that contain offensive or defamatory comments or which are outside the scope of the consultation.

Before publication, the Board will remove personally identifying information from submissions, 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 also 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 information that may be sensitive or may identify an individual or party. 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 want all or part of it treated as confidential.

Contents

The current registration standards for the Chinese medicine profession are published on the Board's website at www.chinesemedicineboard.gov.au/Registration-Standards.aspx and codes and guidelines are published at www.chinesemedicineboard.gov.au/Codes-Guidelines.aspx

Summary

This public consultation paper seeks feedback on draft *Guidelines for safe Chinese herbal medicine practice*.

The Health Practitioner Regulation National Law, as in force in each state and territory (the National Law), empowers the National Boards to develop and approve codes and guidelines to guide the professions.

The National Law requires the Boards to ensure there is wide-ranging consultation on the content of any proposed code or guideline.

Background

These guidelines set out the principles the National Board considers necessary for safe and effective prescription writing, labelling and dispensing of medicines by Chinese medicine practitioners.

Issues for consultation

Potential benefits and costs

Chinese medicine practitioners are already prescribing and dispensing medicines in accordance with their qualifications and registration status. These guidelines make no change to that. The aim of the guidelines is to provide clear guidance on the writing of prescriptions, labelling and dispensing of medicines to support safety and quality in Chinese medicine practice. There may be a cost to some practitioners to correct deficiencies where necessary to meet the minimum standards already established within the profession and expected by the community.

Estimated impacts

There is little impact anticipated on practitioners, business and other stakeholders arising from the guidelines as they primarily reflect existing good practice within the profession and clarify some areas of uncertainty. Some practitioners may need to correct deficiencies to meet the minimum standards. Adopting best practice in labelling herbs will require some adjustment, and the Board has proposed a 12-month transition period to facilitate the transition to best practice.

Options statement

The Board has considered a number of options in developing this proposal.

Option 1 – Status quo (no guideline)

The former Chinese Medicine Registration Board of Victoria (CMBRV) approved *Guidelines for the practice of Chinese herbal medicine including Schedule 1 herbs* that applied to all Chinese medicine practitioners registered in that state. No other state or territory required Chinese medicine practitioners to be registered to practise the profession prior to the start of the National Registration and Accreditation Scheme. The Victorian guidelines were in effect for five years.

Since the transition to the National Scheme, there has not been an approved and published guideline for practitioners to refer to. Chinese medicine practitioners are already prescribing and dispensing medicines and have been for some time, however:

1. Risks of harm associated with Chinese herbal medicine practice provided one of the drivers for registering Chinese herbal medicine practice.
2. The experience of the previous Victorian registration board was that approximately 15 per cent of complaints received involved herbal practice issues.

Under the National Law, the Board has a statutory responsibility to protect the public and a statutory function to develop guidelines for the profession where needed – particularly where there is an identifiable risk that could be addressed by providing appropriate guidance to registrants and clearly stating the Board's expectations about safe practice. If the status quo remained, the risk that is posed by practitioners prescribing and dispensing medicines with no consistent and national guidance would be left unmanaged.

Option 2 – Adopt Victorian guidelines

Under this option, the Board could have effectively adopted the CMBRV guidelines, following the required public consultation as part of the transition to the National Scheme. However, the CMBRV guidelines:

- only applied to Victorian registrants
- were lengthy, prescriptive and complex
- needed modification to be consistent with the approved English language registration standard for Chinese medicine practitioners and the Board-approved *Patient record guidelines*, and
- didn't reflect current recommended Therapeutic Goods Administration Australia (TGA) herbal nomenclature which needed to be reviewed in the interests of patient safety.

Based on the Victorian model see https://web.archive.org/web/20120320103412/http://www.cmrb.vic.gov.au/information/p&c/practiceconduct.html, a new model has been developed for consultation.

Option 3 – A new guideline (preferred option)

Risks associated with Chinese herbal medicine practice were one of the drivers for registering Chinese herbal medicine practice. The experience of the CMBRV was that approximately 15 per cent of complaints involved herbal practice issues.

With the benefit of having an approved registration standard for English language, approved guidelines for patient records, and almost two year experience of regulating the profession (with practitioners registered in all jurisdictions, and not only Victoria), the Board decided a more suitable regulatory approach would be to develop a new guideline that drew on the best of the prior CMBRV guidelines but with appropriate modifications to:

- ensure relevance to the National Scheme
- ensure consistency with the National Law, and
- clarify and simplify the guidance provided to practitioners to ensure its workability.

This is the preferred option as it enables the Board to develop and consult on new and contemporary guidelines that are relevant to all registered Chinese medicine practitioners regardless of the state or territory in which they practice. The Board will be able to assess any likely compliance or other regulatory impacts.

Consultation questions

The Board is interested in your feedback about the draft guidelines. Specific questions we would like you to address are:

1. Do you agree that these guidelines apply to all medicines prescribed and/or dispensed by Chinese medicine 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?
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 labelling?
4. Are the labelling requirements practical to implement?
5. Is the required information for prescriptions appropriate?
6. Do you agree with the circumstances in which a medicine may be supplied for self-medication?
7. Do you agree with the limited role of dispensary assistants as outlined in section 5 of the guidelines?

8. Are there any additional requirements which should apply to the management of a Chinese herbal dispensary?
9. Does the sample label and prescription assist in understanding the requirements set out in the guidelines? Should any other examples be used?
10. Taken as a whole, are the guidelines practical to implement and sufficient for safe practice?
11. Is the content flow and structure of the guideline helpful, clear, relevant and workable?
12. Is there any content that needs to be changed or deleted?
13. Is there anything missing that needs to be added?
14. Do you agree with the proposed 12-month transition period and if so is this period adequate?
15. Should the review period for the guidelines be two, three or five years?
16. Do you have any other comments on the draft guideline?

The Board's draft statement of assessment against AHPRA's *Procedures for development of registration standards* and *COAG principles for best practice regulation* is included as **Attachment B**. Comments about this are welcome too.

Next steps

The Board will consider the consultation feedback on the draft guidelines before finalising them.

Attachments

A. Draft *Guidelines for safe Chinese herbal medicine practice*

B. Board's statement of assessment against AHPRA's procedures for development of registration standards, codes and guidelines and COAG principles for best practice

Attachment A

Guidelines for safe Chinese herbal medicine practice

28 May 2014

Authority

The Chinese Medicine Board of Australia (the Board) has developed these guidelines under section 39 of the Health Practitioner Regulation National Law, as in force in each state and territory (the National Law).

Guidelines approved by the Board may be used as evidence of what constitutes appropriate professional conduct or practice for Chinese medicine in proceedings against a health practitioner under the National Law, or a law of a co-regulatory jurisdiction.

Introduction

These guidelines aim to assist Chinese medicine practitioners to practise Chinese herbal medicine safely. Key safety issues identified in these guidelines are:

- the use of correct herbal nomenclature
- standardised prescription writing
- accurate and informative labelling, and
- precise and professional dispensing of medicines.

The guidelines reflect the standards accepted by the profession, and expected by the profession and the community.

There will be a 12 month transition period prior to the formal commencement of these guidelines in order to allow practitioners to ensure that their practices comply with the requirements contained within these guidelines. The Board will review these guidelines at least every three years.

Background

The Board has identified the policy priority of developing guidelines with regard to the safe practice of Chinese herbal medicine. To a significant extent the decision to regulate Chinese herbal medicine was influenced by the risks associated with the practice of Chinese herbal medicine.

Under the Victoria registration scheme a number of notifications revealed some poor labelling practices. In many examples patients and other members of the healthcare team were unable to ascertain what it was that the patient was taking.

The Australian Commission on Safety and Quality in Health Care has identified medication safety as one of its priorities and as a National Safety and Quality Health Service Standard. The development of guidelines for safe Chinese herbal medicine practice will support that priority.

Who needs to use these guidelines?

They apply to all registered Chinese medicine practitioners (see: glossary) involved in prescribing and dispensing medicines except those with non-practising registration.

These guidelines should also be used by Chinese medicine students who provide clinical treatment and Chinese medicine assistants who provide dispensing assistance.

These guidelines do not apply to retailers selling herbal products. Chinese medicine practitioners may work in businesses that also have a retail outlet in addition to a Chinese herbal dispensary (e.g. health food store or grocery store, etc.). These guidelines do not apply to the retailer; they only apply to Chinese medicine practitioners and staff under their supervision in the performance of their profession as a Chinese medicine practitioner.

All references made in these guidelines to ‘dispensers’, ‘dispensing’, a ‘dispensary’, and ‘dispensary assistants’ relate to Chinese medicine dispensers, dispensing, dispensaries, and dispensary assistants.

What medicines do these guidelines apply to?

These guidelines relate to Chinese herbal medicines, as well as any other medicines prescribed and/or dispensed by registered Chinese medicine practitioners.

Under section 39 of the National Law, the Board may develop and approved guidelines to provide guidance to Chinese medicine practitioners.

Chinese medicine practitioners include practitioners registered in any of the divisions of Acupuncture, Chinese herbal medicine or Chinese herbal dispensing by the Board. The guidelines relate to Chinese herbal medicines as well as any other medicines prescribed and dispensed as part of professional conduct or practice by registered Chinese medicine practitioners.

Chinese medicine practitioners may not legally prescribe, manufacture or supply any substance which is in Schedule 2, 3, 4 or 8 of the Standard for the uniform scheduling of medicines and poisons (SUSMP).

How will the Board use these guidelines?

Section 41 of the National Law states that an approved registration standard, code or guideline approved by the Board is admissible in proceedings under this Law, or a law of a co-regulatory jurisdiction. They can be used as evidence of what constitutes appropriate professional conduct or practice for the profession.

These guidelines will be used to assist the Board in its role of protecting the public, by setting and maintaining standards of Chinese medicine practice. Any person can make a notification (a complaint) about a registered health practitioner. These guidelines will assist the Board in deciding what action to take when the notification is about prescribing, labelling and/or dispensing.

If a Chinese medicine practitioner's professional conduct varies significantly from this guideline, they should be prepared to explain and justify their decisions and actions. Serious or repeated failure to meet these guidelines may constitute behaviour for which health, conduct or performance action may be taken. A financial penalty may apply for a breach under the National Law. The relevant sections of the National Law are outlined at appendix 4.

Practitioners are also expected to maintain and enhance their competence in this area of practice. The Board's *Continuing professional development registration standard* states that 'suitable continuing professional development (CPD) activities should contribute directly to maintaining and improving competence in the profession.'

Contents

Summary of guidelines

This set of guidelines centres on patient safety in the practice of Chinese herbal medicine, and in particular on quality and safety in prescription writing and dispensing and labelling of medicines.

Chinese medicine practitioners must comply with all legislation relevant to the practice of Chinese medicine in the jurisdiction where the dispensing occurs. Practitioners are reminded of their obligations under the Convention on International Trade in Endangered Species of Wild Fauna and Flora (CITES), and restrictions on the supply of herbs according to their categorisation in the Standard for the Uniform Scheduling of Medicines and Poisons (SUSMP), and respective state drugs and poisons legislation.

1. Herbal nomenclature

This section refers to how patient safety is enhanced by the way herbal names appear on prescriptions and labels. The aim is that the herbs are identified in such a way that patients can:

- use the medicine safely and effectively
- readily find the information they need
- access further information if they want to know more about the medicine, and
- allow other members of the healthcare team to identify the medicines that the patient is taking.

It's critical to patient safety that Chinese medicine practitioners take measures to ensure:

- when writing prescriptions, clear and accurate herbal nomenclature is used, and
- when dispensing herbs, clear identification on the label of the specific species used.

The Board has endorsed a nomenclature list of commonly used Chinese herbal medicines[2]. The list cross-references commonly used species by:

- simplified Chinese characters
- *pinyin* name
- common English name
- pharmaceutical/Latin name, and
- botanical (source species) name.

This list may assist in informing patients, practitioners and other health professionals about herbal nomenclature to both enhance accuracy and patient safety. Practitioners should use this list as an authoritative cross-reference between different systems of nomenclature. This list is available on the Boards website at www.chinesemedicineboard.gov.au/News/Consultations.aspx (reference list compiled by Professor Zhongzhen Zhao[3]).

The Chinese Medicine Board has also produced a separate list of legally restricted herbs which is available at www.chinesemedicineboard.gov.au/News/2012-12-19-legally-restricted-herbs.aspx

1.1 Herbal nomenclature for prescriptions

Individual herbs must be written using any one of the botanical name, *pinyin* name or pharmaceutical name. Other forms of nomenclature may be used in addition to these (e.g. Chinese characters) where it is an accurate translation of the name and enhances patient safety and compliance. The common name of a herb must not be used as it cannot accurately identify the correct herbal species.

> e.g. *Angelica sinensis* or *Dang Gui* is acceptable. *Angelica* is not acceptable as it does not indicate the species used.

[2] 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.)

[3] The Chinese Medicine Board of Australia acknowledges the generous support provided by Professor Zhongzhen Zhao, School of Chinese Medicine, Hong Kong Baptist University, Hong Kong SAR, China for the Nomenclature of the herbal list.

When using *pinyin* and there is a possibility for the use of *pinyin* alone to result in confusion, the *pinyin* must be used together with another name, such as the botanical name, pharmaceutical name or Chinese characters. This will allow for the correct herb to be identified by referring to the Board endorsed nomenclature list of commonly used Chinese herbal medicines.

> e.g. *Da Ji* refers to two separate herbs, *Cirsii japonica* (大蓟) and *Euphorbiae pekinenensis* (大戟). The correct herb can only be identified if the botanical name, pharmaceutical name or Chinese characters are included.

When using the botanical name, the plant part and any processing the herb has undergone must be specified, as they may result in different pharmacological properties and outcomes.

1.2 Herbal nomenclature for labels

The botanical name is the only name which clearly indicates the actual species used, therefore in the interest of patient safety the botanical name must be used when labelling medicines.

When using the botanical name, the plant part and any processing the herb has undergone must be specified, as they may result in different pharmacological properties and outcomes.

See Appendix 5 for further information on herbal nomenclature and its relationship to quality and safety in Chinese herbal medicine practice.

2. Labelling requirements for dispensing medicines

Chinese medicine practitioners must label dispensed medicines in accordance with any relevant legislation as well as these guidelines with a view to:

- maximising the benefits of the therapy
- improving the patient's understanding of the treatment
- enhancing compliance
- minimising the risk of adverse effects, and
- maximising patient safety.

Relevant legislation in force in the jurisdiction in which the Chinese medicine practitioner is practising must be followed. This section refers to labelling dispensed medicines. See Appendix 2 for guidelines on labelling bulk stock of herbs. Please note that this section does not apply to retailers selling herbal products to the public.

2.1 Labels

The placement of the dispensing label on the product is largely determined by the design of the medicine package and, in the case of a manufactured medicine, the manufacturer's label.

The dispensing label is to be firmly attached to the immediate container (including each component of multiple-therapy packs) unless the immediate container is too small or constructed in a way that a label would compromise the patient's ability to use the medicine. In these cases, the label should be attached to the primary pack or alternatively, purpose-designed labelling tags or 'winged' labels may be used.

The label should be clearly and legibly printed in plain English. Herbal names must be labelled using the botanical name of the species of herb supplied in accordance with the herbal nomenclature section of these guidelines. In addition to the required English text, the label may also include an accurate translation of that text into languages other than English. See Appendix 5 for additional resources on using correct herbal nomenclature.

The special needs of patients with impairments disabilities, such as those with poor eyesight, should be considered when labelling a medicine to ensure that the patient can understand how to use their medicine safely.

2.2 Label content

For a commercially manufactured medicine (e.g. TGA listed complementary medicine) the TGA labelling requirements have already been met. As long as these details aren't obscured by label placement (in which case they must be duplicated on the attached label), the additional labelling is limited to:

- specific directions for use, including frequency and dose
- the patient's name
- the date of dispensing or supply
- the name, address and telephone number of the dispensary at which the prescription was dispensed, and
- the name of the prescriber if it is different to the dispenser.

For an individualised herbal formulae (extemporaneously prepared medicine, e.g. raw herb formula)

The label is to include the:

- specific directions for use, including route of administration, frequency and dose
- patient's name
- date of dispensing or supply
- name, address and telephone number of the dispensary
- name of the prescriber if different to the dispenser
- required storage directions and expiry date to promote the safe and effective use of the medication
- name and dose of each herb (measured in grams)
- total weight of the dispensed prescription (measured in grams), and
- name of the formula dispensed as described in a standard reference book, where applicable (see: 'nomenclature resources' in section of these guidelines 7 for examples of standard reference sources).

The warning statement '**keep out of reach of children'** must be included on a separate line. For typed labels the statement must in capital letters in a sans serif font (such as Arial) of uniform width and bolded. It must be in a font at least 4/10 of the height of the heading on the label. Hand-written labels must adhere to the principles outlined for typed labels, and the warning statement must be prominent, clear and legible.

See Appendix 4 for an example of a label containing the required information.

3. Writing prescriptions

This section refers to prescriptions that are written for individual patients. The Board's *Patient record guidelines* (available at www.chinesemedicineboard.gov.au/Codes-Guidelines.aspx) detail how patient records are to be kept. This section refers to prescriptions that are to be presented to a separate dispensary and/or given to a patient.

When writing a prescription, dose, frequency and route of administration, duration of treatment, the presence or absence of other medicines, the patient's illness, medication history, and other relevant circumstances need to be taken into account.

Prescriptions must be in English, apart from herbal names which are to be written according to the herbal nomenclature guidelines in this document. Prescriptions must be legible and contain all the information necessary to enable the prescription to be accurately dispensed, used and tracked. In addition to the required English text, the prescription may also include an accurate translation of that text into languages other than English.

The prescription must be included in (or a copy attached to) the patient record. Where the practitioner is both the prescriber and the dispenser, the prescription may consist of an entry in the patient record. A copy of the prescription in English must still be provided to the patient on request.

To reduce errors associated with the use of abbreviations and units of measure, practitioners must not abbreviate herbal names and should use standard abbreviations for other terms consistent with the *Recommendations for terminology, abbreviations and symbols used in the prescribing and administration of medicines* (Australian Commission on Safety and Quality in Healthcare, 2009).

3.1 Information required on prescriptions

See Appendix 3 for an example of a prescription containing the required information. The information required to be recorded on a prescription includes:

- the name, address and contact telephone number of the practitioner

- the name of the patient (and patient's parent or guardian where applicable), as well as patient's address and date of birth
- the date the prescription was written
- the expiry date of the prescription[4]
- the number of times the prescription can be refilled, or 'no repeat' if it's to be filled only once
- the dosage and administration instructions, including frequency and timing of consumption
- the practitioner's signature, and
- any warnings.

In the case of commercially manufactured medicines the name of the formula as found in a standard reference book and brand name must be recorded on a prescription.

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

- name of each herb included in the prescription
- part of the herb (where relevant)
- form of processing (where relevant)
- quantity of each herb in grams
- preparation instructions, and
- number of packets (for raw herbs), with each packet numbered sequentially.

3.2 Providing instructions to the patient

Clear instructions must be provided to the patient in writing, or the patient's parent or guardian, covering the following:

- at-home preparation of the herbal medicine where relevant
- the correct route for consuming or administering the medicine
- how often, when, and for how long the medicine should be taken, and
- information relevant to potential interactions with other concurrent medications (both Chinese and Western), where known and relevant.

Patients should be informed that adverse reactions to medicines can occur, and that they should stop taking the medicine and contact the prescriber if they are concerned about a potential adverse reaction.

Adverse event reporting

It is the professional responsibility of all Chinese medicine practitioners to report adverse events. See Appendix 1 for details on adverse event reporting.

4. Dispensing

A Chinese medicine practitioner must take reasonable steps to ensure that the dispensing of a medicine in accordance with a prescription is safe for the person named in that prescription or order.

4.1 Managing potential conflicts of interest

In the circumstances where a practitioner is both the prescriber and the dispenser, the practitioner must ensure that the decision to prescribe and supply a medicine is always in the best interest of their patient in accordance with the Board's (section 8.11 on conflicts of interest) available at www.chinesemedicineboard.gov.au/Codes-Guidelines/Code-of-conduct.aspx

4.2 Checking prescriptions

In dispensing a prescription a Chinese medicine practitioner has to exercise independent judgment to ensure the medicine is safe and appropriate for the patient, and that it conforms to the prescriber's requirements. The dispenser must scrutinise the prescription prior to dispensing to ensure there are no errors in the names of herbs, dosages or preparation instructions. If there is any doubt, the dispenser must

[4] If no expiry date is recorded, the prescription must expire one month after the day the prescription was written. This means that registered practitioners and dispensers must not make up and supply out-of-date prescriptions.

contact the prescriber. Subsequently, if the dispenser is not satisfied with the safety of the prescription, it should not be dispensed and the prescriber should be informed.

In conforming to the above, dose, frequency and route of administration, duration of treatment, the presence or absence of other medicines, the patient's illness, medication history, and other relevant circumstances need to be taken into account.

4.3 Providing herbs in the form specified

The dispenser or dispensary assistant must provide herbs in the form specified on the prescription and undertake the preparation (i.e. grinding, crushing, etc), processing (i.e. *pao zhi*), and separate packaging of herbs where required.

4.4 Accurate dispensing of the components of a prescription

The dispenser must ensure that the formula the patient receives is identical to that recorded on the prescription and that:

- in the case of prescriptions that specify individual herbs, all herbs written on the prescription are included in the formula in the same form and in the same dosage as specified on the prescription.
- in the case of proprietary formulas, the formula dispensed must have the same name as that on the prescription, and must also contain the same individual herbs.

4.5 Substituting herbs

When a herb or formula is unavailable or the dispenser is unsure of what is written on the prescription, the dispenser must seek advice from the practitioner who wrote the prescription before dispensing it. In these circumstances the copy of the prescription returned to the patient should be signed by the dispenser and clearly marked to indicate that the prescriber has been contacted and to record agreed amendments or clarifications that have been made to the prescription.

4.6 Providing instructions to the patient

Clear instructions must be provided to the patient (or to the patient's parent or guardian) in writing, covering the following:

- the preparation of the herbal medicine (where relevant)
- the correct route for consuming or administering the herbal medicine
- how often, when, and for how long the herbal medicine should be taken
- information relevant to potential interactions with other concurrent medications (including Chinese, Western and all other medicines), where relevant, and
- a warning that if symptoms persist the patients should consult their practitioner. If the patient requests the prescription a copy must be provided.

The dispenser may also wish to encourage patients to keep a record of their own Chinese medicines.

4.7 Provision of repeat prescriptions

The dispenser must only provide the patient with the number of repeats specified on the prescription and no more. In addition:

- when there is no number of repeats specified on the prescription, the dispenser must fill the prescription once only.
- if the patient requests additional repeats, the dispenser must consult the practitioner who wrote the prescription to determine whether additional repeats are required, otherwise the patient must be referred back to their practitioner for advice.

4.8 Self-medication

Consumers may wish to engage in responsible self-medication; using unprescribed medicines to treat an ailment that has not been diagnosed or treated by a Chinese medicine practitioner.

Consumers may make a request of a Chinese herbal dispenser for the supply of a medicine for self-medication. A dispenser is expected to ensure that a medicine is safe and generally suitable for a consumer, whereas a retailer does not have this obligation.

1. Where the supply is a commercially manufactured medicine that is permitted to be supplied directly to a consumer without a consultation (e.g. TGA listed complementary medicines), the dispenser may supply the medicine, provided that the dispenser:
   - has determined that the consumer does not have a known allergy to a component of the medicine
   - has determined that the medicine is indicated for the condition the consumer requests it for
   - has advised the consumer of the correct dosage, and
   - has advised the consumer of any cautions or contra-indications that may apply to the medicine.

2. Where a consumer requests the supply of an extemporaneously prepared medicine (e.g. a raw herb formula), the dispenser may supply it, provided that the medicine is commonly used for self-medication and that the dispenser:
   - has determined that the consumer does not have a known allergy to a component of the medicine
   - has determined that the medicine is indicated for the condition the consumer requests it for
   - has advised the consumer of the correct dosage, and
   - has advised the consumer of any cautions or contra-indications that may apply to the medicine.

4.9 Situations where a dispenser must not supply medicine for self-medication

Where the dispenser is not satisfied that the medicine in safe or suitable for the consumer, they must not dispense the medicine and instead refer the consumer to a Chinese herbal medicine practitioner for professional advice.

A dispenser must not make a diagnosis. If a consumer requests a dispenser to diagnose their condition prior to supplying a medicine, the dispenser must refuse and refer the consumer to a registered practitioner.

4.10 Chinese herbal dispensary record keeping

The dispenser must keep accurate records of all prescriptions dispensed, these records must include the:

- name of the patient
- name and contact details of the prescribing practitioner
- date the prescription was dispensed
- herbs in the prescription and amounts, and
- in the case or raw herbs, the number of packets dispensed.

This requirement may be achieved by printing a duplicate label prepared for labelling the dispensed formulae, and pasting it in a dispensing log.

4.11 Expired and undated prescriptions

The dispenser should not dispense an undated prescription or a prescription that has expired. When no expiry date is recorded, the prescription must expire one month after the day upon which the prescription was written.

If a patient wishes to have an expired or undated prescription dispensed, the dispenser must contact the practitioner who wrote the prescription for advice.

Adverse event reporting

It is the professional responsibility of all Chinese medicine practitioners to report adverse events. See Appendix 1 for details on adverse event reporting.

Management and operation of a Chinese herbal dispensary

See Appendix 2 for requirements for the management and operation of a Chinese herbal dispensary.

5. Dispensary assistants

Chinese medicine practitioners may be assisted by suitably trained persons to dispense medicines, in accordance with these guidelines.

The Chinese medicine practitioner in charge of the dispensary business is responsible for ensuring that assistant functions are limited to those functions that do not require professional judgement or discretion. All relevant state, territory and Commonwealth legislation, and the advice provided within these guidelines should be complied with. The Chinese medicine practitioner is responsible for assessing the appropriateness of the medicines in relation to the full medication history, the final check of dispensed medicines and any counselling of the patient.

A Chinese herbal medicine practitioner or dispenser is responsible for all aspects of the Chinese herbal dispensary.

A Chinese herbal medicine practitioner or dispenser must provide supervision at all times (i.e. in person).

A Chinese herbal medicine practitioner or dispenser must be available to provide advice to dispensary assistants.

Prescriptions must be scrutinised by a Chinese herbal medicine practitioner or dispenser before being passed on to a dispensary assistant and any required clarifications or special instructions provided.

A Chinese herbal medicine practitioner or dispenser may delegate certain tasks to a dispensary assistant.

Duties that a Chinese herbal medicine practitioner or dispenser may delegate to dispensary assistants include:

- preparation of medicines to be dispensed, including identification, weighing, and pao zhi
- inventory management including:
  - ordering and unpacking of stock
  - repackaging stock, and
  - storage of medicines
- preparing dispensing labels
- attaching dispensing and cautionary and advisory labels
- collating prescriptions, and
- infection control tasks.

The Board expects that Chinese herbal medicine practitioners and dispensers will use sound professional judgement in assessing the dispensary assistant's knowledge, training and skills, and in delegating appropriate tasks and not exposing them to any task or level of activity which may exceed their level of training and competence.

The Chinese herbal medicine practitioner or dispenser must not delegate any activity that is required by legislation, or by standards of professional practice, to be performed by a Chinese herbal medicine practitioner or dispenser including:

- allowing a dispensary assistant to offer any opinion on the safety, efficacy or suitability of any medicines dispensed, and
- patient counselling or independent advice.

Chinese herbal medicine practitioners and dispensers must provide dispensary assistants with training in relevant legislation and guidelines. This might include Chinese herbal medicine labelling and dispensing, dispensary management, scheduled substances and endangered species requirements, practitioner registration, confidentiality and privacy requirements, infection control procedures and healthcare ethics.

The Chinese herbal medicine practitioner or dispenser has the responsibility to arrange the clinic layout and the workflow within it to facilitate the direct supervision of dispensary assistants.

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9. Glossary

Administer: To personally apply or introduce a medicine, or personally observe its application or introduction, to the patient's body.

Adverse Drug Reaction (also **adverse reaction)**: 1. A response to a drug which is noxious and unintended and which occurs at doses normally used in many for prophylaxis, diagnosis, or therapy of disease or for modification of physiological function. 2. An unwanted effect of a medicine, also called a side effect

Adverse event: Any untoward medical occurrence in a patient or clinical investigation subject administered a pharmaceutical product and which does not necessarily have to have a casual relationship with this treatment.

Chinese herbal medicine: A medicine which can be found in a Chinese herbal medicine *materia medica*. Includes medicines of plant, animal and mineral origin.

Chinese medicine practitioner: A practitioner registered in any of the divisions of acupuncture, Chinese herbal medicine, or Chinese herbal dispensing by the Chinese Medicine Board of Australia.

Complementary medicines: Medicinal products containing such ingredients as herbs, vitamins, minerals, nutritional supplements, homoeopathic and certain aromatherapy preparations. These medicines are regulated under the Commonwealth Therapeutic Goods Act 1989.

CITES (The Convention on International Trade in Endangered Species of Wild Fauna and Flora): An international agreement between governments. Its aim is to ensure that international trade in specimens of wild animals and plants does not threaten their survival.

Dispense: To make up and supply medicine to a patient in accordance with a prescription.

Dispenser: A Chinese medicine practitioner registered by the Chinese Medicine Board of Australia in either the division of Chinese herbal dispensing or Chinese herbal medicine.

Dispensary assistant: A trained assistant who assists a dispenser in dispensing medicine.

Extemporaneously prepared medicine (compounding):
Medicines prepared for individual patients, either following consultations with that particular patient, or to fill a prescription for that particular patient. These medicines are exempt from the operation of Part 3-3 of the Therapeutic Goods Act 1989 (Manufacturing of therapeutic goods) and therefore the requirement to manufacture certain medicines under GMP. Medicines which are prepared in advance of an individualized prescription do not meet the definition of an extemporaneously prepared medicine and are not exempt from the operation of Part 3-3 of the Act (Manufacturing of therapeutic goods) and must be manufactured in accordance with TGA requirements.

Herbal medicine: A medicine which consists solely of a herbal substance.

Herbal substance: All or part of a plant or substance (other than a pure chemical or a substance of bacterial origin) that is obtained only by drying, crushing, distilling, extracting, expressing, comminuting, mixing with an inert diluent substance or another herbal substance or mixing with water, ethanol, glycerol or aqueous ethanol; and that is not subjected to any other treatment or process other than a treatment or process that is necessary for its presentation in a pharmaceutical form.

Individualised herbal formula: A herbal prescription or formula consisting of medicines individualised for that particular patient following a consultation.

Manufactured medicine: A TGA-listed or registered medicine.

Medicine: Therapeutic goods that are represented to achieve, or are likely to achieve, their principal intended action by pharmacological, chemical, immunological or metabolic means in or on the body of a human or animal.

Must and **should:** Whenever 'must' is used in this document, the instruction is mandatory. Whenever 'should' is used in this document, the instruction given is considered 'best practice'. It is the practitioner's

responsibility to make decisions based on individual circumstances, apply professional judgment and be able to justify this.

Prescribe: To authorise the supply of medicine to a patient.

Prescription: A written document outlining specific directions for taking a specific dose of a specified medicine for a specific person.

Scheduled medicine: A substance included in a schedule to the SUSMP.

Side effect: unintended effect of a medicine or treatment. Side effects are usually harmful and are also known as adverse reactions.

Standard reference book: A *materia medica* or formulatory reference text that is commonly used in Chinese medicine training courses and clinical practice. Examples can be found in section 7 (Nomenclature resources).

Supply: To provide a medicine to a patient for their later use or administration.

SUSMP: Standard for the *Uniform scheduling of medicines and poisons* (also known as the poisons standard). The poisons standard consists of decisions regarding the classification of medicines and poisons into schedules for inclusion in the relevant legislation of the states and territories. The *Poisons standard* also includes model provisions about containers and labels, a list of products recommended to be exempt from these provisions, and recommendations about other controls on drugs and poisons.

Review

These guidelines will be reviewed at least every three years.

Effective from: <<date>>

Review date: <<date>>

Appendix 1: Adverse event reporting

Adverse events are unwanted and usually harmful outcomes. The event may or may not be related to the treatment, and is not the same as a side effect or an adverse event because it's not always clear whether the drug has caused the event.

It is the professional responsibility practitioners to report adverse events. The following section is included to assist practitioners to identify and follow established adverse event reporting protocols.

In Australia, adverse events due to, or thought to be due to, a reaction to a herbal medicine should be reported to the Advisory Committee on the Safety of Medicines (ACSOM) using the blue card system. The TGA has developed a brochure on adverse drug reaction (ADR) reporting for health professionals available at http://www.tga.gov.au/hp/problem-medicine-reporting-reactions.htm

What should you report?

You can report all suspected adverse events to any medicine available in Australia, including prescription medicines, vaccines, over-the-counter medicines and complementary medicines.

The TGA particularly requests reports of:

- suspected (ADRs) to new medicines
- suspected drug interactions
- unexpected ADRs (i.e. reactions that are not described in the product information), and
- serious ADRs, such as those suspected of causing:
  - absence from productive activity
  - admission to hospital
  - prolongation of hospitalisation
  - increased investigation or treatment costs
  - danger to life
  - birth defects, and
  - death.

Reporting adverse events

The adverse drug reactions reporting form (blue card) provides a checklist for the information to include in a report. By providing all data relevant to a specific reaction, a rational and objective assessment of the reaction association can be made by ACSOM professional staff. It is available online (http://www.tga.gov.au/safety/problem-medicines-forms-bluecard.htm) or by contacting the Office of Product Review on 1800 044 114.

Reports can also be submitted online at
https:/wwww.ebs.tga.gov.au/ebs/ADRS/ADRSRepo.nsf?OpenDatabase

Email	adr.reports@tga.gov.au
Phone	1800 044 114
Fax	02 6232 8392

All reports should contain the following data:

- patient information (initials, date of birth and age)
- reporter information (name, address, phone number)
- a description of the reaction
- any medicines suspected of causing the reaction
- any other medicines
- date(s) of:
  - onset of reaction, and
  - starting and stopping the suspected medicine or any other medications
- details of any treatment of the reaction, and
- outcome of the reaction and date of the outcome.

For further information, please see the TGA *Note for guidance on clinical safety data management: Definitions and standards for expedited reporting (CPMP/ICI/377/95)*, available via http://www.tga.gov.au/pdf/euguide/ich37795.pdf

Appendix 2: Management and operation of a Chinese herbal dispensary

General requirements for dispensaries

The following general specifications apply to all Chinese herbal dispensaries:

- The dispensary must be clean and orderly and surfaces must be regularly cleaned.
- Only medicinal substances which can be lawfully dispensed may be kept on the premises.
- Chinese medicine practitioners may not legally prescribe, manufacture or supply any substance which is in Schedule 2, 3, 4 or 8 of the Standard for the Uniform Scheduling of Medicines and Poisons (SUSMP).
- Medicinal substances must be stored and handled in a hygienic manner.
- The dispensary must be organised in such a way as to reduce the risk of error in the selection, preparation, dispensing or supply of medication.
- Staff must be trained and competent to fulfil their duties.
- Facilities for hand washing and separate facilities for the washing of utensils must be readily available.
- Equipment used for measuring and weighing must be accurate.
- Procedures must be established to ensure the accurate dispensing of prescriptions.
- Procedures must be established to prevent prescriptions from being confused, mixed up or mislabelled.

Storage of raw herbs

- Storage procedures must ensure that the quality of herbs is maintained and contamination prevented.
- Herbs must be stored in clean, dry containers that protect from insect and rodent attack.
- Herbs must be periodically inspected and herbs that show signs of mould, discoloration, insect attack or other deterioration discarded.
- When herbs are transferred from storage into the containers from which they are dispensed, they must be checked for any foreign matter. This must be removed and discarded. If foreign matter cannot be completely and safely removed, the entire batch must be discarded.
- Herb storage containers must not be topped up with new herbs leaving older herbs at the bottom. All the herbs in the storage container must be completely used (or discarded) and the containers cleaned and dried prior to being refilled.
- Herbs must be kept out of reach of children and infants. Particular care must be taken in the case of potentially toxic herbs, which should be kept in a locked and secure location inaccessible to the public.
- The most appropriate method of storage will vary according to the particular herb. In general, it is advisable to keep herbs in cool, dry conditions away from direct sunlight. Some herbs are best stored in airtight containers, while others may require a degree of ventilation or periodic exposure to the air to ensure they remain dry and do not become mouldy.

Labelling of herbs in storage

- Herbs must be clearly identified and stored in clearly labelled containers, and/or dispensary drawers, and/or packets. Proper nomenclature must be used in labelling (see guideline 3: herbal nomenclature).
- Herbs that are easily confused due to similarity in appearance or name should be kept in separate locations to reduce the possibility of error. Particular care should be taken in labelling such herbs in order to clearly distinguish them.
- When herbs are purchased, they should be inspected to ensure that the identity of the herbs corresponds to the label. If the wholesaler has supplied incorrectly labelled herbs, the wholesaler should be notified. If the identity of the herb supplied is in doubt, it should be returned to the wholesaler.

Handling herbs

When handling herbs and dispensing herbal prescriptions, care must be taken to maintain cleanliness, avoid contamination and prevent cross-contamination. This is done in accordance with following the guidelines:

- The surfaces or containers on which herbs are dispensed must be clean and free from foreign matter.
- Dispensers must wash and dry their hands prior to dispensing each prescription.
- Scales used for weighing herbs must be accurate and cleaned regularly.
- Utensils used in the processing of herbs must be kept clean.

Inventory record keeping

A record must be kept of the inventory of herbs that includes the:

- identity of the herbs purchased
- name of the wholesaler
- date purchased, and
- the batch number in the case of granulated herbs.

Appendix 3: Sample prescription

The following is an example showing how a prescription and label can comply with the requirements of these guidelines. You do not need to use this format but it will give you some ideas on how to lay out your labels and prescriptions. Labels and prescriptions may be handwritten or printer-generated, as long as they contain the information required by these guidelines.

Sample prescription

Chinese Medicine Clinic

Practitioner details
Joe Citizen
123 Acupuncture Ave
Localburb VIC 3000
Tel: 03 1234 5678

Name: Mr Happy Flower	**Date: 10 Dec 2013**

Rehmannia glutinosa

Prescription including name of herb, dosage and preparation:
Gui Zhi Tang/Decoction桂枝汤
桂枝 Guizhi 9g,
炒白芍 Chao Baishao 12g,
炙甘草 Zhi Gancao 6g,
生姜 Shenjiang 6g, to be cooked after others, 5 mins only
大枣 Dazao 12g

Daily doses for 5 days packed as 5 packages

Administration: Oral

Preparation Instructions (including warnings):
1. Find a pot. Use earthenware or enamel, never use iron or copper.
2. Pour enough clean water into pot to submerge the herbs. Soak for 30 to 60 minutes.
3. Place the pot on the stove, bring to boil then simmer for _15__ minutes, then add fresh Ginger in and cook it with other herbs for 5 more minutes.
4. Filter out the liquid from the pot into a heatproof jug/mug for drinking late on.
5. Add more water (warm) to the pot and repeat the process (bring to boil and simmer again for __15_ minutes).
6. The two liquids should be **mixed** together and then divided into equal portions to be taken _2__ times a day one hour *before/ after* meals.

Special Instructions:
Leave a lid on during the cooking process.

Expiry Date: by your scheduled next appointment **Repeats: 0**
If unexpected symptoms occur stop taking the herbs and contact your practitioner.

Notes

1. Example shows *pinyin*, but botanical name can be used instead. Chinese characters are optional unless necessary to remove ambiguity.
2. Instructions for preparation may be given as a separate document or included on the prescription form.

Appendix 4: Sample label

Sample label one: Raw herb formula using botanical name, with optional *pinyin* and optional Chinese characters

KEEP OUT OF REACH OF CHILDREN	
Patient Name: Mr Happy Flower	**Date:** 10 Dec 2013
Practitioner details: Joe Citizen **Dispenser details (if different from the practitioner):** Herb Dispensing Company 123 Herbal Street Localburb VIC 3000 Tel: 03 1234 9865	Tel: 03 1234 5678
Name/description of herb or formula and quantity **Gui Zhi Tang/Decoction桂枝汤** Cinnamomum cassia, dried twigs 9g 桂枝 Guizhi , Paeonia lactiflora, root, panfried 12g 炒白芍 Chao Baishao , Glycyrrhiza glabra, honey fried 6g炙甘草 Zhi Gancao , Zingiber officinale, fresh rhizome 6g 生姜 Shenjiang , Ziziphus jujube, dried fruit 12g 大枣 Dazao	
Dosage & Instructions: Prepare entire packet as per separate instructions. Take half of the decoction twice a day, one hour before meals. If symptoms persist consult your practitioner	

Notes

1. The botanical name will be available on the source herbal stock.

Sample label two: Prepared medicine

KEEP OUT OF REACH OF CHILDREN	
Patient Name: Mr Happy Flower	**Date:**10 Dec 2013
Practitioner details: Joe Citizen Dispenser details (if different from the practitioner):	Tel: 03 1234 5678
Name/description of herb or formula and quantity Gui Zhi Fu Ling Wan	
Dosage & Instructions: Take 12 pills three times a day one hour before meals.	

Notes

1. If the name of each herbal ingredient and dosage is obscured on the original container by the placement of the label, then this information must be included on the label.
2. If the AUST L number[5], expiry date or any warnings on the original container are obscured by the placement of the label, then this information must be included on the label.

[5] This shows that the medicines are accepted by the Therapeutic Goods Administration for supply in Australia and are included in the Australian Register of Therapeutic Goods. AUST L medicines can only contain pre-approved low-risk ingredients. They are used for minor health problems and are reviewed for safety and quality. A purpose must be included on the label.

Appendix 5: A Guide to herbal medicine nomenclature

Chinese herbal medicines have historically been identified by one of several systems of nomenclature: Chinese characters, *pinyin* name, common name and the pharmaceutical name (sometimes referred to as Latinised name).

Best practice in pharmacovigilance[6] is to identify the herb used by a single species using the botanical name, however variation exists in species used both within and between countries. It has been calculated that approximately 27 per cent of herbs in the Chinese pharmacopeia (2005)[7] are sourced from multiple species. Different species dispensed under the same herbal name may have differing pharmaceutical properties. For the above reasons it is critical that Chinese medicine practitioners take measures to ensure clear herbal nomenclature when writing prescriptions, and when dispensing herbs are able to identify the specific species used on the label.

Herbal nomenclature glossary

Botanical name: The scientifically accepted method of positively identifying a specific species. The name consists of a first part, capitalised which refers to the genus of the herb. A genus may consist of many different species, each which may have its own pharmacological properties. By convention a botanical name is written in italics with the first word (the genus) capitalised, and the second word (the specific) in lower case. This is a reliable method of identifying plants and animalsand is the naming convention for pharmacovigilance endorsed by the World Health Organisation.

e.g. *Lilium lancifolium*

Chinese name (*for herbal medicine*): The method of naming a herb with Chinese characters. Chinese characters are specific for each herb in the pharmacopeia. A herb in the pharmacopeia is not the same as a species however, and a given herb in the pharmacopeia may relate to several commonly used species, and differ both within and between countries. While for some herbs only one species is commonly used, for others several may be used. For each Chinese name there may be several species, each species with its own Chinese name equivalent.

e.g. 百合 represents three different species: 卷丹 *Lilium lancifolium Thunb.*；百合 *Lilium brownii F.E. Brown ver. Viridulum Baker*；细叶百合 *Lilium pumilum DC*.

Common name: Names in any language that refer to certain plant species. These names will be very local and refer to groups of related or unrelated species with similar properties.

e.g. Lily bulb

Genus and species: The final two steps in a taxonomic process to differentiate biological organisms. A genus may refer to many different species with similar characteristics; a species is a unique identifier.

Latinised name: See 'Pharmaceutical name'.

***Pinyin*:** A method of writing the Chinese name using the Roman alphabet. This system writes the name phonetically. Because of this it is possible for same *pinyin* to refer to two different herbs where the herbal names sounds the same (homonym) but is identified differently when written in Chinese characters. The addition of Chinese characters, or the pharmaceutical name, or the species removes ambiguity.

e.g. *Baihe*

[6] Pharmacovigilance (PV) is defined as the science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other drug-related problem. WHO established its Programme for International Drug Monitoring in response to the thalidomide disaster detected in 1961. Together with the WHO Collaborating Centre for International Drug Monitoring, Uppsala, WHO promotes PV at the country level. At the end of 2010, 134 countries were part of the WHO PV Programme. The aims of PV are to enhance patient care and patient safety in relation to the use of medicines; and to support public health programs by providing reliable, balanced information for the effective assessment of the risk-benefit profile of medicines. For further information, see http://www.who.int/medicines/areas/quality_safety/safety_efficacy/pharmvigi/en/

[7] Zhongzhen Zhao , Yani Hu , Zhitao Liang, Jessie Pui-Sai Yuen, Zhihong Jiang , Kelvin Sze-Yin Leung *Authentication is Fundamental for Standardization of Chinese Medicines* Planta Med 2006; 72(10): 865-874.

Pharmaceutical name: Also referred to as the Latinised name. Refers to a system of nomenclature that Latinises the genus of the herb and includes information referring to the part of the plant used and any processing performed in Latin. A pharmaceutical name is usually not species specific, and can therefore refer to several different species of the genus commonly used for the same therapeutic purpose.

e.g. Lilii bulbus

Table 1: Example of the above nomenclature demonstrating separate species represented by the same Chinese, pinyin, pharmaceutical and common names

Chinese name	Pinyin name	Common Name	Pharmaceutical (Latinised) name	Genus	Botanical name (Genus and species)	Source species in Chinese
百合	Baihe	Lily Bulb	Lilii Bulbus	*Lilium*	*Lilium brownii var. viridulum*	百合
百合	Baihe	Lily Bulb	Lilii Bulbus	*Lilium*	*Lilium lancifolium*	卷丹
百合	Baihe	Lily Bulb	Lilii Bulbus	*Lilium*	*Lilium pumilum*	细叶百合

Appendix 6: Extracts of relevant provisions from the National Law

Part 5, Division 3 Registration standards and codes and guidelines

Section 39 – Codes and guidelines

A National Board may develop and approve codes and guidelines:

1. to provide guidance to the health practitioners it registers, and
2. about other matters relevant to the exercise of its functions.

Example: A National Board may develop guidelines about the advertising of regulated health services by health practitioners registered by the Board or other persons for the purposes of section 133.

Section 40 – Consultation about registration standards, codes and guidelines

1. If a National Board develops a registration standard or a code or guideline, it must ensure there is wide ranging consultation about its content.
2. A contravention of subsection (1) does not invalidate a registration standard, code or guideline.
3. The following must be published on a National Board's website—
   3.1 a registration standard developed by the Board and approved by the Ministerial Council;
   3.2 a code or guideline approved by the National Board.
4. An approved registration standard or a code or guideline takes effect—
   4.1 on the day it is published on the National Board's website; or
   4.2 if a later day is stated in the registration standard, code or guideline, on that day.

Section 41 – Use of registration standards, codes or guidelines in disciplinary proceedings

An approved registration standard for a health profession, or a code or guideline approved by a National Board, is admissible in proceedings under this Law or a law of a co-regulatory jurisdiction against a health practitioner registered by the Board as evidence of what constitutes appropriate professional conduct or practice for the health profession.

Attachment B

Statement of assessment

Chinese Medicine Board of Australia's statement of assessment against AHPRA's procedures for development of registration standards and COAG principles for best practice regulation

The Australian Health Practitioner Regulation Agency (AHPRA) has *Procedures for the development of registration standards* and procedures for consultation which are available at: www.ahpra.gov.au/Legislation-and-Publications/AHPRA-Publications.aspx#procedures.

This process is also considered appropriate for development of practice guidelines in the interest of best practice.

Below is the Boards' assessment of its proposed draft guidelines against the three elements outlined in the AHPRA procedures.

1. The proposal takes into account the National Registration and Accreditation Scheme's objectives and guiding principles set out in section 3 of the Health Practitioner Regulation National Law, as in force in each state and territory (the National Law).

Board assessment

The Board considers that the draft Guidelines for safe Chinese herbal medicine practice meet the objectives and guiding principles of the National Law.

The guidelines will protect the public by ensuring competent clinical practice that meets the high expectations of the community. It will assist Chinese medicine practitioners to meet their obligation to provide quality service to their patients.

The publication of these detailed guidelines will support the National Scheme to operate in a transparent, accountable, efficient, effective and fair way.

2. The consultation requirements of the National Law are met

Board assessment

The National Law requires wide-ranging consultation on proposed registration standards. The National Law also requires the Board to consult other Boards on matters of shared interest. This is initially addressed in this preliminary consultation.

The Board is ensuring that there is public exposure of its proposals and the opportunity for public comment by undertaking an eight week public consultation process. The process will include the publication of the consultation paper (and attachments) on its website.

The Board has drawn this paper to the attention of stakeholders including the other National Boards.

The Board will take into account the feedback it receives when finalising these guidelines.

3. The proposal takes into account the *Council of Australian Governments* (COAG)*principles for best practice regulation*

Board assessment

In developing the draft Guidelines for safe Chinese herbal medicine practice, the Board has taken into account the COAG principles.

As an overall statement:

- the Board has taken care not to propose unnecessary regulatory burdens that would create unjustified costs for the profession or the community, and
- is conducting wide-ranging consultation to inform this goal.

The Board makes the following assessment specific to each of the COAG principles expressed in the AHPRA procedures.

COAG principles

A. Whether the proposal is the best option for achieving the stated purpose and protection of the public.

Board assessment

The Board considers that its proposal is the best option for achieving the stated purpose. The Board identified that a policy priority was the development of guidelines concerning the prescribing, labelling and dispensing of medicines. To a significant extent the decision to regulate Chinese medicine was influenced by the risks associated with Chinese herbal medicine practice.

The Board considers that the guidelines will have a low impact on the profession. These low impacts are significantly outweighed by the benefits of protecting the public and providing clearer, simpler requirements, in the public interest.

Chinese medicine practitioners are already prescribing and dispensing medicines consistent with their qualifications and registration status. This guideline makes no change to that. What this guideline does is provide clear guidance on writing prescriptions, labelling and dispensing of medicines to support safety and quality in Chinese herbal medicine practice.

B. Whether the proposal results in an unnecessary restriction of competition among health practitioners.

Board assessment

The Board considered whether its proposals could result in an unnecessary restriction of competition among health practitioners. The proposal is not expected to impact on the current levels of competition among health practitioners.

C. Whether the proposal results in an unnecessary restriction of consumer choice.

Board assessment

The Board considers that the draft guidelines will support consumer choice, by establishing clear standards for competent and safe clinical practice.

D. Whether the overall costs of the proposal to members of the public and/or registrants and/or governments are reasonable in relation to the benefits to be achieved.

Board assessment

The Boards considered the overall costs of the revised registration standards to members of the public, registrants and governments and concluded that any costs are appropriate. Chinese medicine practitioners are already prescribing and dispensing medicines in accordance with their qualifications and registration status. These guidelines make no change to that, and provide clear guidance on the writing of prescriptions, labelling and dispensing of medicines to support safety and quality in Chinese herbal medicine practice. Any additional costs could only be necessary to correct deficiencies and meet the minimum standards already established within the profession and expected by the community.

Subject to stakeholder feedback these guidelines should have only minimal impact on the costs to registrants and the community.

E. Whether the requirements are clearly stated using ‘plain English’ to reduce uncertainty, enable the public to understand the requirements, and enable understanding and compliance by registrants.

Board assessment

The Board aims to ensure that these guidelines are written in plain English that will help practitioners to understand the requirements and is seeking expert input about this specific aspect.

F. Whether the Board has procedures in place to ensure that the proposed registration standard, code or guideline remains relevant and effective over time

Board assessment

The Board will review these guidelines at regular intervals and include an assessment against the objectives and guiding principles in the proposed National Law and the COAG principles.

One of the consultation questions is, 'Should the review period be two, three or five years?' Whatever the review period is, the Board may choose to review the guidelines earlier, in response to any issues which arise or new evidence which emerges to ensure the guidelines' continued relevance and workability.