Guidelines for safe Chinese herbal medicine practice

November 2015

Authority

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

The Board holds all registered Chinese medicine practitioners to account against the standards it sets. Board-approved guidelines may be used as evidence of what constitutes appropriate professional conduct or practice for Chinese medicine, in proceedings under the National Law, or a law of a co-regulatory jurisdiction.

Summary

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

- use clear and consistent herbal nomenclature
- record adequate details of Chinese herbal medicines in patient health records
- write adequate prescriptions
- ensure medicine labelling is accurate and informative, and
- ensure compounding and dispensing of medicines is precise and professional.

The Board endorses the use of the **authorised *pin yin*[1]** as the most appropriate herbal nomenclature for use in Chinese medicine in Australia.

There will be a two-year transition period before these guidelines take formal effect in 2017. This transition will allow practitioners to make sure their practice complies with these requirements.

The Board will review these guidelines at least every three years.[2]

Background

The decision to regulate Chinese medicine was influenced by identified risks associated with the practice of Chinese herbal medicine.

The Board has developed these guidelines to support the safe practice of Chinese herbal medicine and address the risks it has identified from dealing with notifications (complaints),

The Australian Commission on Safety and Quality in Health Care[3] has identified medication safety as one of its priorities and established it as a National Safety and Quality Health Service Standard. Developing guidelines for safe Chinese herbal medicine practice will support that priority.

[1] All references to *pin yin* in these guidelines refer to the authorised *pin yin* as found in the *Herbal nomenclature compendium* of commonly used Chinese herbs commissioned by the Board - see section 1.2.

[2] The first review period will commence three years following the end of the two-year transition period, or earlier if required.

[3] www.safetyandquality.gov.au/

There is expanding use of herbal medicines globally and their safety is increasingly important to the public. In the Australian clinical context, a consistent, widely accepted nomenclature which can be interpreted by other health care workers needs to be adopted. It is widely recognised that there are potential toxicity issues with some Chinese herbs (de Smet, 2004; Shaw, 2010). Greater attention is being focussed on pharmacovigilance and the analysis of adverse reactions induced by natural products including traditional Chinese herbal medicines (Kennedy and Seely, 2010; Zeng and Jiang, 2010; Zhang et al, 2012; Paik and Lee, 2015).

There are several different nomenclature systems currently used for Chinese herbs. *Pin yin* and Chinese characters are widely used in clinical practice. The use of the scientific name[4] for herbs and herbal ingredients has been furthered by developments in the regulation of herbal medicines and of pharmacovigilance systems for tracking adverse reactions to herbal 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 herbal 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 herb names.

Pin yin names, however, 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 by all healthcare professionals. The best option is the use of *pin yin* names, because these can be read by everyone and readily searched.

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 the minimum regulatory force to manage identified risk. These guidelines aim to establish the minimum standards needed for good professional practice that are feasible to implement.

Who needs to use these guidelines?

These guidelines apply to all practising registered[5] Chinese medicine practitioners.[6]

Chinese medicine students who perform supervised clinical treatment, and dispensary assistants who are supervised by registered practitioners, should also 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[7] who sell herbal 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 or any 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.

Injectable medicines (intravenous or intramuscular) are not covered by these guidelines.

Chinese herbal medicines include the following product types:

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

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

[6] This refers to 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.

[7] It is acknowledged that registered practitioners can also act as retailers.

- raw herbs (fresh, dried and/or traditionally processed)
- decoctions of single or multiple ingredients
- extracts (powders, granules or liquids)
- 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, 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.

These guidelines will be used to assist the Board in its role of protecting the public by setting and maintaining standards of Chinese medicine practice. Any person can make a notification about a registered health practitioner. These guidelines will assist the Board to decide what if any regulatory action is needed 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, they should be prepared to explain and justify their decisions and actions. Serious or repeated failure to meet these guidelines may constitute behaviour for which health, conduct or performance action may be taken. A financial penalty may apply for a breach under the National Law. The relevant sections of the National Law are outlined at Appendix 1.

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

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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, and
- supervising and ensuring accountability of 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 Chinese Medicine Board of Australia (Board) Guidelines for health record keeping (formerly *Patient record guidelines*).

Chinese medicine practitioners must comply with all legislation relevant to the practice of Chinese medicine in the jurisdiction where they practise. Practitioners are also reminded of:

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

The Board commissioned the development of a *Herbal nomenclature compendium* of commonly used Chinese herbal medicines (see section 1.2), based on *The pharmacopoeia of the People's Republic of China (Zhong Hua Ren Min Gong He Guo Yao Dian)* 2010 edition (中华人民共和国药典) (PPRC 2010). This compendium is freely available on the Board's website to assist all health practitioners.

Other members of the patient's healthcare team sometimes need to be informed of the herbal medicines that the patient is taking.[8] Writing herb names in *pin yin* enables ready searching of the compendium. Herb 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 herbal prescriptions.

In particular Chinese medicine practitioners are to:

- use clear and accurate herbal nomenclature in all records
- attach the label, including details of the herbs, to the product
- provide proper instructions for herbal preparation, and
- use English language on all prescriptions and labels.

The Board endorses the use of the **authorised *pin yin*[9]** as the most appropriate nomenclature in Chinese medicine in Australia, based on PPRC 2010. This is a minimum requirement for herbal nomenclature.

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

Pin yin names are:

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

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

[9] All references to *pin yin* in these guidelines refer to the authorised *pin yin* as found in the *Compendium of commonly used Chinese herbs* – see section 1.2.

1. Herbal nomenclature

1.1 Background

Herbs used in Chinese herbal medicine are known by various names. This can be confusing to consumers and other 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.

There are several recorded serious incidents in which consumption of Chinese herbs has resulted in renal failure due to the toxin aristolochic acid. Some authors attribute such serious events to a lack of clarity in naming and/or confusion between herbs with similar names (Zhao et al, 2006; Wu et al, 2007).

The herb name in Chinese characters corresponds to the herb name in *pin yin* as found in the PPRC 2010. However, the herb name does not always refer to a single species name, since one herb may be sourced from more than one species (Zhao et al, 2006; Wu et al, 2007; Chan et al, 2012).

1.2 Introduction

The Board reviewed the risks, benefits and compliance burden of different systems of herbal 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. Herb 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 herbs 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 herbal medicine. Sometimes other members of the patient's healthcare team need to be informed of the herbal medicines that the patient is taking.[10] 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 has disadvantages in clinical practice, even though they are commonly used in scientific publications, by regulatory bodies and in pharmacovigilance databases the scientific names for herbs. The scientific names are often long and may be difficult to spell accurately. They may not contain all the information required to adequately describe the Chinese herb.

Chinese medicine practitioners use Chinese medicine reference books, textbooks and research reports in which herbal medicines are usually referred to by their traditional names in Chinese characters, *pin yin* or other languages. Official pharmacopoeias, such as the PPRC 2010, use a combination of names including the name in Chinese characters, the herb name in *pin yin* and the scientific name(s). The herb names written in *pin yin,* as per the PPRC 2010, directly correspond with the herb names written in Chinese characters.

Australian students of Chinese medicine are taught Chinese herbal names in *pin yin* (CMBA Accreditation Standards, 2013).

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

These guidelines, used with the Board's *Herbal nomenclature compendium* (see section 1.2), aim to make sure that herbs are identified so that patients can:

- use the medicine safely
- know what herbs they are taking, and
- readily find the information they need about the medicine or access further information.

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

1.3 CMBA's *Herbal nomenclature compendium*

The Board commissioned[11] the development of the *Herbal nomenclature compendium*[12] of commonly used Chinese herbs which is published on the Board's website and cross-references the herbs by:

- authorised name in *pin yin*
- simplified and traditional Chinese characters (with character keystrokes)
- all acceptable scientific names (source species)
- pharmaceutical name
- Chinese species
- plant part and/or processing (where relevant), and
- 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 compendium will help inform patients, Chinese medicine practitioners and other health professionals about herbal 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 website version is always the authoritative, most current version.

1.4 Restricted herbs

Chinese herbal medicine practitioners and herbal dispensers in Australia are currently restricted in their ability to prescribe, compound and dispense some Chinese herbs. A Chinese herb may be affected by the SUSMP:

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

and/or

  - a common name.

and/or

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

Some herbs are affected by a combination of these things. (Note: the dosage of the chemical constituent(s) may impact on whether a herb is affected by a particular schedule or not.)

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 herbs, unless they are also a registered medical practitioner, dentist, veterinary surgeon or pharmacist.

The Board has published a Nomenclature compendium of commonly used Chinese herbal medicines which includes information about those herbs which are legally restricted in Australia .

1.5 Required herbal nomenclature for prescriptions and labels

Prescriptions and labels are to be written in English and individual herb names are to be written using the herb name in *pin yin*. In addition to the name in *pin* yin, the practitioner may choose to use other forms of nomenclature including:

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

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

[12] Available on the CMBA website.

2. 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.[13]

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 on request.

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 hand-written clearly and legibly, in plain English. Herb names are to be in *pin yin* in accordance with the herbal nomenclature section of these guidelines (see section 1.3).

The same information can also be provided in another language to promote compliance and safety.

2.1 Information required on prescriptions for raw herbs and herbal extracts

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 herbs in *pin yin* and amounts of each herb (measured in grams)
- form of processing (when relevant)
- specific directions for use (dose, preparation/cooking, route of administration, frequency, timing of consumption).
- number of packets (where relevant)
- the expiry date of the prescription (i.e. date 'not to be dispensed after')
- specific warnings[14] (when appropriate), and
- the practitioner's signature.

This information is to be provided in 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 herbs should be provided in English or in the patient's language. These instructions can be on a separate sheet of paper, on the prescription, or on the label.

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

2.2 Information required on prescriptions for manufactured herbal medicines

Sometimes a practitioner may need to write a prescription for a manufactured herbal medicine. In these cases 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)

[13] 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.

[14] 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.

- name of medication: *pin yin* or English name (and other as appropriate)
- 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 etc.)
- the expiry date of the prescription (i.e. date “not to be dispensed after”)
- specific warnings[15] (when appropriate), and
- the practitioner’s signature.

This information is to be provided in English.

The same information can also be provided in another language to promote patient compliance and safety.

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

3. Labelling requirements for dispensed medicines

Chinese medicine practitioners are to label dispensed medicines in accordance with relevant state/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
- minimise the risk of adverse effects, and
- maximise patient safety.

This section refers to the labelling of compounded and dispensed medicines (raw herbs and herbal extracts). See Appendix 4 for guidance on labelling bulk stock of herbs.

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.

3.1 Raw herbs

The label[16] is to be clearly and legibly printed or hand-written. Herb names are to be labelled in accordance with the herbal nomenclature section of these guidelines (see section 1.3).

For an individualised raw herb formula, 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 herbs in *pin yin* and amounts of each herb (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, frequency, timing of consumption) as required, and
- specific warnings[17] when appropriate.

This information is to be provided in English.

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[15] As above.

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

[17] 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.

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 herbs should be provided in English or in the patient's language. These instructions can be on a separate sheet of paper, on the prescription, or on the label.

Raw herbs are often dispensed in multiple packs, with each pack containing the same formula for preparation 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.

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 dispensing raw herbs.

3.2 Herbal extracts

Medicines that are dispensed or extemporaneously compounded by practitioners are exempt from certain operations of the *Therapeutic Goods Act 1989* under certain Schedules of the Therapeutic Goods Regulations 1990. Practitioners may be exempt from manufacturing under Good Manufacturing Practice (GMP) and the herbal products they dispense may not be required to be included on the ARTG (Australian regulatory guidelines for complementary medicines, 2014).[18]

The label is to be clearly and legibly printed or hand-written. Herb names are to be labelled using the name/s in *pin yin* of the dispensed herb/s in accordance with the herbal nomenclature section of these guidelines (see section 1.3).

Herbal extracts (powders, granules or liquids) may be prescribed by the practitioner as an individualised extract formula.

For an individualised extract formula, the label[19] 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 herbs in *pin yin* and amounts of each herb (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[20] (when appropriate), and
- specific directions for use (dose, route of administration, frequency, timing of consumption).

* When all herb granules used in the prescription have the same concentration, write 'all 5:1 concentration' under the list of herbs and amounts.

[18] 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 legislation will apply in their particular circumstances.

[19] There are various commercial labelling systems available to facilitate this process.

[20] 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.

This information is to be provided in 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.

Extracts are sometimes dispensed in multiple packs, with each pack containing the same formula for preparation 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 the information listed above. The practitioner should advise the patient to retain it for future reference.

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 herbal extracts.

3.3 Manufactured herbal medicines

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

When a registered Chinese medicine practitioner supplies a manufactured herbal medicine as part of a consultation, the medicine is to retain the original label.[21]

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.

3.4 Repackaging manufactured herbal medicines

The Board strongly discourages repackaging of listed or registered medicines. Manufactured herbal medicines should be supplied with the manufacturer's original packaging intact. Occasionally there may be a valid reason to dispense a small 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.

4. Patient information requirements

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

- good clinical practice, and
- consistent with the requirements for informed consent (see the Board's Code of conduct section 3.5).

The Board advises practitioners to encourage patients to keep a record of their Chinese medicines.

Practitioners should provide patients with the correct herbal information about the herbs they are prescribing as described in section 3, every time herbs are prescribed or dispensed, not only the first time they see the patient.

4.1 Prescriber is also compounder/dispenser

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

- the medicine labelled according to section 3 of these guidelines, and
- written instructions for preparation, administration and storage as outlined in section 4.3 (unless the full information is provided on the label), and

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

- if the patient requests it, a copy of the prescription as outlined in section 2.1 and/or 2.2.

The full details of the medicine/s are to be recorded in the health record[22] in accordance with the nomenclature section (see section 1.3).

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

4.2 Using an independent compounder/dispenser

When the prescribing practitioner is authorising and instructing an independent dispenser, they must provide the patient with a written prescription that complies with section 2.1 and/or 2.2 of these guidelines.

The dispenser is also to provide the patient with written instructions for preparation, administration and storage. This information may be on a separate sheet of paper, or stated in the prescription, or on the label, provided all required information is included (see section 6.5).

4.3 Providing instructions to the patient

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

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

The prescribing practitioner 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 section 3.5).

5. Health records

5.1 Patient health records

The 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 herbs are 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 herbal 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
- duration over which the medicine should be used, and
- relevant, specific warnings when appropriate.

5.2 Chinese herbal dispensary record-keeping

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

[22] Please refer to the Board's published guidelines on health records available at www.chinesemedicineboard.gov.au/Codes-Guidelines.aspx

- name of the patient and contact details
- name and contact details of the prescriber
- date the prescription was dispensed
- herbs in the prescription and amounts
- details of any substitutions (see section 6.4), and
- in the case of raw herbs, the number of packets dispensed.

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 practitioner and one for the dispenser to keep.

5.3 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 in relation to the retention and destruction of patient health records vary between states and territories. Good practice involves being aware 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 retention and management of health records.

6. Compounding and dispensing

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

6.1 Checking the prescription

In dispensing a prescription, a dispenser is to exercise independent judgement to make sure that it 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 herbs, dosages or preparation instructions. If there is any doubt, the dispenser is to contact the prescriber.

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 or restricted herbs which may cause ill-effects) they should contact the prescriber.

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

6.2 Providing herbs accurately and in the form specified

The dispenser is to provide herbs in the form specified on the prescription and undertake the preparation (i.e. grinding, crushing, etc.), processing (i.e. *pao zhi*), and separate packaging of herbs, 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 herbs, all herbs written on the prescription are included in the formula in the same form and in the same dosage as specified on the prescription
- when manufactured formulae are used, the formula dispensed is to have the same name as that on the prescription, and
- the person who checks that the herbs prescribed match the herbs dispensed, signs or initials the record to this effect.

6.3 Substituting herbs

When a herb or herbal formula is unavailable or the dispenser is unsure of 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.

6.4 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 herbal medicine (when relevant)
- the correct route for consuming or administering the herbal medicine (i.e. oral, topical etc.)
- how often, when, and for how long the herbal medicine should be taken
- the conditions of storage to minimise deterioration
- relevant, specific warnings when appropriate, and
- when the prescriber has provided it, information relevant to potential interactions with other concurrent medications (both Chinese and western), when known and relevant.

Instructions for preparing or cooking herbs should be provided in English 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.

6.5 Repeat prescriptions

The 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 formulae is to be supplied once only.

6.6 Expired and undated prescriptions

The dispenser is not to dispense an undated prescription or a prescription that has expired.

An expiry date of a prescription is a specified date after when it is not to be dispensed (see section 2.1).

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.

6.7 Managing potential conflicts of interest

As 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.

This is consistent with the Board's Code of conduct (see section 8.11 on conflicts of interest).

6.8 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 raw herbs 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 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 dispenser supplies a medicine, the dispenser is to refuse and refer the consumer to a treating practitioner.

The Board expects Chinese medicine practitioners to be committed to safety and quality in healthcare (The Australian Commission on Safety and Quality in Health Care is at www.safetyandquality.gov.au).

6.9 Management and operation of a Chinese herbal dispensary

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

7. 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.

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11. Glossary

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

Adverse drug reaction (also **adverse reaction**)**:** 1. A response to a drug which is noxious and unintended and which occurs at doses normally used in many for prophylaxis, diagnosis, or therapy of

disease or for modification of physiological function. 2. An unwanted effect of a medicine, also called a side effect.

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

Authorised *pin yin:* The name in *pin yin* used in the CMBA *Herbal nomenclature compendium*.

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

Chinese medicine practitioner: A practitioner registered by the CMBA 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*.

Compounding: The extemporaneous preparation of a medicine for a specific person in response to an identified clinical need.

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.

Decoction: The product derived from boiling single or multiple plants (or parts of plants) in water. The plant parts may be fresh or dried. This can also refer to a solution of granules in water.

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 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. The Regulations also provide exemption for specified complementary medicine practitioners from the requirement to manufacture medicines under the principles of Good Manufacturing Practice (GMP).

The TGA's *Australian regulatory guidelines for complementary medicines* (ARGCM), Version 5.3 July 2015 provide advice on dispensing medicines to consumers who request supply of an extemporaneously prepared medicine for their self-medication. It is important to note that ingredients that are pre-packaged for therapeutic purposes or formulated as a dosage form are subject to TGA assessment for quality and safety as appropriate, and are required to be included in the ARTG. Practitioner exemptions (from GMP and being required to be included in the ARTG) relating to extemporaneous compounding and dispensing only apply where a health practitioner prepares a medicine for an individual patient following consultation with that particular patient. The exemption does not cover a situation where the health practitioner makes up medicines in advance, in anticipation of patients who may come onto the premises and ask for that medicine.

Extracts of herbs: Extracts (usually concentrated but not always) of herbs sold to practitioners for dispensing.

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 herbal formula: A herbal prescription or formula individualised for that particular patient following a consultation.

Manufactured herbal medicine: A finished herbal product, usually consisting of a herbal formula, made from several herbs, which has been manufactured under 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'.

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

***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.

Raw herbs: Fresh or dried herbs or minimally processed, e.g. lightly roasted.

Retailer: 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.

Standard reference book: A *materia medica* or formulatory reference text that is commonly used in Chinese medicine training courses and clinical practice. Examples can be found in section 10 (Nomenclature resources).

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

SUSMP: Standard for the Uniform Scheduling of Medicines and Poisons (also known as the Poisons Standard). The poisons standard consists of decisions regarding the classification of medicines and poisons into schedules for inclusion in the relevant legislation of the states and territories.

12. Acronyms

ADR	Adverse drug reaction
ADRAC	Australian Drug Reaction Reporting System
ARGCM	*Australian regulatory guidelines for complementary medicine*
ARTG	Australian Register of Therapeutic Goods
AUSTL	A medicine listed on the ARTG
AUSTR	A medicine registered on the ARTG
CITES	Commission on International Trade in Endangered Species of Wild Fauna and Flora
CMBA	Chinese Medicine Board of Australia
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 Organisation

Review

These guidelines will be reviewed three years after implementation or earlier if required.

Effective from: 2 years from the 2015 date of publication, that is 12 November 2017.

Review date: To commence by November 2019.

Appendix 1: Extracts of relevant provisions from the National Law

Part 5, Division 3 Registration standards and codes and guidelines

Section 39 – Codes and guidelines

A National Board may develop and approve codes and guidelines:

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

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

Section 40 – Consultation about registration standards, codes and guidelines

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

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

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

Appendix 2: Overview of herbal medicine nomenclature

Introduction

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

Nomenclature for describing herbal medicines and ingredients of plant origin in medicines 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 a herbal 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 traditional medicines. An unambiguous, definitive system for identifying herbal medicines, ingredients of plant origin and other complex ingredients used in Chinese medicine is essential.

Historically, Chinese herbal medicines 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 bearing the same Chinese name and pharmaceutical name. In most cases these herbs will have medically equivalent effects and be truly interchangeable. In some cases substitute species may be used that have similar names but different effects. An example of this the well-known example of toxic *Aristolochia* species being used in place of the usual species due to similarity in the Chinese names (Zhao et al, 2006; Wu et al, 2007).

Purpose

The purpose of this Appendix is to outline briefly the various ways in which herbs are named and provide examples of nomenclature. The examples are all plant-based medicines 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 herbal medicine): The method of naming herbs with Chinese characters or *pin yin* (see later definition). Chinese characters are specified for each herb in the PPRC 2010. 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 2010 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 (see examples below). 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 herbs share or have similar common names.

For example, the common name ‘Fritillaria bulb’ may refer to the herb Chuan Bei Mu 川贝母 mentioned above, 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 document the *pin yin* name 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 川贝母. 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. It 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 2010, 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 2010 (p.34) 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* (S. Y. Tang et S. C. Yue) Z. D. Liu, S. Wang et S. C. Chen.

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 as 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. It is 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 Organisation (Farah et al, 2006). The use of the full scientific name is rapidly becoming the standard for scientific publication (Chan et al, 2012). However, the PPRC 2010 is not organised according to scientific name – rather, it is organised by Chinese herbal name.

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

1. Relationship of *pin yin* name 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 2010, 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 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 2010 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.	b á i m á o g ē n 白 茅根
	Hydrastis canadensis L.	b á i m á o g è n 白 茅 莨
Da Ji	*Cirsium japonicum* Fisch. ex DC.	d à j ì d à j ì 大 薊 /大 薊
	Euphorbia pekinensis Rupr.	d à j ǐ 大 戟 (京大戟)
Mu Ju	*Matricaria chamomilla* L.	m ǔ j ú 母 菊
	Aegle marmelos (L.) Correa.	m ù j ú 木 橘
Mu Lan	*Bruguiera gymnorhiza* (L.) Lam.	m ù l ǎ n 木 欖
	Indigofera tinctoria L.	m ù l á n 木蓝

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

* This plant is one of the species used as Wu Zhu Yu 吴茱萸 (see PPRC 2010 p.160). 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 大蓟
- *Pin yin* + Scientific name: Da Ji (Cirsium japonicum)
- *Pin yin* + Pharmaceutical name: Da Ji (Cirsii Japonica Herba)

2. Relationship of name in *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 utilising different parts of the same plant (e.g. root, leaves, bark, fruit etc.) or by different methods of processing the same plant (e.g. cooking, honey processing etc). 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*[23] 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	桑瘿	*Morus alba* L.	burl of the matured tree	dried
Sang Li	桑沥	*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 2010 but Gua Lou Gen is equal in terms of precision and is listed in many books.

[23] The official source of these herbs is *Morus alba* L. (PPRC, 2010 p 279-28, Bensky et al 2004) 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. In order to eliminate possible confusion the PPRC 2010 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 plant identity and pharmacovigilence. Provided that the name in *pin yin* is precise and accords with the name used in the PPRC 2010, confusion in the identity of a herb is unlikely when the name in *pin yin* is used. It is also concise and convenient to apply.

Appendix 3: Prescriptions

The following are examples showing how a prescription can comply with these guidelines. You do not need to use this format but it 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 herbs. Nomenclature of herbs in *pin yin*

<table>
<tr><td colspan="3">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</td></tr>
<tr><td colspan="3">Patient: Ms May Citizen</td></tr>
<tr><td colspan="3">Date: 2 December 2014</td></tr>
<tr><td>Ingredients</td><td>(g)</td><td rowspan="16">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 ¾ 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.</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">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
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 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: Mr Ivan Citizen

Date: 2 December 2014

Ingredients	**(g)**		**Directions for use (example)**
Dang Shen	**9g**	党参	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 ¾ 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.
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	

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
shengDiHuang	15g	生地黄
Bai Shao	9g	白芍
Dang Gui	9g	当归
Chuan Xiong	6g	川芎
SangJisheng	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 LingXian	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 extracts. 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 2014

Ingredients	**(g) 5:1**	**Directions for use (example):** Mix well before use. Dissolve 2 heaped measuring-spoons of herbs in half a cup of boiling water, drink it while warm after meal, twice daily. 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 herbal dispensary and supervision of dispensary assistants

This is only to be considered as 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
- 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 hand washing 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 which results in production of any dangerous inhalable airborne particles or particles that may enter the eye
- procedures are to be established to ensure the accurate dispensing of prescriptions, and
- procedures are to be established to prevent prescriptions from being confused, mixed up or mislabelled.

Storage of raw herbs

- Storage procedures are to ensure that the quality of herbs is maintained and contamination prevented.
- Herbs are to be stored in clean, dry containers that protect from insect and rodent attack.
- Herbs are to be periodically inspected and any that show signs of mould, discoloration, insect attack or other deterioration discarded.
- When herbs are transferred from storage into the containers from which they are dispensed, they are to be checked for any foreign matter. This 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 herb storage includes regular cleaning of storage containers and careful management of refilling.
- Herbs are to be kept out of reach of children and infants.
- The most appropriate method of storage will vary according to the particular herb. In general, it is advisable to keep herbs in cool, dry conditions away from direct sunlight. Some herbs are best stored in airtight containers, while others may require a degree of ventilation or periodic exposure to the air to ensure they remain dry and do not become mouldy.

Labelling of herbs in storage

- Herbs 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).
- Herbs that are easily confused due to similarity in appearance or name should be kept in separate locations to reduce the possibility of error. Particular care should be taken in labelling these herbs in order to clearly distinguish them.
- If the identity of the herb supplied is in doubt, it should be returned to the wholesaler and not dispensed to patients.

Handling herbs

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

- the surfaces or containers on which herbs 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 herbs are to be accurate and cleaned regularly, and
- utensils used in the processing of herbs 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 herbs purchased
- quantity purchased
- name of the wholesaler
- date purchased, and
- the batch number 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 herbal 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 herbal 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, and
- 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 herb preparation (*pao zhi*)
- inventory management including
  - ordering and unpacking of stock
  - repackaging stock, and
  - storage of medicines
- preparing dispensing labels
- attaching dispensing and cautionary and advisory labels
- collating prescriptions, and
- 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, and
- 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: Labels

The following examples show how labels can comply with these guidelines. 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 herbs is an alternative way to meet this requirement.

Label 1: Individualised formula – raw 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 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: 02 Dec 2014

Take within: 7 days

No. of repeats left: 0

No. of packets: 3

Directions for use
Empty the content of a pack of herbs into a clay-pot.
Submerge herbs in 3 cups of water and bring the contents to the boil.
After 5 minutes of medium intense heat, turn down and allow to simmer until ¾ of the bowl of liquid is left.
Drain the liquid into a cup and drink it all while warm, after a meal.
Keep herbs in fridge overnight, repeat cooking procedure next day.
Discard the herbs after the second cooking.
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.

Label 2a: Individualised formula – raw 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: 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)

Prescribing date: 02 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 ¾ 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.

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 extracts. 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**
当归	Dang Gui	**4g**
川芎	Chuan Xiong	**4g**
桑寄生	Sang Ji Sheng	**4g**
独活	Du Huo	**4g**
怀牛膝	Huai Niu Xi	**4g**
秦艽	Qin Jiao	**3g**
防风	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 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: 02 Dec 2014

Herbs valid for 7 days only

No. of repeats left: 0

No. of packets: 3

Directions for use
Mix well before use. Dissolve 2 heaped measuring-spoons of herbs in half a cup of boiling water, drink it while warm after meal, twice daily.

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. There are regulations about the marketing and advertising of listed products, which the sponsor must follow. These are also specified in the ARGCM.

Occasionally there may be a valid reason to dispense a small 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 patient, date of dispensing and details of practitioner are to be provided in accordance with section 3.3 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.

The following section is included to help 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[24], date of birth and age)
- reporter information (name, address, phone number)
- a description of the reaction
- any medicines suspected of causing the reaction
- 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, and
- 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.

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