# Guidelines for safe Chinese herbal medicine practice

December 2021

**Authority**

The Chinese Medicine Board of Australia (the Board, has approved these *Guidelines for safe Chinese herbal medicine practice* (the guidelines) for Chinese medicine practitioners under section 39 of the Health Practitioner Regulation National Law (the National Law), as in force in each state and territory.

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

**Summary**

The guidelines aim to assist Chinese medicine practitioners to practise Chinese medicine safely. They require practitioners to write in English on prescriptions and labels and:

- use clear and consistent medicinal ingredient nomenclature
- record necessary details of medicines in patient health records
- contain the necessary information in prescriptions
- ensure medicine labelling is accurate and informative
- ensure compounding and dispensing of medicines is precise and professional.

These guidelines apply primarily to Chinese herbal medicine practitioners and Chinese herbal dispensers which are protected titles under the National Law so the title of the guidelines refer to Chinese herbal medicine practice.

Practitioners need to be aware of changes and directives by state, territory and Commonwealth governments about responding to pandemics, epidemics and other emergency situations.

The Board will review these guidelines at least every five years.

**Background**

The decision by governments to regulate the Chinese medicine profession within the National Registration and Accreditation Scheme was influenced by possible risks associated with the practice of Chinese medicine.

Use of herbal and other medicines is expanding globally and their quality and safety is increasingly important to consumers. It is widely recognised that there are potential toxicity issues with some Chinese herbs and other ingredients of natural origin. Greater attention is being focussed on pharmacovigilance and the analysis of adverse reactions induced by medicinal products including traditional Chinese medicines.

The Australian Commission on Safety and Quality in Health Care[1] has identified medication quality and safety as one of its priorities and established it as a National Safety and Quality Health Service Standard. The COAG Health Council has agreed to make the Quality Use of Medicines and Medicines Safety as the tenth National Health Priority Area. The Board expects all Chinese medicine practitioners to be committed

[1] www.safetyandquality.gov.au

to safety and quality in healthcare and the Board has developed these guidelines to support the safe practice of Chinese herbal medicine.

The Board recognises that these guidelines must be practical to adopt and enforce. The regulatory principles in the National Scheme guide the Board's decision-making. These require the Board to use proportionate regulatory responses to manage identified risks. These guidelines aim to establish the minimum standards needed for good professional practice that are feasible to implement.

In the Australian clinical context, an important component of safe practice is having a consistent, widely accepted medicinal nomenclature which can be interpreted by other healthcare workers.

There are several different nomenclature systems currently used in Chinese medicine practice. *Pin yin* and Chinese characters are widely used in clinical practice.

The use of the scientific names[2] for herbs and other medicinal ingredients has been furthered by developments in the regulation of medicines and of pharmacovigilance systems for tracking adverse reactions to medicines. However, scientific names are often long and may be difficult to spell accurately due to the use of scientific Latin. They do not necessarily contain all the information conveyed by the names in *pin yin* or Chinese characters.

There are risks associated with using Chinese characters (alone) as only those skilled in Chinese can read the ingredient names.

*Pin yin,* however, is widely used in Chinese medicine textbooks, can be understood and used by both English and non-English speakers, and can be readily searched on the internet by all healthcare professionals and others.

The Board endorses the use of the **authorised *pin yin***[3] as the most appropriate medicinal ingredient nomenclature for use in Chinese medicine in Australia.

**Who needs to use these guidelines?**

These guidelines apply to all practising registered[4] Chinese medicine practitioners[5] who prescribe and/or dispense Chinese medicinal materials.

Chinese medicine students who perform supervised clinical treatment, and unregistered dispensary assistants who are supervised by registered practitioners, need to be familiar with these guidelines.

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

**Who do these guidelines not apply to?**

These guidelines do not apply to retailers who sell medicines, when the sale is not part of a consultation with a registered practitioner.

**What medicines do these guidelines apply to?**

These guidelines apply to Chinese herbal medicines and other medicines prescribed, and/or compounded and/or dispensed as part of the professional practice of registered Chinese medicine practitioners. They apply to all oral and topically applied medicines.

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[2] Also known as the botanical name, scientific binomial name, binomial name, or Latin name.

[3] All references to *pin yin* in these guidelines refer to the authorised *pin yin* as found in the Nomenclature compendium of commonly used herbs and other ingredients of Chinese medicine commissioned by the Board – see section 1.3.

[4] That is, registered in Australia under the National Law.

[5] Any person registered in any of the divisions of acupuncture, Chinese herbal medicine, or Chinese herbal dispensing by the Chinese Medicine Board of Australia; the term Chinese medicine practitioner includes Chinese herbal medicine practitioners, acupuncturists and dispensers.

Injectable medicines (intravenous or intramuscular) are not covered by these guidelines because these are not used in Chinese medicine practice in Australia.

Medicines used in Chinese medicine practice include the following types:

- raw herbs and other medicinal ingredients of natural origin such as minerals, animal products and fungus (fresh, dried and/or traditionally processed – the latter are also known as decoction pieces)
- decoctions of single or multiple ingredients
- extracts (powders, granules, liquids or tinctures)
- oral presentations such as pills, tablets or capsules
- compounded topical preparations including washes, liniments, ointments, etc.

**How will the Board use these guidelines?**

Section 41 of the National Law states that a registration standard approved by the COAG Health Council or a code or guideline approved by the Board is admissible in proceedings under this Law, or a law of a co-regulatory jurisdiction. Guidelines can be used as evidence of what constitutes appropriate professional conduct or practice for the profession. The relevant sections of the National Law are outlined at Appendix 1.

These guidelines are used to assist the Board in its role of protecting the public by providing guidance about standards of Chinese medicine practice. Any person can make a notification about a registered health practitioner. These guidelines informs regulatory action to be taken by the Board to manage risk to patients and maintain public safety, when making a decision about a notification about prescribing, labelling, compounding and/or dispensing.

If a Chinese medicine practitioner's professional conduct varies significantly from these guidelines, the practitioner 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.

In addition, practitioners are expected to maintain and enhance their competence in this area of practice. (refer to the the Board's Continuing Professional Development Standard).

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## Summary of guidelines

These guidelines focus on patient safety in the practice of Chinese herbal medicine in:

- writing health records and prescribing and providing patient information
- compounding, dispensing and labelling medicines
- supervising and ensuring accountability of dispensary assistants.

The Board recognises that professional competency in Chinese herbal medicine requires broad knowledge and skills, not all of which are dealt with in these guidelines. These guidelines should be read in conjunction with the Board's Guidelines: patient health records and the statement of professional capabilities of Chinese medicine practitioners.

Chinese medicine practitioners must also comply with all legislation relevant to the practice of Chinese medicine in the state or territory where they practise. Practitioners are reminded of their obligations to comply with:

- the Australian version of the Convention on International Trade in Endangered Species of Wild Fauna and Flora (CITES)
- restrictions on the supply of herbs and other medicinal ingredients according to their categorisation in the Standard for the Uniform Scheduling of Medicines and Poisons (SUSMP), and respective state and territory drugs and poisons legislation.

The Board commissioned the development of a Nomenclature compendium of commonly used herbs and other ingredients of Chinese medicine (the Nomenclature compendium) (see section 1.3), based on *The pharmacopoeia of the People's Republic of China (Zhong Hua Ren Min Gong He Guo Yao Dian)* (中□ □ □ □ □ □ □ ) (PPRC) to support consistent terminology. This Nomenclature compendium is freely available on the Board's website to assist all health practitioners.

Other members of the patient's healthcare team may need to be informed of the Chinese medicines that the patient is taking.[6] Writing medicinal ingredient names in *pin yin* enables ready searching of the Nomenclature compendium. Names written only in Chinese characters cannot be understood except by Chinese speakers and this is not acceptable.

Patient safety requires Chinese medicine practitioners to comply with these guidelines when:

- writing health records, instructions and information for patients, and/or
- writing, compounding or dispensing prescriptions.

Providing clear information to the patient assists that person to undertake their own research and to discuss the information with other health practitioners if they wish.

In particular, Chinese medicine practitioners are to:

- use clear and accurate medicinal nomenclature in *pin yin* in all records
- attach the label, including details of the medicine, to the product
- provide proper instructions for the medicine's preparation
- use English language on all prescriptions and labels.

The Board endorses the use of the **authorised *pin yin***[7] as the appropriate nomenclature in Chinese medicine in Australia, based on the PPRC. This is a minimum requirement for medicinal nomenclature.

The *pin yin* of medicinal ingredients may be combined with other names, such as the name in Chinese characters, or scientific name, or pharmaceutical name.

[6] For example on admission to hospital, when seeing another health practitioner or on being prescribed other medicines.

[7] All references to *pin yin* in these guidelines refer to the authorised *pin yin* as found in the Nomenclature compendium – see section 1.3.

*Pin yin* is:

- widely used in Chinese medicine textbooks and can be understood and used by both English and non-English speakers
- readily searched on the internet
- taught in Board-approved Chinese herbal medicine courses in Australia.

## 1. Medicinal nomenclature in Chinese medicine

### 1.1 Background

Medicinal ingredients used in Chinese herbal medicine are known by various names. This can be confusing to consumers and healthcare practitioners. The various naming or nomenclature systems in use (Chinese characters, *pin yin,* common English names, pharmaceutical names and scientific names) are described in Appendix 2.

The medicinal name in Chinese characters corresponds to the name in *pin yin* as found in the PPRC. However, the name does not always refer to a single species name, since one ingredient may be sourced from more than one species. This can result in confusion that represents a risk to public safety, for example there are several recorded incidents in which consumption of Chinese herbs has resulted in renal failure due to the toxin aristolochic acid and the events have been attributed to a lack of clarity in naming leading to confusion between herbs with similar names. If an ingredient is written as fang ji 防己, it can be mistaken as *mu fang ji* 木防己 (Aristolochiae seu Cocculi radix), or *guang fang ji* 广防己 (Aristolochiae fangchi), or *han fang ji* 汉防己 (Stephania tetrandra S. Moore).

### 1.2 Introduction

The Board reviewed the risks, benefits and compliance burden of different systems of medicinal nomenclature for use in the Chinese medicine clinical setting in Australia. This review concluded that the use of the authorised *pin yin* name, with or without the addition of other nomenclature such as Chinese characters, makes it clear to all users and is concise and easy to apply. Medicinal names in *pin yin* are widely used in Chinese medicine textbooks, can be understood and used by both English and non-English speakers, and can be readily searched on the internet.

Practitioners who trained overseas may have learned the Chinese, Korean, Japanese or Vietnamese names of the medicinal ingredients and be used to using these names. However, in Australia, when records are written only in a foreign language, it may be difficult for other health practitioners to understand the ingredients of a medicine. Sometimes other members of the patient's healthcare team need to be informed of the medicines that the patient is taking. For example, when a patient is admitted to hospital, when there is a suspected adverse event, or when prescribing another medicine which may interact with the herbal medicine(s).

Using the scientific names for herbs and other ingredients has disadvantages in clinical practice, even though they are commonly used in scientific publications, by regulatory bodies and in pharmacovigilance databases. The scientific names are often long and may be difficult to spell accurately. They may not contain all the information required to adequately define the ingredient.

Chinese medicine practitioners use Chinese medicine reference books, textbooks and research reports in which medicinal ingredients and medicines are usually referred to by their traditional names in Chinese characters, *pin yin* or other languages. Official pharmacopoeias, such as the PPRC, use a combination of names including the name in Chinese characters, the name in *pin yin* and the scientific name(s). The names written in *pin yin,* as per the PPRC, directly correspond with the names written in Chinese characters.

Australian students of Chinese medicine are taught medicinal names in *pin yin* (see the Board's Accreditation Standards).

Patient safety is enhanced when there is consistency in the way medicinal names appear in various written health records and documents, including on medicine labels.

These guidelines, used with the Board's Nomenclature compendium (see section 1.3), aim to make sure that herbs and other ingredients are identified so that patients can:

- use the medicine safely
- know what medicinal ingredients they are taking
- readily find the information they need about the medicine or access further information.

### 1.3 The Board's Nomenclature compendium

The Board commissioned[8] the development of the Nomenclature compendium of commonly used herbs and other ingredients of Chinese medicine [9] which is published on the Board's website and is updated annually.

The Nomenclature compendium cross-references the medicinal ingredients by:

- authorised *pin yin*
- simplified and traditional Chinese characters (with character keystrokes)
- all acceptable scientific names (source species)
- pharmaceutical name
- Chinese species name
- plant or other part and/or processing (where relevant)
- information about any restrictions and warnings related to the Standard for Uniform Scheduling of Medicines and Poisons (SUSMP) and the Convention on International Trade in Endangered Species of Wild Fauna and Flora (CITES).

This Nomenclature compendium helps to inform patients, Chinese medicine practitioners and other health professionals about medicinal nomenclature to enhance accuracy and patient safety. Practitioners should use the compendium as an authoritative cross-reference between different systems of nomenclature. The compendium may also help trace potential adverse reactions.

As the compendium may be updated from time to time, please note that the Board's website version is always the authoritative, current version. However, as the SUSMP and CITES are also separately updated periodically, it is practitioner's responsibility to be aware of and comply with the current requirements.

Yellow highlighting in the compendium identifies those medicinal ingredients subject to restrictions on supply because of the requirements of the SUSMP or CITES.

### 1.4 Restricted medicinal ingredients

Chinese herbal medicine practitioners and dispensers in Australia are restricted in their ability to prescribe, compound and dispense some medicinal ingredients traditionally used in Chinese medicine because of restrictions under the SUSMP. A Chinese medicinal ingredient may be affected by the SUSMP:

- by being listed in a schedule or appendix of the SUSMP under
  - its botanical name (genus and species)
  - the genus alone

and/or

  - a common name.

and/or

- when a chemical constituent of the medicinal ingredient is listed in a schedule or appendix.

Some medicinal ingredients are affected by a combination of these things.

In some cases the restriction on the medicinal ingredient depends on the amount of the ingredient in the prescribed dose of the medicine.

It is currently illegal (except when the concentration of a restricted substance is below the legal threshold) for a Chinese medicine practitioner or herbal dispenser to 'obtain, possess, use, sell or supply' (this includes prescribe, compound or dispense) these scheduled medicinal ingredients, unless they are also a

[8] The Board commissioned the National Institute of Complementary Medicine (NICM) to develop the Nomenclature compendium.

[9] Available on the Board's website at www.chinesemedicineboard.gov.au/Codes-Guidelines/Guidelines-for-safe-practice.

registered medical practitioner or a registered practitioner who is endorsed under the National Law to prescribe scheduled medicines.

The Board's Nomenclature compendium includes information about those medicinal ingredients whose use is restricted in Australia by the SUSMP.

A state or territory is able to vary SUSMP requirements for a medicinal ingredient or medicine through its drugs and poisons legislation. This usually occurs in response to a local public health concern.

### 1.5 Required medicinal nomenclature for prescriptions and labels

Prescriptions and labels are to be:

- written in English
- individual medicinal ingredient names are to be written in *pin yin*.

In addition to the *pin* yin, the practitioner may choose to also use other forms of nomenclature including:

- Chinese, Vietnamese, Korean or Japanese characters/scripts
- scientific names (plus plant part and/or processing method, when relevant)
- pharmaceutical names.

## 2. Prescribing/dispensing versus manufacture

Medicines that are extemporaneously compounded or dispensed by a registered practitioner specifically for a particular patient are exempt from certain operations of the *Therapeutic Goods Act 1989.* These requirements include entering products onto the Australian Register of Therapeutic Goods before supply and the requirements for manufacturers to be licenced and comply with Good Manufacturing Practice (GMP).

The exemption does not cover medicinal ingredients or extracts that are pre-packaged for supply, for example where a health practitioner pre-prepares medicines in anticipation of future supply. If a practitioner makes medicines for supply without being specifically made for a patient associated with a consultation, the practitioner needs to check with the Therapeutic Goods Administration about possible obligations under the *Therapeutic Goods Act 1989* (see also the TGA's Australian regulatory guidelines for complementary medicines, or ARGCM).[10]

## 3. Prescription requirements

This section refers to prescriptions that are written for individual patients to be presented to a separate dispenser who is not the prescriber, and/or given to a patient.[11]

When the practitioner is both the prescriber and the dispenser, the prescription may be replaced by a detailed entry in the patient record. However, a copy of a prescription in English is still to be provided to a patient because this information is useful to supply to another health practitioner or is available in case of an adverse event associated with the medication.

Prescriptions are to contain all the information necessary to enable the prescription to be accurately compounded, dispensed, used and tracked. Prescriptions are to be printed or handwritten clearly and legibly, in plain English. Medicinal ingredient names are to be in *pin yin* in accordance with the nomenclature section of these guidelines (see section 1.3).

In addition to English, the same information can also be provided in another language to promote compliance and safety.

### 3.1 Information required on prescriptions for individualised formulations

[10] This information is general in nature and must not be considered legal advice. Practitioners are encouraged to seek their own legal advice about how the therapeutic goods legislation will apply in their particular circumstances.

[11] Using a prescription book which has duplicate or triplicate pages will greatly simplify adhering to the prescription requirements: one copy for patient, one for practitioner, one for dispenser to keep.

Individualised formulations are prescribed by practitioners registered in the division of Chinese herbal medicine.

The following information is required on the prescription:

- the name of the patient (given name and family name) (and patient's parent or guardian or agent when applicable)
- the name, registration number and contact telephone number of the prescriber
- date prescribed (day/month/year)
- names of the medicinal ingredients in authorised *pin yin* and the amount of each medicinal ingredient (measured in grams)
- form of processing (when relevant)
- specific directions for use (dose, preparation/cooking, storage, route of administration, frequency, timing of consumption, period of consumption).
- number of packets (where relevant)
- number of repeats of the prescription
- the expiry date of the prescription (i.e. the date 'not to be dispensed after')
- specific warnings[12] (when appropriate), and
- the practitioner's signature.

This information is to be provided in English.

In addition to English, the same information can also be provided in another language to promote patient compliance and safety.

It is acceptable for the label to be a copy of the prescription, provided all the required information is included. If this is intended then the instructions for preparing or cooking medicinal ingredients should be provided in English and, if desirable, also in the patient's language and can be on a separate sheet of paper.

See Appendix 3 for examples of prescriptions containing the required information.

### 3.2 Information required on prescriptions for manufactured medicines

Sometimes a practitioner may need to write a prescription for a manufactured medicine. On these occasions the following information is required on the prescription:

- the name of the patient (given name and family name) (and patient's parent or guardian or agent when applicable)
- the name, registration number and contact telephone number of the prescriber
- date prescribed (day/month/year)
- name of the medicine (*pin yin* or English name)
- dosage: number of pills/tablets; how many times per day: e.g. 8 pills, 3 times a day, if different from the standard label
- duration of consumption (e.g. 2 weeks, while symptoms persist, until finished.)
- number of repeats of the prescription
- the expiry date of the prescription (i.e. date 'not to be dispensed after')
- specific warnings[13] (when appropriate)
- the practitioner's signature.

This information is to be provided in English.

In addition to English, the same information can also be provided in another language to promote patient compliance and safety.

[12] Warnings on keeping out of reach of children may be required for example when even a small quantity if ingested could be toxic or where a choking hazard occurs due to the size of parts of herbs. Such warnings are to be legible and prominent.

[13] As above.

See Appendix 3 for an example of prescriptions containing the required information.

## 4. Labelling requirements for dispensed medicines

Chinese medicine practitioners are to label dispensed medicines, in accordance with the relevant state or territory legislation of the jurisdiction in which they practise and in accordance with these guidelines, to:

- maximise the benefits of the therapy
- improve the patient's understanding of the treatment
- enhance patient compliance with prescribed medicines
- minimise the risk of adverse effects
- maximise patient safety.

This section refers to the labelling of compounded and dispensed medicines (raw or processed medicinal ingredients and extracts).

Practitioners should consider the special needs of patients with impairments or disabilities, such as those with poor eyesight, when labelling a medicine to make sure that the patient can understand how to use their medicine safely.

### 4.1 Individualised formulations using raw and processed medicinal ingredients

Processed medicinal ingredients may be referred to as decoction pieces (yin pian 饮片).

The label[14] is to be clearly and legibly printed or hand-written. Medicinal ingredient names are to be labelled in accordance with the nomenclature section of these guidelines (see section 1.3).

For an individualised formulation, the label is to include the:

- name of patient (given name and family name) (and patient's parent or guardian or agent where applicable)
- names of the medicinal ingredients in *pin yin* and amounts of each medicinal ingredient (measured in grams)
- date dispensed (day/month/year)
- name and contact telephone number of the dispenser
- name of the prescriber if different from the dispenser
- specific directions for use (dose, route of administration, storage, frequency, timing of consumption and period of consumption) as required
- the number of packets, when relevant
- specific warnings[15] when appropriate.

This information on the label is to be provided in English.

In addition to English, the same information can also be provided in another language to promote patient compliance and safety.

It is acceptable for the label to be a copy of the prescription, provided all the required information is included.

Instructions for preparing or cooking medicinal ingredients should be provided in English and, if desirable, in the patient's language. These instructions can be on a separate sheet of paper, on the prescription, or on the label.

[14] Various commercial labelling systems are available to facilitate this process.

[15] Warnings on keeping out of reach of children may be required for example when even a small quantity if ingested could be toxic or where a choking hazard occurs due to the size of parts of herbs. Such warnings are to be legible and prominent.

Individualised formulations are often prescribed and then dispensed in multiple packs, with each pack containing the same medicinal ingredients and administration over a series of days and/or weeks. The individual packs may be packaged inside an outer package.

The label is to be attached to the outer package and include all the information listed above. The practitioner should also advise the patient to retain the label for future reference. It is acceptable for the label to be a copy of the prescription provided all the required information is included.

All individual inner packs are to be labelled with the name of the patient and the dispensing date. Alternatively, each package can be fully labelled.

See Appendix 5 for examples of labels containing the required labelling information for a medicine of raw or processed herbs.

### 4.2 Individualised formulations using extracts of medicinal ingredients

Medicinal ingredient extracts (powders, granules 浓缩颗粒 or liquids) may be prescribed by the practitioner as components in an individualised extract formulation.

The label is to be clearly and legibly printed or handwritten. Medicinal ingredient names are to be labelled using the name/s in *pin yin* of the dispensed medicinal ingredient/s in accordance with the nomenclature section of these guidelines (see section 1.3).

For an individualised formulation using extracts of medicinal ingredients, the label[16] is to include the:

- name of patient (given name and family name) (and patient's parent or guardian or agent where applicable)
- names of the medicinal ingredient in *pin yin* and amounts of each medicinal ingredient (measured in grams)
- date dispensed (day/month/year)
- concentration ratio of the extract (e.g. 5:1)
- name and contact telephone number of the dispenser
- name of the prescriber if different to the dispenser
- specific warnings[17] (when appropriate), and
- specific directions for use (dose, preparation, storage, route of administration, frequency, timing of consumption).

If all medicinal ingredient extracts, such as granules, used in the prescription have the same concentration write, for example, ‘all 5:1 concentration’ under the list of medicinal ingredients and amounts.

This information on the label is to be provided in English.

In addition to English, the same information can also be provided in another language to promote patient compliance and safety.

The dispensing label is to be firmly attached to the **immediate container**. It is acceptable for the label to be a copy of the prescription, provided all the required information is included.

Formulations of extracts are sometimes dispensed in multiple packs or bottles, with each pack or bottle containing the same formulation for preparation and administration over a series of days and/or weeks.

If the individual packs are placed in an outer package, the label is to be attached to the outer package and include the information listed above. The practitioner should advise the patient to retain the outer package for future reference.

[16] Various commercial labelling systems are available to facilitate this process.

[17] Warnings on keeping products out of reach of children may be required for example when even a small quantity if ingested could be toxic or when there is a choking hazard due to the size of parts of herbs. Such warnings are to be legible and prominent.

When it is feasible, all individual inner packs should be labelled with the name of the patient and the dispensing date. Alternatively, each package can be fully labelled.

See Appendix 5 for examples of a label containing the required labelling information for a medicine of medicinal ingredient extracts.

### 4.3 Manufactured medicines

Chinese medicine practitioners use unmodified manufactured medicines (成药 cheng yao) in their practice.

When a registered Chinese medicine practitioner supplies a manufactured medicine as part of a consultation, the medicine is to retain the original label.[18]

These medicines must be either listed or registered on the Australian Register of Therapeutic Goods (ARTG) and comply with Good Manufacturing Practice (GMP) for supply to be lawful.

If a registered Chinese medicine practitioner opens a manufactured medicine and adds one or more medicinal ingredients or extracts to it, the labelling requirements for individualised formulations apply.

Registered Chinese medicine practitioners who import manufactured medicines for use with their patients or for more general supply become the legal sponsor of those goods on the Australian market and must comply with the requirements of the *Therapeutic Goods Act 1989*.

### 4.4 Repackaging manufactured medicines

The Board strongly discourages repackaging of listed or registered medicines. Manufactured medicines should be supplied with the manufacturer's original packaging intact. Occasionally there may be a valid reason to dispense a smaller quantity of a manufactured medicine for a specific patient for a specific reason. The conditions under which this is allowed and the way in which safe dispensing can be achieved are described in Appendix 6.

## 5. Patient information requirements

Registered Chinese medicine practitioners are expected to provide patients with clear and detailed information about the medicines that have been prescribed and/or dispensed. This is:

- good clinical practice
- consistent with the requirements for informed consent (see the Board's Code of conduct for registered health practitioners).

The Board advises practitioners to encourage patients to keep a record of their Chinese medicines and to explain to the patient the benefits of keeping the information.

Practitioners should provide patients with the correct information about the medicines they are prescribing, as described in section 4, every time medicines are prescribed or dispensed, not only the first time they see the patient.

### 5.1 The prescriber is also the compounder/dispenser

When the prescriber is dispensing the medicine, they are to provide the patient with:

- the medicine labelled according to section 4 of these guidelines, and
- written instructions for preparation, administration and storage as outlined in section 5.3 (unless the full information is provided on the label)
- a copy of the prescription as outlined in section 3.1 and/or 3.2.

The full details of the medicine/s are to be recorded in the health record[19] in accordance with the nomenclature section (see section 1.3).

[18] These details must not be obscured if notations or additional labels are added.

The prescriber is to provide the patient with a copy of the written prescription at a later date if this is requested.

### 5.2 Using an independent compounder/dispenser

When the prescribing practitioner is authorising and instructing an independent, registered dispenser, they must provide a written prescription to the dispenser either directly or via the patient that complies with section 3.1 and/or 3.2 of these guidelines.

The registered dispenser is also to provide the patient with written instructions for preparation, administration and storage of the medicine in accordance with the prescription. This information may be on a separate sheet of paper, or stated in the prescription, or on the label, providing all required information is included (see section 7.4).

### 5.3 Providing instructions to the patient

The prescribing practitioner and the dispenser are to provide clear instructions in writing to the patient, or the patient's parent or guardian, about:

- the preparation of the medicine when relevant
- the correct route for consuming or administering the medicine (i.e. oral, topical.)
- how often, when, and for how long the medicine should be taken
- the conditions of storage to minimise deterioration
- relevant, specific warnings when appropriate.

The prescribing practitioner and the dispenser should inform patients that unexpected symptoms in response to medicines can occur, and tell patients to contact the prescriber or a medical practitioner if they are concerned about a potential adverse reaction.

This is consistent with the requirements for informed consent (see the Board's Code of conduct for registered health practitioners).

## 6. Health records

### 6.1 Patient health records

The registered Chinese medicine practitioner is to include details of the prescribed medicine/s in the patient's health record (or attach a copy of the prescription to the health record).

Clear and complete information about each prescription of medicines is to be recorded for every specific consultation date in the health record. If the prescription at the next consultation is identical, it does not need to be repeated in full in the health record. If it is modified in any way at any subsequent consultation, the full, modified or new prescription is to be recorded for that consultation date.

When prescribing manufactured medicines, the practitioner is to record (either by making notes in the record or retaining a copy of the information provided to the patient) the:

- name of the medication prescribed – *pin yin* or English name is sufficient for a standard formula
- dosage recommended if different from the standard label
- batch number and expiry date
- duration over which the medicine should be used
- relevant, specific warnings when appropriate.

**Chinese medicine dispensary record-keeping**

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[19] Refer to the Board's published guidelines on health records available at www.chinesemedicineboard.gov.au/Codes-Guidelines.

When the dispensary service/records are separate from practitioner consultation/treatment records, the registered dispenser is to keep accurate records of all prescriptions dispensed. These records are to include the:

- name of the patient and contact details
- name and contact details of the prescriber
- date the prescription was dispensed
- the medicinal ingredients in the prescription and amounts
- details of any substitutions when applicable (see section 7.3)
- in the case of raw or processed medicinal ingredients, the number of packets dispensed.

In the case of manufactured medicines, the expiry date and batch number written on the bottle or the package are to be recorded by the dispenser.

Using a prescription book with duplicate or triplicate pages will make it easier to comply with the prescription requirements. For example, there is one copy for the patient, one for the registered Chinese medicine practitioner and one for the registered Chinese medicine dispenser to keep.

### 6.2 Retention of records

Registered Chinese medicine practitioners must comply with their own state/territory laws as some states may have specific requirements for the retention of records and other relevant matters.

The requirements about the retention and destruction of patient health records vary between states and territories. Good practice involves understanding the requirements of the relevant laws and practices wherever the practitioner practices, and observing those standards.

In addition, practitioners who work in multi-practitioner clinics should be mindful of their contractual arrangements regarding ownership, retention and management of health records.

## 7. Compounding and dispensing

The Board expects registered Chinese medicine practitioners to take reasonable steps to ensure that the compounding and dispensing of a medicine complies strictly with the prescription.

### 7.1 Checking the prescription

In dispensing a prescription, a dispenser is to exercise independent judgement to make sure that the dispensed prescription conforms to the prescriber's requirements. The dispenser is to scrutinise the prescription before dispensing, to ensure there are no errors in the names of medicinal ingredients, dosages or preparation instructions. If there is any doubt, the dispenser is to contact the prescriber before dispensing.

A dispenser should not dispense a prescription when they assess that there are potential safety issues. If the dispenser is not satisfied with the safety of a prescription (for example an unusual prescription, large dosages, concern about allergies or non-compliance with CITES or SUSMP requirements) they should contact the prescriber before dispensing.

When a correction or alteration is made after contacting the prescriber, the prescription form is to be annotated accordingly and the patient informed about the change.

### 7.2 Providing medicinal ingredients accurately and in the form specified

The dispenser is to provide medicinal ingredients in the form specified on the prescription and undertake the preparation (pao zhi) such as grinding, crushing, dry frying, or honey, vinegar or wine prepared ingredients and the separate packaging of medicinal ingredients, when required.

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

- when prescriptions specify individual medicinal ingredients, all medicinal ingredients written on the prescription are included in the formula in the same form and in the same dosage as specified on the prescription

- when manufactured medicines are used, the formula dispensed is to have the same name and content as that on the prescription
- the person who checks that the medicinal ingredients prescribed match the medicinal ingredients dispensed, signs or initials the record to this effect.

### 7.3 Substituting medicinal ingredients

When a medicinal ingredient or formula is unavailable or the dispenser is unsure or has concerns about what is written on the prescription, the dispenser is to seek advice from the prescriber before dispensing a substitute. 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. The patient copy should record agreed amendments or clarifications that have been made to the prescription.

### 7.4 Providing instructions to the patient

The dispenser is to provide clear instructions to the patient (or to the patient's parent or guardian) in writing, about:

- the preparation of the medicine (when relevant)
- the correct route for consuming or administering the medicine (i.e. oral, topical)
- how often, when, and for how long the medicine should be taken
- the conditions of storage to minimise deterioration
- relevant, specific warnings when appropriate
- when the prescriber has provided it, information relevant to potential interactions with other concurrent medications (both Chinese and western), when known and relevant. For example, informing the patient to take medicines two hours apart from their other medication.

Instructions for preparing or cooking medicinal ingredients should be provided in English and/or in the patient's language. These instructions can be on a separate sheet of paper, on the prescription, or on the label.

The Board expects the dispenser to explain these instructions to the patient, to promote compliance and safety.

### 7.5 Repeat prescriptions

The registered dispenser is only to provide the patient with the number of repeats specified on the prescription and no more.

If there are no repeats specified on the prescription the formula is to be supplied once only.

### 7.6 Expired and undated prescriptions

The registered dispenser is not to dispense an undated or expired prescription.

An expiry date of a prescription is a specified date after when it is not to be dispensed (see section 3).

If a patient wishes to have an expired or undated prescription dispensed, the dispenser is to refer the patient back to the prescriber for advice.

### 7.7 Managing potential conflicts of interest

As registered Chinese medicine practitioners are often both the prescriber and the dispenser, they are to ensure that the decision to prescribe and supply a medicine is always in the best interest of their patient. A conflict of interest exists where a financial benefit to a person influences the service they provide to others.

This is consistent with the Board's Code of conduct for registered health practitioners.

### 7.8 Consumer self-medication: the role of the registered practitioner

Consumers may wish to engage in responsible self-medication to treat an ailment that has not been diagnosed or treated by a Chinese medicine practitioner and they may ask a practitioner to supply a medicine.

It is also common practice for some members of the public to seek to purchase a range of medicinal ingredients to maintain their health. Supply of these materials can be a retail task and is therefore not regulated by the Board and is not covered by these guidelines.

Manufactured medicines (listed on the ARTG) may be supplied on request by either practitioners or retailers. The Board acknowledges that registered practitioners can also act as retailers.

A registered dispenser who is not a treating practitioner is not to make a diagnosis. If a consumer asks for health advice or a diagnosis of their condition before the registered dispenser supplies a medicine, the dispenser is to refuse and refer the consumer to a registered treating practitioner.

### 7.9 Management and operation of a Chinese medicine dispensary

See Appendix 4 for requirements for the management and operation of a Chinese medicine dispensary.

## 8. Adverse event reporting

It is the professional responsibility of all Chinese medicine practitioners to report suspected adverse events to the Therapeutic Goods Administration (TGA). The Board strongly encourages vigilant reporting of all such occurrences. Active, professionally responsible reporting of adverse events contributes to professional knowledge and better health outcomes. See Appendix 7 for details on adverse event reporting.

## 9. Quality of medicinal ingredients

The efficacy of medicinal formulations is also dependent on the quality of active ingredients such as medicinal materials and extracts.

Ingredients should be sourced from reputable suppliers who can provide a certificate of analysis for each batch. Each certificate should show the name of the testing laboratory and that the batch meets recognised standards such as ISO or pharmacopoeial requirements covering aspects including identity, active content, absence or limits for contaminants such as heavy metals or pesticides and any expiry date for the batch.

The medicinal ingredient should be stored by the practitioner in a manner which maintains its quality and is used within an expiry period if given. If no expiry date is provided, it is the responsibility of the practitioner to store the medicinal ingredient in a manner which maintains its quality and which ensures the quality is at the expected standard and appropriate for use before release to consumers.

## 10. Advertising of Chinese medicine services

The Board requires that therapeutic claims made in advertising to the public about health services are supported by good quality, scientific evidence (see the Board's Advertising guidelines for advertising regulated health services).

The Board's position is that while traditional use evidence forms part of the clinical evidence for Chinese medicine practice, it does not provide the level of reliability of evidence necessary for public advertising. Therefore, this form of evidence used alone is not sufficient to ensure the accuracy needed for public advertising where the information is provided without any involvement of the expertise of the practitioner (such as in a clinical consultation).

In addition, there are detailed requirements for the advertising of medicines, which are administered by the TGA (www.tga.gov.au/hubs/advertising-therapeutic-goods).

## 11. Insurance

If therapeutic goods are supplied or dispensed by practitioners, they should ensure that their professional indemnity insurance includes coverage for product liability.

## 12. References

Australian Commission on Safety and Quality in Healthcare. Available at www.safetyandquality.gov.au/our-work/medication-safety

Current Accreditation Standards: Chinese Medicine. Chinese Medicine Board of Australia. Available at www.chinesemedicineboard.gov.au/Accreditation

Current *Code of conduct for registered health practitioners*, Chinese Medicine Board of Australia. Available at www.chinesemedicineboard.gov.au/Codes-Guidelines/Code-of-conduct

. Current *Guidelines: patient health records,* Chinese Medicine Board of Australia. Available at www.chinesemedicineboard.gov.au/Codes-Guidelines

Convention on International Trade in Endangered Species of Wild Fauna and Flora (CITES). Available at www.environment.gov.au/biodiversity/wildlife-trade/cites

State Pharmacopoeia Commission of the PRC (*The pharmacopoeia of the People's Republic of China* (Chinese or English Edition) Volume 1. (Beijing): People's Medical Publishing House

SUSMP: Standard for the Uniform Scheduling of Medicines and Poisons. Available at www.tga.gov.au/publication/poisons-standard-susmp

TGA *Australian regulatory guidelines for complementary medicines* (ARGCM), Available at www.tga.gov.au/publication/australian-regulatory-guidelines-complementary-medicines-argcm

TGA Therapeutic Goods Order no. 69 — General requirements for labels for medicines as amended made under section 10 of the *Therapeutic Goods Act 1989*. Available at www.comlaw.gov.au/Details/F2009C00264

## 13. 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 in response to a treatment which does not necessarily have a causal relationship with this treatment.

**Authorised *pin yin:*** The name in *pin yin* used in the Board's *Nomenclature compendium*.

**Chinese medicine:** A medicine documented in Chinese medicine *materia medica* and includes medicines of plant, animal and mineral origin.

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

**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. The Australian government amends the international CITES to reflect national considerations and this is the version relevant to Chinese medicine in Australia.

**Decoction:** The product derived from boiling single or multiple medicinal ingredients, in water. The ingredients may be fresh, dried or processed (decoction pieces).

**Decoction pieces:** Medicinal materials of natural origin which have been processed according to the specific requirements of traditional processing principles. A common example is herbal slices.

**Dispense:** To review a prescription, assessing the accuracy, dosage and any safety issues, to select the product, label and supply the medicine to the patient in accordance with the prescription together with any necessary information.

**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 person employed or engaged by a Chinese herbal medicine practitioner or dispenser to assist under supervision with work in a Chinese herbal dispensary, whether paid or unpaid.

**Extemporaneously compounded medicine:** The Therapeutic Goods Regulations 1990 (the Regulations) provide exemption from inclusion in the Australian Register of Therapeutic Goods (ARTG) for medicines that are extemporaneously compounded and dispensed by practitioners for their patients. The regulations also provide exemption for specified complementary medicine practitioners from the requirement to manufacture medicines under the principles of Good Manufacturing Practice (GMP).

**Extracts of medicinal ingredients:** Medicinal materials processed into derivative products such as tinctures or granules.

**Granules:** Extracts of medicinal ingredients where the ingredient has been percolated in an aqueous solvent and the solvent then evaporated down and the resultant concentrate absorbed onto a base material such as starch.

**Herbal medicine:** A medicine which includes herbs, herbal materials, herbal preparations and finished herbal products.

**Immediate container:** The bottle or pack, which contains the herbal medicine.

**Individualised formulation:** A prescription or formula individualised by the practitioner for that particular patient following a consultation.

**Manufactured medicine:** A finished product, usually consisting of a formula, made from several medicinal ingredients, which has been manufactured in accordance with Good Manufacturing Practice. It is supplied in dose-ready form. These medicines are required to be listed or registered on the Australian Register of Therapeutic Goods (the ARTG). Manufactured medicines are commonly referred to in Chinese medicine as 'patent medicines' or 'proprietary medicines'.

**Medicinal ingredient:** The individual component of natural origin added to an individualised formulation or to a manufactured medicine to contribute to the therapeutic effect.

**Medicines:** Medicines are 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. These guidelines cover medicines relevant to Chinese herbal medicine practice.

***Pao zhi:*** Pao zhi refers to stir frying or frying with liquid or quick frying or calcining or roasting in ashes or steaming or boiling or crystallisation or water trituration etc in the Chinese medicine paradigm.

***Pin yin*:** A system for transcribing the sounds of Chinese language into romanised script.

**Pharmacovigilance:** The science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other drug-related problem. Together with the WHO Collaborating Centre for International Drug Monitoring, Uppsala, WHO promotes pharmacovigilance at the country level. For further information, see www.who.int/medicines/areas/quality_safety/safety_efficacy/pharmvigi/en/.

**Prescribe:** To recommend and authorise a certain medicine to treat a specific condition in a specific patient.

**Prescriber:** Registered treating practitioner who has written a prescription.

**Prescription:** A written document outlining the composition of a medicine, specific directions for taking a specific dose of a specified medicine for a specific person and authorises the supply of such from a dispenser.

**Processed medicinal ingredient**: see **decoction pieces**

**Raw medicinal ingredient:** Fresh or dried ingredient or minimally processed, e.g. lightly roasted.

**Retaile**r: Person who sells consumer goods and/or commodities to customers. Purely retail operations are separate from consultations where a product may be recommended to a particular patient.

**Scheduled medicine:** A substance included in a schedule (or Appendix) to the SUSMP.

**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.

## 14. Acronyms

| | |
|---|---|
| **ADR** | Adverse drug reaction |
| **ADRAC** | Australian Drug Reaction Reporting System |
| **ARGCM** | *Australian regulatory guidelines for complementary medicines* |
| **ARTG** | Australian Register of Therapeutic Goods |
| **AUSTL** | A medicine listed on the ARTG |
| **AUSTR** | A medicine registered on the ARTG |
| **CITES** | Convention on International Trade in Endangered Species of Wild Fauna and Flora |
| **CMBA** | Chinese Medicine Board of Australia |
| **COAG** | Council of Australian Governments |
| **CPD** | Continuing professional development |
| **GMP** | Good Manufacturing Practice |
| **PPRC** | *Pharmacopoeia of the People's Republic of China* |
| **PRC** | People's Republic of China |
| **SUSMP** | Standard for Uniform Scheduling of Medicines and Poisons (the Poisons Standard) |
| **TGA** | Therapeutic Goods Administration |
| **TGO** | Therapeutic Goods Order |
| **WHO** | World Health Organization |

## Schedule for review of the guidelines

These guidelines will be reviewed at least every five years after the effective date or earlier if required.

**Effective date: ……..**

# Appendix 1: Extracts of relevant provisions from the National Law

**Part 2 Ministerial Council**

**12 Approval of registration standards**

(1) The Ministerial Council may approve a registration standard about—
(a) the registration, or renewal of registration, of persons in a health profession; or

(b)the endorsement, or renewal of the endorsement, of the registration of registered health practitioners.

(2) The Ministerial Council may approve a registration standard for a health profession only if—
(a) its approval is recommended by the National Board established for the health profession; and

(b) it does not provide for a matter about which an accreditation standard may provide.

**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.

# Appendix 2: Overview of Chinese medicine nomenclature

## Introduction

As explained in the guidelines, the recommended nomenclature is *pin yin.*

Nomenclature for describing medicines and ingredients used in Chinese medicine is complex and can be a problem in pharmacovigilance and in medicine in general, especially when trying to collate data about the adverse responses to an ingredient or product when different systems of nomenclature are used to describe the same ingredients.

Pharmacovigilance is essential for developing reliable information on the safety-in-use of medicines. An unambiguous, definitive system for identifying medicines, ingredients of plant origin and other complex ingredients used in Chinese medicine is essential.

Historically, medicinal ingredients used in Chinese medicine have been identified by one of several systems of nomenclature: Chinese characters, the corresponding name in *pin yin* 拼音, the common English name and the pharmaceutical name (sometimes referred to as Latinised name). The use of scientific names has come into greater use with increasing regulation and the development of systems to monitor adverse drug and herb reactions.

Best practice in pharmacovigilance is to identify the herb according to the plant species using the scientific name together with the plant part and preparation. It is also important that animal and mineral products be identified accurately. Some Chinese medicinal herbs are sourced from more than one species while having the same Chinese name and pharmaceutical name. In most cases these herbs will have medically equivalent effects and be truly interchangeable. In some cases different species may be used that have similar names but different effects. An example of adverse consequences of this, is the well-known example of toxic *Aristolochia* species being used by mistake in place of the usual species due to similarity in the Chinese names.

**Purpose**

The purpose of this appendix is to outline the various ways in which medical ingredients are named and provide examples of nomenclature. The following descriptions and the examples are all plant-based ingredients but the principle of accurate identification applies equally to animal or mineral-based medicines.

**Systems of nomenclature**

The different nomenclatures in use are described below.

**Chinese name (for the medicinal ingredient):** The method of naming the medicinal ingredient with Chinese characters or *pin yin*.

Chinese characters are specified for each herb in the PPRC. These are written in simplified form, for example 川贝母 (Chuan Bei Mu). The same herb name can look different when traditional Chinese characters are used, for example 川贝母 is written 川貝母.

The Chinese herb name in the PPRC does not necessarily refer to a single species name since one herb may be sourced from more than one species. This is because they are considered to have the same properties from the perspective of herbal medicine practice. In a few cases, one herb can be sourced from different genera – for example 马勃 (Ma Bo), can be sourced from *Lasiosphaera fenzlili* Reich, or *Calvatia gigantea* (Batsch ex Pers.) Lloyd or *Calvatia lilacina* (Mont. et Berk.) Lloyd.

**Common English name:** Names in any language that refer to certain plant species.

The same species may have multiple common names, some of which may have regional usage. Also, the same or a similar common name can refer to related or unrelated species. Confusion may arise when different medicinal ingredients share or have similar common names.

For example, the common name ‘Fritillaria bulb’ may refer to the herb Chuan Bei Mu 川贝母 or to the herb Zhe Bei Mu 浙贝母 which is derived from the species *Fritillaria thunbergii* Miq. and is considered to have

different properties to Chuan Bei Mu. Consequently, common names tend to be imprecise and are not recommended for use in a clinical setting.

**Latinised name**: See 'Pharmaceutical name'.

***Pin yin:*** The phonetic spelling of Chinese using the Roman alphabet.

In this appendix *pin yin* refers to the herb name written in *pin yin*. For example, Chuan Bei Mu is the *pin yin* equivalent of the Chinese characters for the herb 川□ □ . The purpose of *pin yin* is to make Chinese readable by those who do not read Chinese characters.

*Pin yin* is properly written with diacritic marks to indicate the tones of Chinese but these are generally omitted. When the tones are added, the *pin yin* appears as: chuān bèi mǔ.

*Pin yin* is the recommended nomenclature in these guidelines as it has a low safety risk, is referred to in Chinese medicine reference books, is taught in Australian courses in Chinese herbal medicine and can be readily understood and written by English as well as non-English speakers.

**Pharmaceutical name:** Also referred to as the Latinised name. This refers to a system of nomenclature that Latinises the herb name.

The pharmaceutical name usually includes the genus, the part of the plant used, the species and whether any processing was performed. For example, 'Bulbus Fritillariae Cirrhosae' refers to the herb Chuan Bei Mu which is principally sourced from the bulb of the plant *Fritillaria cirrhosa* D. Don. The pharmaceutical name and the scientific name may appear similar since both are based on Latin.

In the PPRC, pharmaceutical names are listed in addition to the name in Chinese characters and *pin yin*. A pharmaceutical name may not be species specific, so when a herb is potentially sourced from multiple species, each species shares the same pharmaceutical name.

For example, the herb Chuan Bei Mu 川贝母, which is known by the pharmaceutical name 'Bulbus Fritillariae Cirrhosae', is listed in PPRC as being sourced from the following species and varieties:

*Fritillaria cirrhosa* D. Don

*Fritillaria unibracteata* P.K.Hsiao & K.C.Hsia

*Fritillaria przewalskii* Maxim.

*Fritillaria delavayi* Franch.

*Fritillaria taipaiensis* P. Y. Li

*Fritillaria unibracteata* P.K.Hsiao & K.C.Hsia var *wabuensis*

The dried bulbs of these plants are considered medicinally equivalent and interchangeable, i.e. they can all be used as the herb Chuan Bei Mu.

**Scientific name (also known as the botanical name, scientific binomial name, binomial name , or Latin name):** The scientifically accepted method of positively identifying a specific species.

For regulatory purposes, the Therapeutic Goods Administration (TGA), which regulates complementary medicines (including Chinese herbal medicines), requires the herbal ingredients of a listed or registered complementary medicine to be provided using scientific names. The Department of Agriculture, which regulates the import of herbal teas and natural medicines, also requires herbs to be identified by the scientific name.

There are formal and internationally adopted procedures for creating Latin scientific names for plant species and cross-referencing them to physical plant specimens. These procedures that make the scientific names unambiguous. These procedures are bound by internationally agreed guidelines laid down in the International Code of Botanical Nomenclature (ICBN).

By convention the scientific name is written in italics. Scientific names are binomial names, meaning they consist of the genus name followed by the species name. A genus may comprise many different species, each of which may have its own pharmacological properties. The first letter of the first word (the genus) is

capitalised, and the first letter of the second word (the species) is in lower case. When a variety of a species is designated an additional name appears after 'var.'. In addition the initials or name of the botanist may also be included as the authority. In some cases the name of the plant family will follow, e.g. *Fritillaria cirrhosa* D. Don, (Liliaceae).

This is a reliable method of identifying plants and animals and is the naming convention for pharmacovigilance endorsed by the World Health Organization. The use of the full scientific name is rapidly becoming the standard for scientific publication. However, the PPRC is not organised according to scientific name – rather, it is organised by the Chinese name.

**Potential issues related to identification of herbs based on *pin yin***

### 1. Relationship of *pin yin* to the name in Chinese characters

The Chinese name can be written in characters or in *pin yin*. There is a direct correspondence between the *pin yin* name of a herb and the Chinese characters as it appears in the PPRC, so the same herb can be reliably identified using the *pin yin* or Chinese characters in most cases. However, different characters can have the same pronunciation and therefore the *pin yin* can be the same.

**Table 1: Examples of some Chinese herbs where *pin yin* is written without the tones being marked may correspond to more than one herb by scientific name.**

In a very small number of cases the name of a herb in *pin yin* when used alone (and without diacritics for the tones) may result in confusion, such as when names in *pin yin* are the same for different plants or when the name in *pin yin* might be confused with a similar sounding name in *pin yin*.

When necessary, the addition of another form on the written name, such as the scientific name (with the plant part and/or processing method, where relevant), the name in Chinese characters or the pharmaceutical name removes ambiguity.

In each of the six pairs of herbs in Table 1, confusion between these examples is unlikely, since one of the plants in a pair is not in common use. Therefore, it is very unlikely that these plants will be mistakenly dispensed based on the name in *pin yin*. The only pair listed in PPRC is Da Ji. In this case, *Euphorbia pekinensis* Rupr (Jing da ji) is not commonly used due to its toxicity while *Cirsium japonicum* Fisch. Ex DC (Da ji) is in occasional use.

| Chinese *pin yin* | Scientific name | Chinese characters |
|---|---|---|
| Bai Mao Gen | *Imperata cylindrica* (L.) Raeusch. | báimáogēn<br>白茅根 |
| | *Hydrastis canadensis* L. | báimáogèn<br>白茅莨 |
| Da Ji | *Cirsium japonicum* Fisch. ex DC. | dàjì dàjì<br>大蓟/大薊 |
| | *Euphorbia pekinensis* Rupr. | dàjǐ<br>大戟 （京大戟） |
| Mu Ju | *Matricaria chamomilla* L. | mǔjú<br>母菊 |
| | *Aegle marmelos* (L.) Correa. | mùjú<br>木橘 |
| Mu Lan | *Bruguiera gymnorhiza* (L.) Lam. | mùlǎn<br>木榄 |
| | *Indigofera tinctoria* L. | mùlán<br>木蓝 |

| | | |
|---|---|---|
| | *Magnolia liliiflora* Descr. | mù lán<br>木兰 |
| Pu Tao | *Vitis vinifera* L. | pú táo<br>葡萄 |
| | *Syzygium jambos* (L.) Alston | p ú táo<br>蒲 桃 |
| Shi Hu | *Dendrobium nobile* Lindl. | shí h ú<br>石 斛 |
| | *Evodia* rutaecarpa (Juss.) var. *officinalis (Dode) Huang** | shí h ū<br>石 虎 |

* This plant is one of the species used as Wu Zhu Yu 吴茱萸 (see PPRC). The main species cited for Wu Zhu Yu is *Evodia rutaecarpa* (Juss.) Benth.

When there is potential for confusion when the name in pin yin is used alone, an additional name should be used to make it clear, for example:

- *Pin yin* + Chinese characters: Da Ji 大□
- *Pin yin* + Scientific name: Da Ji (Cirsium japonicum)
- *Pin yin* + Pharmaceutical name: Da Ji (Cirsii Japonica Herba)

## 2. Relationship of *pin yin* to species

As discussed above, a single Chinese herbal medicine may be sourced from more than one species. For example, the herb *Xin Yi Hua* (which means 'Magnolia flower') may be sourced from the flower buds of three Magnolia species: *Magnolia biondii* Pamp., *Magnolia denudata* Desr. and *Magnolia sprengeri* Pamp. These herbs are all from the same genus and are considered to be equivalent from the perspective of herbal medicine practice.

In other cases, one herb may be sourced from species from different genera. For example Zi Cao can be sourced from the roots of:

- *Arnebia euchroma* (Royle) Johnst.; or
- Arnebia guttata Bunge.; or
- Lithospermum erythrorhizon Sieb.et Zucc.

These herbs are considered to be equivalent in terms of their actions and all three species contain shikonin, which is considered to be the principal active compound.

## 3. Relationship of the Chinese name (characters or *pin yin*) to plant part and processing

Herbal products may be produced by using different parts of the same plant (e.g. root, leaves, bark, fruit) or by different methods of processing the same plant (e.g. cooking, honey processing. When different parts of the same plant are used, these are distinguished by the Chinese and names in *pin yin*, for example Sang Ye 桑叶 refers to the leaf of *Morus alba* L. whereas Sang Shen Zi 桑椹子 refers to the fruit of *Morus alba* L.

Similarly, the form of processing can be indicated by the Chinese name in both characters and *pin yin*. For example, Mi Sang Ye 蜜桑叶 refers to the leaves of *Morus alba* L. processed using honey. More examples of herbal products derived from *Morus alba* L. and their associated names in *pin yin* are provided in Table 2.

**Table 2: Different parts of the plant and different processing methods of *Morus alba*[20] resulting in different herbal products**

| *Pin yin* | Chinese characters | Scientific name | Plant part | Processing |
|---|---|---|---|---|
| Sang Ye | 桑叶 | *Morus alba* L. | leaves | dried |
| Mi Sang Ye | 蜜桑叶 | *Morus alba* L. | leaves | processed with honey |
| Sang Ye Zhi | 桑叶汁 | *Morus alba* L. | leaf | juice from fresh leaves |
| Sang Ye Lu | 桑叶露 | *Morus alba* L. | leaf | distilled liquid from the leaf juice |
| Sang Ying | 桑□ | *Morus alba* L. | burl of the matured tree | dried |
| Sang Li | 桑□ | *Morus alba* L. | twig | liquid extract from twigs |
| Sang Zhi | 桑枝 | *Morus alba* L. | new twig growth | dried |
| Sang Zhi Pi | 桑枝皮 | *Morus alba* L. | twig bark | dried |
| Sang Gen | 桑根 | *Morus alba* L. | root | dried |
| Sang Bai Pi | 桑白皮 | *Morus alba* L. | white section of the bark of the root | dried |
| Sang Pi Zhi | 桑皮汁 | *Morus alba* L. | root bark | liquid from the bark of the trunk |
| Sang Chai Hui | 桑柴灰 | *Morus alba* L. | wood | ash from the wood |
| Sang Shen Zi | 桑椹子 | *Morus alba* L. | fruit | dried |

Table 2 is intended for illustration purposes. Of the products of *Morus alba* L. used in Chinese medicine that are listed in Table 2, Sang Ye 桑叶, Sang Zhi 桑枝, Sang Bai Pi 桑白皮 and Sang Shen Zi 桑椹子 are in common use.

In cases when there is no need to differentiate between different herbal products based on the plant part, the name in *pin yin* may not make mention of the plant part. For example, the herb name Chuan Bei Mu makes no mention of the plant part because the bulb is the only part typically used. Similarly, when only one form of processing is typically used, such as drying, this is not mentioned in the name in *pin yin*.

## 4. The use of alternative, abbreviated, and non-standard names

A number of herbs are known by two or more different herbal names which are used interchangeably. For example, the root of *Trichosanthes kirilowii* Maxim. can be named Tian Hua Fen 天花粉 or Gua Lou Gen 瓜蒌根. Tian Hua Fen is the official name in PPRC but Gua Lou Gen is equal in terms of precision and is listed in many books.

[20] The official source of these herbs is *Morus alba* L. (PPRC). In some regions *Morus australis* Poir, *Morus mongolica* (Bur.) Schneid or *Morus cathayana* Hemsl. are used.

Some herbs can share the same abbreviated name but can be distinguished when the full name is used. For example, the abbreviated name Bei Mu 贝母 can refer to either Chuan Bei Mu 川贝母 or Zhe Bei Mu 浙贝母 which are considered different herbs. In some cases Tian Hua Fen is abbreviated to Hua Fen 花粉, a term that can also refer to pollen. Abbreviations can lead to confusion. To eliminate possible confusion the PPRC uses the full names in *pin yin* and in Chinese characters.

Some practitioners have used non-standard 'prescription' names. Typical examples include Yun Ling 云苓 in place of Fu Ling 茯苓 for *Poria cocos* F.A.Wolf, and Chuan lian 川连 in place of Huang Lian 黄连 for *Coptis chinensis* Franch. These synonyms are well known among Chinese medicine practitioners but they can be difficult to find in the literature and have the potential to lead to confusion. Therefore, the use of standard names is recommended.

**Conclusions**

Overall, the issues associated with the use of the name in *pin yin* are the same as those associated with the use of the Chinese name from the point of view of medicinal ingredient identity and pharmacovigilance. Provided that *pin yin* is precise and accords with the name used in the PPRC, confusion in the identity of a medicinal ingredient is unlikely when the name in *pin yin* is used. It is also concise and convenient to apply.

## Appendix 3: Examples of prescriptions

Theseexamples show how a prescription can comply with these guidelines. Practitioners do not have to use this format but these examples will give you some ideas about how to lay out your prescriptions. Prescriptions may be handwritten or printer-generated, as long as they contain the information required by these guidelines.

**Prescription 1: Individualised formula – raw or processed herbs. Nomenclature of herbs in *pin yin***

<table>
<tr><td colspan="3">Dr White Tiger,<br>Gentle Chinese Medicine Clinic<br>Registration number: CMR 00012345<br>23 Evergreen Ave, Morningmeadow, NSW, 2000<br>Phone: 02 1234 5678; AH 0400 123 456</td></tr>
<tr><td colspan="3">Patient: Ms May Citizen</td></tr>
<tr><td colspan="3">Date: 2 December 2019</td></tr>
<tr><td>Ingredients</td><td>(g)</td><td rowspan="16">Directions for use (example)<br><br>Empty the contents of a packet of the medicine into a clay-pot. Submerge the ingredients in 3 cups of water and bring to the boil.<br>After 5 minutes of medium intense heat, turn down and simmer until ¾ of the liquid is left. Drain the liquid into a container.<br><br>Drink one cup of the warm liquid half an hour after a meal in the morning and repeat in the evening.<br><br>Keep the drained ingredients in the fridge overnight and repeat the cooking procedure the next morning. Discard the ingredients after the second cooking.<br><br>Repeat using the other packets, taking the medicine for 3 days or until finished.<br><br>Do not use metal utensils in the preparation or storage of the ingredients</td></tr>
<tr><td>Dang Shen</td><td>9g</td></tr>
<tr><td>Fu Ling</td><td>9g</td></tr>
<tr><td>Sheng Gan Cao</td><td>6g</td></tr>
<tr><td>Sheng Di Huang</td><td>15g</td></tr>
<tr><td>Bai Shao</td><td>9g</td></tr>
<tr><td>Dang Gui</td><td>9g</td></tr>
<tr><td>Chuan Xiong</td><td>6g</td></tr>
<tr><td>Sang Ji Sheng</td><td>9g</td></tr>
<tr><td>Du Huo</td><td>9g</td></tr>
<tr><td>Huai Niu Xi</td><td>9g</td></tr>
<tr><td>Qin Jiao</td><td>9g</td></tr>
<tr><td>Fang Feng</td><td>9g</td></tr>
<tr><td>Wei Ling Xian</td><td>9g</td></tr>
<tr><td>Rou Gui</td><td>2g</td></tr>
<tr><td>Du Zhong</td><td>9g</td></tr>
<tr><td colspan="3">To be divided into three packets</td></tr>
<tr><td colspan="3">Not to be dispensed after: 1 month from date of prescription</td></tr>
<tr><td colspan="3">Number of repeats: 1</td></tr>
<tr><td colspan="3">Warnings<br>If symptoms persist or you experience any unexpected symptoms, contact the Chinese medicine practitioner or medical practitioner.</td></tr>
<tr><td colspan="3">Signature:</td></tr>
</table>

**Prescription 2a: Individualised formula – raw or processed herbs. Nomenclature of herbs in *pin yin* with the addition of Chinese characters**

Dr White Tiger
Gentle Chinese Medicine Clinic
Registration number: CMR 00012345
23 Evergreen Ave, Morningmeadow, NSW, 2000
Phone: 02 1234 5678; AH 0400 123 456

**Patient:** Ms May Citizen

**Date:** 2 December 2014

| **Ingredients** | **(g)** | | **Directions for use (example)** |
|---|---|---|---|
| Dang Shen | **9g** | 党参 | Empty the contents of a packet of the medicine into a clay-pot.<br>Submerge the ingredients in 3 cups of water and bring to the boil.<br>After 5 minutes of medium intense heat, turn down and simmer until ¾ of the liquid is left.<br>Drain the liquid into a container.<br><br>Drink one cup of the warm liquid half an hour after a meal in the morning and repeat in the evening.<br><br>Keep the drained ingredients in the fridge overnight and repeat the cooking procedure the next morning. Discard the ingredients after the second cooking.<br><br>Repeat using the other packets, taking the medicine for three days or until finished.<br><br>Do not use metal utensils in the preparation or storage of the ingredients |
| Fu Ling | **9g** | 茯苓 | |
| Sheng Gan Cao | **6g** | 生甘草 | |
| Sheng Di Huang | **15g** | 生地 | |
| Bai Shao | **9g** | 白芍 | |
| Dang Gui | **9g** | 当□ | |
| Chuan Xiong | **6g** | 川芎 | |
| Sang Ji Sheng | **9g** | 桑寄生 | |
| Du Huo | **9g** | 独活 | |
| Huai Niu Xi | **9g** | □ 牛膝 | |
| Qin Jiao | **9g** | 秦艽 | |
| Fang Feng | **9g** | 防□ | |
| Wei Ling Xian | **9g** | 威灵仙 | |
| Rou Gui | **2g** | 肉桂 | |
| Du Zhong | **9g** | 杜仲 | |

To be divided into three packets

**Not to be dispensed after:** 1 month from date of prescription

**Number of repeats:** 1

**Warnings**
If symptoms persist or you experience any unexpected symptoms, contact the Chinese medicine practitioner or medical practitioner.

**Signature**:

**Prescription 2b: Handwritten sample (same as 2a)**

Dr White Tiger,
Gentle Chinese Medicine Clinic
Registration number: CMR 00012345
23 Evergreen Ave, Morningmeadow, NSW, 2000 Phone: 02 1234 5678; AH 0400 123 456

**Patient:** Mr. Ivan Citizen

**Date:** 2 December 2014

| Ingredients | (g) | |
|---|---|---|
| Dang Shen | 9g | 党参 |
| Fu Ling | 9g | 茯苓 |
| ShengGanCao | 6g | 生甘草 |
| sheng DiHuang | 15g | 生地黄 |
| Bai Shao | 9g | 白芍 |
| Dang Gui | 9g | 当归 |
| Chuan Xiong | 6g | 川芎 |
| Sang Ji sheng | 9g | 桑寄生 |
| Du Huo | 9g | 独活 |
| Huai Niu Xi | 9g | 怀牛膝 |
| Qin Jiao | 9g | 秦艽 |
| Fang Feng | 9g | 防风 |
| Wei Ling Xian | 9g | 威灵仙 |
| Rou Gui | 2g | 肉桂 |
| Du Zhong | 9g | 杜仲 |

**Directions for use (example)**

Empty contents into a clay pot. Submerge herbs in 3 cups of water and bring to the boil. After 5 minutes of medium, intense heat, turn down and simmer until 3/4 of the liquid is left.

Drain the liquid into a cup and drink it all, while warm, after a meal.

Keep herbs in the fridge overnight and repeat the cooking procedure next day.

Discard the herbs after the second cooking.

Do not use metal utensils in the preparation or storage of herbs.

**Not to be dispensed after:** 1 month from date of prescription

**Number of repeats:** 1

**Warnings** If symptoms persist or you experience any unexpected symptoms, contact the Chinese medicine practitioner or medical practitioner.

**Signature:**

**Prescription 3: Individualised formula – herbal granules. Nomenclature of herbs in *pin yin***

Dr White Tiger
Gentle Chinese Medicine Clinic
Registration number: CMR 00012345
23 Evergreen Ave, Morningmeadow, NSW, 2000
Phone: 02 1234 5678; AH 0400 123 456

**Patient:** Ms May Citizen

**Date:** 2 December 2019

| **Ingredients** | **(g)**<br>**5:1** | **Directions for use (example):**<br><br>Mix the granules well before use. Dissolve 3 grams of the mixed granules in half a cup of boiling water.<br><br>Drink it while warm half an hour after a meal in the morning and repeat again in the evening, until finished.<br><br>Do not use metal utensils in the preparation or storage of herbs. |
|---|---|---|
| Dang Shen | **4g** | |
| Fu Ling | **4g** | |
| Sheng Gan Cao | **3g** | |
| Sheng Di Huang | **4g** | |
| Bai Shao | **4g** | |
| Dang Gui | **4g** | |
| Chuan Xiong | **4g** | |
| Sang Ji Sheng | **4g** | |
| Du Huo | **4g** | |
| Huai Niu Xi | **4g** | |
| Qin Jiao | **3g** | |
| Fang Feng | **3g** | |
| Wei Ling Xian | **4g** | |
| Rou Gui | **3g** | |
| Du Zhong | **4g** | |

**Not to be dispensed after:** 1 month from date of prescription

**Number of repeats:** 1

**Warnings**
If symptoms persist or you experience any unexpected symptoms, contact the Chinese medicine practitioner or medical practitioner.

**Signature**:

## Appendix 4: Management and operation of a Chinese medicine dispensary and supervision of dispensary assistants

This is only general guidance. When specific risks arise practitioners should seek their own legal advice that is specific to their own circumstances.

**General requirements for dispensaries**

The following general specifications apply to all Chinese herbal dispensaries:

- The dispensary is to be clean and orderly and surfaces regularly cleaned and disinfected in accord with any required government Infection Prevention and Control guidelines.
- Chinese medicine practitioners may not legally prescribe, manufacture or supply any substance which is restricted by Schedule 2, 3, 4, 7, 8, 9 or 10 of the Standard for the Uniform Scheduling of Medicines and Poisons (SUSMP) and are to be aware of their ethical obligations with regard to CITES.
- Medicinal substances are to be stored and handled in a hygienic manner.
- The dispensary is to be organised in such a way as to reduce the risk of error in the selection, preparation, dispensing or supply of medication.
- A system is to be in place enabling urgent contact of patients should the need arise (see 5.2).
- Staff are to be trained and competent to fulfil their duties.
- Facilities for handwashing and separate facilities for the washing of utensils are to be readily available.
- Ensure that equipment used for measuring and weighing is accurate.
- For the health and safety of the staff, protective masks and safety glasses should be worn when doing certain preparation tasks, such as grinding of a substance that results in production of any dangerous inhalable airborne particles or particles that may enter the eye.
- Establish procedures to ensure the accurate dispensing of prescriptions.
- Establish procedures to prevent prescriptions from being confused, mixed up or mislabelled.

**Storage of medicinal ingredients**

- Establish storage procedures to ensure that the quality of medicinal ingredients is maintained and contamination prevented.
- Medicinal ingredients are to be stored in clean, dry containers that protect from insect and rodent attack.
- Medicinal ingredients are to be periodically inspected and any that show signs of mould, discoloration, insect attack or other deterioration discarded.
- When medicinal ingredients are transferred from storage into the containers from which they are dispensed, they are to be checked for any foreign matter. Any foreign matter is to be removed and discarded. If foreign matter cannot be completely and safely removed, the entire batch is to be discarded.
- Good practice in the storage of medicinal ingredients includes regular cleaning of storage containers and careful management of refilling.
- Medicinal ingredients are to be kept out of reach of children and infants.
- The most appropriate method of storage will vary according to the particular medicinal ingredient. In general, it is advisable to keep medicinal ingredients in cool, dry conditions away from direct sunlight. Some medicinal ingredients 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 medicinal ingredients in storage**

- Medicinal ingredients are to be clearly identified and stored in clearly labelled containers, and/or dispensary drawers, and/or packets. Proper nomenclature is to be used in labelling (see section 1 of these guidelines).
- Medicinal ingredients 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 these medicinal ingredients in order to clearly distinguish them.
- If the identity of the medicinal ingredients supplied is in doubt, it should be returned to the wholesaler and not dispensed to patients.

**Handling medicinal ingredients**

When handling medicinal ingredients and dispensing prescriptions, care is to be taken to maintain cleanliness, avoid contamination and prevent cross-contamination. This means:

- the surfaces or containers on which medicinal ingredients are dispensed are to be clean and free from foreign matter
- dispensers should have clean and dry hands when compounding and dispensing a prescription
- scales used for weighing medicinal ingredients are to be accurate and cleaned regularly
- utensils used in the processing of medicinal ingredients are to be kept clean.

**Inventory record-keeping**

A record is to be kept of the inventory of herbs that includes the:

- name of the medicinal ingredients purchased
- quantity purchased
- name of the wholesaler
- date purchased
- the batch number where possible, especially in the case of granulated herbs.

**Management supervision and training of dispensary assistants**

Registered practitioners are professionally accountable for the medicines prescribed and dispensed to their patients and the Board holds them responsible for all aspects of the Chinese medicine dispensary.

Chinese medicine practitioners may choose to be assisted by suitably trained, unregistered persons (dispensary assistants) to dispense medicines, in accordance with these guidelines. The practitioner is responsible for the proper training of these assistants.

A registered practitioner is to be available at all times to provide advice to dispensary assistants. The Chinese medicine practitioner in charge of the dispensary business is professionally responsible and accountable for all aspects of the Chinese medicine dispensary including:

- providing (ongoing) training to their assistants
- assessing the level (and currency) of the assistants' knowledge, and their skills
- supervising assistants at all times (i.e. in person)
- ensuring that assistant functions are limited to functions that do not require professional judgement or discretion
- responsibility for every formula/medicine compounded and dispensed.

All relevant state, territory and Commonwealth legislation, and the advice provided in these guidelines are to be complied with. The treating 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 medicine practitioner may delegate certain tasks to a dispensary assistant. Duties that a Chinese medicine practitioner may delegate to dispensary assistants include:

- preparation of medicines to be dispensed, including identification, weighing, and medicinal ingredient preparation (*pao zhi*)
- inventory management including
  - ordering and unpacking of stock
  - repackaging stock
  - storage of medicines
- preparing dispensing labels
- attaching dispensing and cautionary and advisory labels
- collating prescriptions
- cleaning and hygiene responsibilities and tasks.

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

The practitioner is not to delegate to an unregistered assistant any activity that is required by legislation, or by standards of professional practice, to be performed by a registered practitioner including:

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

Chinese medicine practitioners are to provide dispensary assistants with training in relevant legislation and guidelines and retain a record of this training. 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 medicine practitioner is responsible for arranging the clinic layout and the workflow within it to facilitate the direct supervision of dispensary assistants.

## Appendix 5: Examples of labels

These examples show how labels can comply with these guidelines. Practitioners do not have to use this format but these examples will give you some ideas about how to lay out your labels. Labels may be handwritten or printer-generated, as long as they contain the information required by these guidelines. A copy of the prescription covering all the labelling information attached to the outer package of the medicine is an alternative way to meet this requirement.

**Label 1: Individualised formula – raw or processed herbs. Nomenclature of herbs in *pin yin***

| **Ingredients** | **(g)** |
|---|---|
| Dang Shen | **9g** |
| Fu Ling | **9g** |
| Sheng Gan Cao | **6g** |
| Sheng Di Huang | **15g** |
| Bai Shao | **9g** |
| Dang Gui | **9g** |
| Chuan Xiong | **6g** |
| Sang Ji Sheng | **9g** |
| Du Huo | **9g** |
| Huai Niu Xi | **9g** |
| Qin Jiao | **9g** |
| Fang Feng | **9g** |
| Wei Ling Xian | **9g** |
| Rou Gui | **2g** |
| Du Zhong | **9g** |

**Patient:** Ms May Citizen

**Dispensed Date:** 02 Dec 2019

**Dispenser:** Green Dragon
ABC Dispensary P/L
123 Wellbeing St.
Morningmeadow NSW 2002

**Tel**: 02-1239 6789

**Prescriber** (if different from the dispenser):
Dr White Tiger (CM), Tel: 02 1234 5678

**Prescribing date:** 02 Dec 2019

**Take within:** 14 days

**No. of repeats left:** 0

**No. of packets**: 3

**Directions for use (example)**
Empty the contents of a packet of the medicine into a clay-pot. Submerge the ingredients in 3 cups of water and bring to the boil. After 5 minutes of medium intense heat, turn down and simmer until ¾ of the liquid is left. Drain the liquid into a container.

Drink one cup of the warm liquid half an hour after a meal in the morning and repeat in the evening.

Keep the drained ingredients in the fridge overnight and repeat the cooking procedure the next morning. Discard the ingredients after the second cooking.

Repeat using the other packets, taking the medicine until finished.

Do not use metal utensils in the preparation or storage of the ingredients

**Warnings**
If symptoms persist or you experience any unexpected symptoms, contact your Chinese medicine practitioner or medical practitioner.

**Label 2a: Individualised formula – raw or processed herbs. Nomenclature of herbs in *pin yin* with the addition of Chinese name**

| **Ingredients** | | **(g)** |
|---|---|---|
| 党参 | Dang Shen | **9g** |
| 茯苓 | Fu Ling | **9g** |
| 生甘草 | Sheng Gan Cao | **6g** |
| 生地 | Sheng Di Huang | **15g** |
| 白芍 | Bai Shao | **9g** |
| 当□ | Dang Gui | **9g** |
| 川芎 | Chuan Xiong | **6g** |
| 桑寄生 | Sang Ji Sheng | **9g** |
| 独活 | Du Huo | **9g** |
| □牛膝 | Huai Niu Xi | **9g** |
| 秦艽 | Qin Jiao | **9g** |
| 防□ | Fang Feng | **9g** |
| 威灵仙 | Wei Ling Xian | **9g** |
| 肉桂 | Rou Gui | **2g** |
| 杜仲 | Du Zhong | **9g** |

**Patient:** Ms May Citizen

**Dispensed Date:** 02 Dec 2014

**Dispenser:** Green Dragon
ABC Dispensary P/L
123 Wellbeing St.
Morningmeadow NSW 2002

**Tel**: 02-1239 6789

**Prescriber** (if different from the dispenser):
Dr White Tiger (CM), Tel: 02 1234 5678

**Prescribing date:** 02 Dec 2019

**Take within:** 14 days

**No. of repeats left:** 0

**No. of packets**: 3

**Directions for use (example)**
Empty the contents of a packet of the medicine into a clay-pot. Submerge the ingredients in 3 cups of water and bring to the boil. After 5 minutes of medium intense heat, turn down and simmer until ¾ of the liquid is left. Drain the liquid into a container.

Drink one cup of the warm liquid half an hour after a meal in the morning and repeat in the evening.

Keep the drained ingredients in the fridge overnight and repeat the cooking procedure the next morning. Discard the ingredients after the second cooking.

Repeat using the other packets, taking the medicine until finished.

Do not use metal utensils in the preparation or storage of the ingredients

**Warnings**
If symptoms persist or you experience any unexpected symptoms, contact your Chinese medicine practitioner or medical practitioner.

**Label 2b: Handwritten sample (same as 2a)**

| Ingredients | | (g) |
|---|---|---|
| 党参 | Dang Shen | 9g |
| 茯苓 | Fu Ling | 9g |
| 生甘草 | Sheng Gan Cao | 6g |
| 生地黄 | Sheng Di Huang | 15g |
| 白芍 | Bai Shao | 9g |
| 当归 | Dang Gui | 9g |
| 川芎 | Chuan Xiong | 6g |
| 桑寄生 | Sang Ji Sheng | 9g |
| 独活 | Du Huo | 9g |
| 怀牛膝 | Huai Niu Xi | 9g |
| 秦艽 | Qin Jiao | 9g |
| 防风 | Fang Feng | 9g |
| 威灵仙 | Wei Ling Xian | 9g |
| 肉桂 | Rou Gui | 2g |
| 杜仲 | Du Zhong | 9g |

**Patient:** Mr. Ivan Citizen

**Dispensed Date:** 2 Dec 2014

**Dispenser:** Green Dragon
ABC Dispensary P/L
123 Wellbeing St.
Morningmeadow NSW 2002

**Tel:** 02-1239 6789

**Prescriber** (if different from the dispenser):
Dr. White Tiger (CM)

**Prescribing date:** 2 Dec 2014

**Take within:** 7 days

**No. of repeats left:** 0

**No. of packets:** 3

**Directions for use (example)**

Empty contents into a clay pot.
Submerge herbs in 3 cups of water and bring to the boil.
After 5 minutes of medium, intense heat, turn down and simmer until 3/4 of the liquid is left. Drain the liquid into a cup and drink it all, while warm, after a meal.
Keep herbs in the fridge overnight and repeat the cooking procedure next day.
Discard the herbs after the second cooking.
Do not use metal utensils in the preparation & storage of herbs.

**Warnings**

If symptoms persist or you experience any unexpected symptoms, contact your Chinese medicine practitioner or medical practitioner.

**Label 3: Individualised formula – herbal granules. Nomenclature of ingredients is in *pin yin* and Chinese**

| **Ingredients** | | **(g) (5:1)** |
|---|---|---|
| 党参 | Dang Shen | **4g** |
| 茯苓 | Fu Ling | **4g** |
| 生甘草 | Sheng Gan Cao | **3g** |
| 生地 | Sheng Di Huang | **4g** |
| 白芍 | Bai Shao | **4g** |
| 当□ | Dang Gui | **4g** |
| 川芎 | Chuan Xiong | **4g** |
| 桑寄生 | Sang Ji Sheng | **4g** |
| 独活 | Du Huo | **4g** |
| □ 牛膝 | Huai Niu Xi | **4g** |
| 秦艽 | Qin Jiao | **3g** |
| 防□ | Fang Feng | **3g** |
| 威灵仙 | Wei Ling Xian | **4g** |
| 肉桂 | Rou Gui | **3g** |
| 杜仲 | Du Zhong | **4g** |

**Patient:** Ms May Citizen

**Dispensed Date:** 02 Dec 2019

**Dispenser:** Green Dragon
ABC Dispensary P/L
123 Wellbeing St.
Morningmeadow NSW 2002

**Tel**: 02-1239 6789

**Prescriber** (if different from the dispenser):
Dr White Tiger (CM), Tel: 92 1234 5678

**Prescribing date:** 02 Dec 2019

**Herbs valid for 7** days only

**No. of repeats left:** 0

**Directions for use (example)**

Mix the granules well before use.
Dissolve 3 grams using the 1g spoon supplied (or half a teaspoon) of the mixed granules in half a cup of boiling water.

Drink it while warm half an hour after a meal in the morning and repeat again in the evening, until finished.

Do not use metal utensils in the preparation or storage of herbs.

**Warnings**
If symptoms persist or you experience any unexpected symptoms, contact your Chinese medicine practitioner or medical practitioner.

## Appendix 6: Repackaging manufactured medicines

Manufactured medicines that are listed or registered on the ARTG should be prescribed or sold in their original containers with the manufacturer's original packaging intact. This ensures all the information provided on the label is available to the patient or consumer. This safeguards patient safety and provides adequate information to consumers.

In most instances, the Board strongly discourages repackaging of listed or registered medicines into smaller quantities. The TGA has approved the listing of these products at a particular dose size. If the repackaged product is intended for retail supply rather than dispensing there are regulations such as about the marketing and advertising of listed products, which the person responsible for their supply must follow. These are also specified in the ARGCM (see also section 2).

Occasionally there may be a valid reason to dispense a smaller quantity of a manufactured medicine for a specific patient or for a specific reason. For example, for a child or when there is a safety concern about prolonged use.

In this case, the pills or capsules should be dispensed with care into a clean container ensuring there is no contamination or substitution of the wrong medicine in the process. All the information about the product that was on the original label must be reproduced so that the patient is fully informed about the contents of the container. In addition the name of the patient, date of dispensing and details of practitioner are to be provided in accordance with section 3.2 of these guidelines. The dosage, duration of consumption and any other specific instructions on taking the medicine must be specified precisely. Specific warnings should be given when appropriate.

Practitioners are not to pre-dispense multiple smaller doses into multiple fresh containers as 'trial packs' from a larger bulk quantity, in anticipation of patients who may come onto the premises and ask for that medicine.

# Appendix 7: Adverse event reporting

An adverse event is any unwanted and unfavourable sign or medical occurrence in a patient who has been administered a medicine. The event may or may not be related to the medicine or treatment.

Practitioners have the professional responsibility to report suspected adverse events. Patients or any member of the public may also report adverse events online to the Therapeutic Goods Administration (TGA).

For further information about reporting an adverse event see: www.tga.gov.au/reporting-problems.

These section helps 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:

- directly to the TGA via the online Adverse Drug Reaction Reporting System at www.ebs.tga.gov.au/ebs/ADRS/ADRSRepo.nsf?OpenDatabase, or
- through a pre-paid reporting form (Blue card report) at www.tga.gov.au/reporting-problems, or
- by telephoning the TGA on 1800 044 114, or
- by fax 02 6232 8392, or
- by email to adr.reports@tga.gov.au.

**What should you report?**

TGA encourages reporting of all suspected reactions to any medicine available in Australia, including prescription medicines, vaccines, herbal, traditional, over-the-counter medicines and alternative remedies.

The TGA particularly requests reports of:

- all suspected adverse drug reactions (ADRs) to new medicines
- all suspected drug interactions, and
- suspected reactions causing death, admission to hospital, increased investigations or treatment, birth defects.

**Reporting adverse events**

All reports should contain the following data:

- patient information (initials only[21], date of birth and age)
- reporter information (name, address, phone number)
- a description of the reaction
- any medicines suspected of causing the reaction
- for manufactured medicines, the Aust L, Aust L(A) or Aust R number from the Australian Register of Therapeutic Goods
- dosage at which adverse event occurred
- 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
- outcome of the reaction and date of the outcome.

The reports are analysed by TGA staff to determine whether there is a safety signal. By providing all data relevant to a specific reaction, a rational and objective assessment of the reaction association can be made.

[21] The full name should not be provided due to privacy concerns.