Chinese Medicine Board
Ahpra

Guidelines for safe Chinese herbal medicine practice

September 2023

Summary

The *Guidelines for safe Chinese herbal medicine practice* (the guidelines) aim to help Chinese medicine practitioners to practise Chinese medicine safely. They require practitioners to write in English on prescriptions and labels and:

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

The guidelines apply primarily to Chinese herbal medicine practitioners and Chinese herbal dispensers, which are protected titles under the National Law, and so the title of the guidelines refers to Chinese herbal medicine practice.[1]

A summary of the background to the development of these guidelines and an overview of Chinese medicine nomenclature is in Appendix 1.

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

Introduction

In the Australian clinical context, an important component of safe practice is having a consistent, widely accepted Chinese herbal medicine nomenclature that 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 for herbs and other Chinese herbal medicine ingredients has been furthered by developments in the regulation of medicines and of pharmacovigilance systems for tracking adverse reactions to medicines.[2] 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 Chinese Medicine Board of Australia (the Board) endorses the use of the **authorised *pin yin*** as the most appropriate nomenclature for use in Chinese medicine in Australia.[3]

The Board recognises these guidelines must be practical to adopt and enforce. The regulatory principles in the National Registration and Accreditation 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.

[1] The Health Practitioner Regulation National Law, as in force in each state and territory (the National Law).

[2] Herb scientific names are 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.

What medicines do the guidelines apply to?

The guidelines apply to Chinese herbal medicines and other medicines or products 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 because they are not used in Chinese medicine practice in Australia.

Medicines used in Chinese herbal medicine practice include the following types:

- raw herbs and other Chinese herbal medicine ingredients of natural origin such as minerals, animal products and fungus (fresh, dried and/or traditionally processed). They may also be 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.

Who needs to use the guidelines?

The guidelines apply to all practising, registered Chinese medicine practitioners who prescribe and/or dispense Chinese herbal medicine materials.[4]

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

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

Who do the guidelines not apply to?

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

[4] Any person registered in Australia under the National Law in any of the divisions of acupuncturist, Chinese herbal medicine practitioner, or Chinese herbal dispenser by the Chinese Medicine Board of Australia; the term Chinese medicine practitioner includes Chinese herbal medicine practitioners, acupuncturists and dispensers.

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Summary of guidelines

The *Guidelines for safe Chinese herbal medicine practice* (the 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 Chinese herbal medicines
- supervising and ensuring accountability of dispensary assistants.

The Chinese Medicine Board of Australia (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. The guidelines should be read in conjunction with the Board's Guidelines: patient health records and the Professional capabilities for 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)[5]
- restrictions on the possession, use, sale, and supply of herbs and other Chinese herbal medicine ingredients according to their categorisation in the Standard for the Uniform Scheduling of Medicines and Poisons (SUSMP), in accordance with respective state and territory drugs and poisons legislation.

The Board commissioned the development of a Nomenclature compendium of commonly used herbs and other ingredients in 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)* (中华人民共和国药典) (PPRC) to support consistent terminology. This Nomenclature compendium is freely available on the Board's website to help 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 Chinese medicine 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 for safe practice.

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 helps that person to do 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 Chinese herbal medicine nomenclature in *pin yin* in all records
- attach the label, including details of the Chinese herbal medicine, to the product
- provide proper instructions for the Chinese herbal medicine's preparation
- use English language on all prescriptions and labels.

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

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

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.

[5] Information on CITES is available at www.dcceew.gov.au/environment/wildlife-trade/cites

[6] For example, on admission to hospital, when seeing another health practitioner or when 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 1.4.

1. Nomenclature in Chinese herbal medicine

1.1 Background

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 Chinese herbal medicine 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 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. Chinese herbal medicine 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 Chinese herbal medicine 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 Chinese herbal medicine. Sometimes other members of the patient's healthcare team need to be informed of the Chinese herbal 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 that may interact with the Chinese 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 or describe the Chinese herbal medicine.

Chinese medicine practitioners use Chinese medicine reference books, textbooks and research reports in which Chinese herbal 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 Chinese herbal medicine names in *pin yin* (see the Board's Accreditation standards).

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

These guidelines, used with the Board's Nomenclature compendium (see section 1.4), aim to make sure that Chinese medicine herbs and other ingredients are identified so that patients can:

- use the medicine safely
- know what Chinese herbal medicines they are taking
- readily find the information they need about the medicine or access further information.

1.3 Required nomenclature for Chinese herbal medicine prescriptions and labels

Prescriptions and labels are to be:

- written in English
- individual Chinese herbal medicine 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.

1.4 The Board's Nomenclature compendium

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

The Nomenclature compendium cross-references the Chinese herbal medicine ingredients by using:

- 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 included in 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 Chinese herbal medicine 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 Chinese herbal medicine ingredients subject to restrictions on supply because of the requirements of the SUSMP or CITES.

1.5 Restricted Chinese herbal medicine ingredients

Chinese herbal medicine practitioners and dispensers in Australia are restricted in their ability to prescribe, compound and dispense some traditionally used Chinese herbal medicine ingredients because the substances are included in a schedule of the SUSMP and access is controlled under state and territory legislation. A Chinese herbal medicine 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 Chinese herbal medicine ingredient is listed in a schedule or appendix.

Some Chinese herbal medicine ingredients are affected by a combination of these things. In some cases, the restriction 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 Chinese herbal medicine ingredients, unless they are also a 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 Chinese herbal medicine ingredients that are included in the schedules of the SUSMP, where use is controlled under state and territory legislation.

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).[9]

The exemption does not cover Chinese herbal medicine 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,

[8] The Board commissioned the National Institute of Complementary Medicine (NICM) to develop the Nomenclature compendium. This is available on the Board's website at www.chinesemedicineboard.gov.au/Codes-Guidelines/Guidelines-for-safe-practice.

[9] 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.

the practitioner needs to check with the Therapeutic Goods Administration (TGA) about possible obligations under the *Therapeutic Goods Act 1989* (see also the TGA's Australian regulatory guidelines for complementary medicines, or ARGCM).

3. Prescription requirements

Chinese medicine practitioners are required to provide a prescription to patients for all Chinese herbal medicines. Furthermore, the Chinese herbal medicines must be labelled.

If the prescription is dispensed by a separate dispenser, who is not the prescriber, additional information is required.

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 the prescription that complies with these guidelines must still be provided to the patient. This information is useful to supply to another health practitioner or to have 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.

Chinese herbal medicine 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/manufactured medicines

Individualised formulations are prescribed by practitioners registered in the division of Chinese herbal medicine. Sometimes a practitioner may need to write a prescription for a manufactured medicine. The following table presents the information required for prescriptions of either individualised formulations or manufactured medicines.

Table 1: Details required on prescriptions

Information required on all prescriptions	
Name of patient (given name and family name) and, when applicable, details of patient's parent, guardian, or agent	
The name, address, registration number, and contact telephone number of the prescriber	
Date prescribed (day/month/year format)	
Specific warnings (when appropriate)	
Name(s) of the Chinese herbal medicine (in authorised *pin yin*)	
Expiry date of prescription (i.e: 'date not to be dispensed after')	
Number of repeats of the prescription	
Prescribing practitioner's signature	
Specific information required for prescriptions for individualised formulations using raw and processed Chinese herbal medicine ingredients	**Specific information required on prescriptions for manufactured medicines**
Specific directions for use (dose, preparation/ cooking, storage, route of administration, frequency, timing of consumption, duration of consumption)	Dosage (number of pills/tablets and instructions on how many times per day if different from the standard label (e.g: 'eight pills, three times a day')
Amount of each Chinese herbal medicine ingredient (measured in grams)	Duration of consumption (e.g: 'two weeks', 'while symptoms persist', 'until finished')
Form of processing (when relevant)	
Number of packets (when relevant)	

All information is to be provided in English.

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

It is acceptable for the label to be a copy of the prescription, provided all the required information is included. Where a copy of the prescription serves as the label, instructions for preparing or cooking the Chinese herbal medicine 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 2 for examples of prescriptions containing the required information.

4. Labelling requirements for dispensed medicines

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

4.1 Individualised formulations using raw and processed Chinese herbal medicine ingredients or extracts of Chinese herbal medicine ingredients

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

This information covers labelling for dispensed individualised formulations using raw and processed Chinese herbal medicine ingredients (sometimes referred to as decoction pieces – yin pian饮片) and Chinese herbal medicine ingredient extracts (powders, granules浓缩颗粒 or liquids) which may be prescribed as components in an individualised extract formulation.

The label is to be clearly and legibly printed or handwritten in English.

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

Chinese herbal medicine names are to be labelled using the name/s in *pin yin* of the dispensed Chinese herbal medicine ingredient/s in accordance with the nomenclature section of these guidelines (see section 1.3).

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.

The following table sets out the labelling requirements for dispensed medicines, whether they are individualised formulations using raw and processed ingredients or extracts.

Table 2: Labelling requirements for dispensed medicines

Information required on labels for all dispensed medicines (The dispensing label is to be firmly attached to the immediate container)	
Name of patient (given name and family name) and, when applicable, details of patient's parent, guardian, or agent	
The name, address, registration number, and contact telephone number of the dispenser	
The name of prescriber, if different from the dispenser	
Date dispensed (day/month/year format)	
Specific warnings (when appropriate)	
Name(s) of the Chinese herbal medicine (in authorised *pin yin*)	
Specific directions for use (dose, preparation/cooking, storage, route of administration, frequency, timing of consumption, duration of consumption). Instructions for preparing or cooking Chinese herbal medicine 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.	
Dispenser's signature	
Specific information required for dispensing labels using raw and processed Chinese herbal medicines individualised formulations	**Specific information required on dispensing labels for individualised formulations using extracts of Chinese herbal medicine ingredients**
Number of packets (when relevant)	Concentration ratio of the extract (e.g: 5:1) If all Chinese herbal medicine extracts, such as granules used in the prescription, have the same concentration, for example 5:1 then this can be stated as 'all 5:1 concentration' under the list of Chinese herbal medicine ingredients and amounts.

Individualised formulations, whether they use raw and processed ingredients or extracts of Chinese herbal medicine ingredients, are sometimes dispensed in multiple packs or bottles, with each pack or bottle containing the same Chinese herbal medicine for preparation and administration over a series of days and/or weeks. Where this occurs, the label can be attached to the outer package and include all the information required in the table above. All individual inner packs are to be labelled with the name of the patient and the dispensing date, where this is feasible. Alternatively, each package can be fully labelled.

The practitioner should advise the patient to retain the outer package for future reference.

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

See Appendix 2 for examples of labels containing the required information.

4.2 Manufactured Chinese herbal medicines

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

When a registered Chinese medicine practitioner supplies a manufactured Chinese herbal medicine as part of a consultation, the medicine is to retain the original label.[10]

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 Chinese herbal medicine and adds one or more Chinese herbal medicine ingredients or extracts to it, the labelling requirements for individualised formulations apply.

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

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*.

4.3 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, manufactured medicines (e.g. 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 of the 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.

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 Chinese herbal medicines they are prescribing, as described in sections 3 and 4, every time medicines are prescribed or dispensed, not only the first time they see the patient.

5.1 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 Chinese herbal medicine when relevant
- the correct route for consuming or administering the medicine (i.e. oral or 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).

5.2 When 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 the guidelines

- written instructions for preparation, administration and storage as outlined in section 5.1, and
- a copy of the prescription as outlined in section 3.

Full details of the medicine/s are to be recorded in the health record in accordance with the nomenclature section (see section 1.3).[11]

5.3 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 of the 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 10.4).

6. Health records

Accurate records of prescribed medicines should appear in the patient health records and/or dispensary service records.

Practitioners should be aware of and comply with the requirements of relevant local state or territory laws regarding patient health records particularly regarding retention and destruction of patient health records, which may vary from state to state.

In addition, practitioners who work in multi-practitioner clinics should be mindful of their contractual arrangements regarding ownership, retention, and management of 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). Practitioners should firstly be aware of any patient's allergies or other medications which herbs could affect.

Clear and complete information about each prescription of Chinese herbal 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 Chinese 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
- batch number and expiry date
- duration over which the medicine should be used
- relevant, specific warnings when appropriate.

6.2 Chinese medicine dispensary record keeping

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 Chinese herbal medicine ingredients in the prescription and amounts
- details of any substitutions when applicable (see section 10.3) (and as firstly agreed or authorised by the prescribing practitioner)
- in the case of raw or processed Chinese herbal medicine 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.

Records can be kept electronically or in hard copy. 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.

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

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.

It is the professional responsibility of all Chinese medicine practitioners to report suspected adverse events to the Therapeutic Goods Administration (TGA). Patients or any member of the public may also report adverse events online to the TGA.

The Board strongly encourages vigilant reporting by practitioners of all such occurrences. Active, professional responsible reporting of adverse events contributes to professional knowledge and better health outcomes.

See Appendix 4 for details on adverse event reporting to the TGA.

8. Quality of Chinese herbal medicine ingredients

The efficacy of Chinese herbal medicine formulations is also dependent on the quality of active ingredients such as Chinese herbal medicine 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 pharmacopeial 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.

Chinese herbal medicine ingredients 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 Chinese herbal medicine ingredient in a manner that maintains it's quality and ensures the quality remains at the expected standard and is appropriate for use by consumers.

9. Insurance

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

10. Compounding and dispensing

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

10.1 Checking the prescription

In dispensing a prescription, a dispenser is to exercise independent judgement to make sure 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 Chinese herbal medicine ingredients, dosages, or preparation instructions.

Only prescriptions from Chinese herbal medicine practitioners who are registered in Australia should be dispensed. 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 restrictions or because the ingredient is included in a schedule of the SUSMP) 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.

10.2 Providing Chinese herbal medicine ingredients accurately and in the form specified

The dispenser is to provide Chinese herbal medicine 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 Chinese herbal medicine ingredients, when required.

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

- when prescriptions specify individual Chinese medicine ingredients, all 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 Chinese herbal medicines are used, the formula dispensed is to have the same name and content as that on the prescription
- the person who checks the Chinese herbal medicine ingredients prescribed match the ingredients dispensed, signs or initials the record to this effect.

10.3 Substituting Chinese herbal medicine ingredients

When a Chinese herbal medicine 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.

10.4 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 Chinese herbal medicine (when relevant)
- the correct route for consuming or administering the Chinese herbal medicine (i.e. oral, topical)
- how often, when, and for how long the Chinese herbal 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 Chinese herbal medicine 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.

10.5 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.

10.6 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.

10.7 Managing potential conflicts of interest

As registered Chinese medicine practitioners are often both the prescriber and the dispenser, they are to ensure 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 Code of conduct for registered health practitioners.

10.8 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 choose to buy a range of Chinese herbal medicines to maintain their health. Supply of these materials can be a retail task and is 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.

10.9 Management and operation of a Chinese medicine dispensary

See Appendix 3 for requirements for the management and operation of a Chinese medicine dispensary.

11. Authority

The Chinese Medicine Board of Australia (the Board) has approved the *Guidelines for safe Chinese herbal medicine practice* 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).

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.

12. Schedule for review

A scheduled review of the guidelines will occur at least every five years after the effective date or earlier, if required.

13. Effective date

The guidelines take effect on 1 December 2023. The Board will monitor these guidelines for effectiveness and review them every three years.

14. References

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

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

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

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

Convention on International Trade in Endangered Species of Wild Fauna and Flora (CITES). 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. www.tga.gov.au/publication/poisons-standard-susmp

TGA *Australian regulatory guidelines for complementary medicines* (ARGCM). www.tga.gov.au/resources/publication/publications/australian-regulatory-guidelines-listed-medicines-and-registered-complementary-medicines

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

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

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: Chinese herbal medicine 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*.

The Convention on International Trade in Endangered Species of Wild Fauna and Flora (CITES): This is an international agreement between governments that aims is to ensure 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 Chinese herbal medicine ingredients, in water. The ingredients may be fresh, dried or processed (decoction pieces).

Decoction pieces: Chinese herbal medicine (Chinese herbal medicine materials) of natural origin in raw form or 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 help 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 provide exemption for specified complementary medicine practitioners from the requirement to manufacture medicines under the principles of Good Manufacturing Practice (GMP).

Extracts of Chinese herbal medicines: Chinese herbal medicine materials processed into derivative form to make products such as tinctures or granules.

Granules: Extracts of Chinese herbal medicines 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 that contains the herbal medicine.

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

Manufactured medicine: A finished product usually consisting of a formula, made from several Chinese herbal medicines, 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'.

Medicines: Medicines are therapeutic substances that aim to achieve, or 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, calcining, roasting in ashes, steaming, boiling, crystallisation, water trituration or other methods 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. Globally this activity is managed by the WHO's Collaborating Centre for International Drug Monitoring. The 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 an individual patient.

Prescriber: A registered treating practitioner who has written a prescription.

Prescription: A written document outlining the composition of a medicine, with specific directions for dosage to an individual patient. This document authorises the supply of such medicine from a dispenser.

Processed Chinese herbal medicine (or **Chinese herbal medicine ingredients**): Prepared herbs or decoction pieces for use.

Raw (**Chinese herbal medicine** or **Chinese herbal medicine ingredient**): Fresh or dried ingredient 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.

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

Standard for the Uniform Scheduling of Medicines and Poisons (SUSMP): The standard consists of decisions regarding the classification of medicines and poisons into schedules that are adopted by reference and controlled in the relevant legislation of the states and territories.

16. 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 (publication)
PRC	People's Republic of China
SUSMP	Standard for Uniform Scheduling of Medicines and Poisons
TGA	Therapeutic Goods Administration
TGO	Therapeutic Goods Order
WHO	World Health Organisation

Appendix 1: Background to the guidelines and overview of Chinese medicine nomenclature

Background to the guidelines

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 herbal medicine.

Use of herbs 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 placed on pharmacovigilance and the analysis of adverse reactions induced by medicine products including traditional Chinese medicines.

The Australian Commission on Safety and Quality in Health Care has identified medication quality and safety as one of its priorities and established a National Safety and Quality Health Service Standard.[12] In 2019, the COAG Health Council agreed to make the Quality Use of Medicines and Medicines Safety its 10th National Health Priority Area. The Board expects all Chinese medicine practitioners to be committed to safety and quality in healthcare and the Board has developed these guidelines to support the safe practice of Chinese herbal medicine.

In the Australian clinical context, an important component of safe practice is having a consistent, widely accepted Chinese herbal medicine nomenclature that 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 for herbs and other Chinese herbal medicine ingredients has been furthered by developments in the regulation of medicines and of pharmacovigilance systems for tracking adverse reactions to medicines.[13] 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*** as the most appropriate nomenclature for use in Chinese medicine in Australia.[14]

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. It 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.

Ingredients used in Chinese herbal medicine have historically been identified by one of several systems of nomenclature, these include: 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 animal and mineral products be identified accurately. Some Chinese herbal medicine 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.

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[12] www.safetyandquality.gov.au

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

[14] 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 1.4.

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 Chinese herbal medicine ingredient): The method of naming the Chinese herbal medicine with Chinese characters or *pin yin*.

Chinese characters are specified for each herb in the Pharmacopoeia of the People's Republic of China (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 Chinese herbal medicine 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 the 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 Chinese herbal 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 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.

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 (below), confusion between these examples is unlikely, since one of the plants in a pair is not in common use. Therefore, it is very unlikely 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.

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.

Chinese *pin yin*	Scientific name	Chinese characters
Bai Mao Gen	*Imperata cylindrica* (L.) Raeusch.	báimáogēn 白茅根
	Hydrastis canadensis L.	báimáogèn 白茅莨
Da Ji	*Cirsium japonicum* Fisch. ex DC	dàjì dàjì 大 蓟 / 大 薊
	Euphorbia pekinensis Rupr.	dàjǐ 大 戟（京大戟）
Mu Ju	Matricaria chamomilla L.	mǔjú 母 菊
	Aegle marmelos (L.) Correa.	mùjú 木 橘

Mu Lan	*Bruguiera gymnorhiza* (L.) Lam.	mùlǎn 木 榄
	Indigofera tinctoria L.	mùlán 木 蓝
	Magnolia liliiflora Descr	mùlán 木 兰
Pu Tao	*Vitis vinifera* L.	pútáo 葡 萄
	Syzygium jambos (L.) Alston	pútáo 蒲 桃
Shi Hu	Dendrobium nobile Lindl.	shíhú 石 斛
	Evodia rutaecarpa (Juss.) var. *officinalis* (*Dode*) *Huang**	shíhǔ 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 大蓟
- *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 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.
- Arnebia guttata Bunge., or
- Lithospermum erythrorhizon Sieb.et Zucc.

These herbs are considered equivalent in terms of their actions and all three species contain shikonin, which is regarded as 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: Listing of different parts of the plant and different processing methods of *Morus alba* L. resulting in different herbal products[15]

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 for illustration purposes only. Of the Morus alba L. products 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

Many 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.

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 connected with the use of the Chinese name from the point of view of Chinese herbal medicine 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 Chinese herbal medicine ingredient is unlikely when the name in *pin yin* is used. It is also concise and convenient to apply.

[15] 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.

Appendix 2: Examples of labels and prescriptions

Examples of prescriptions

These examples show how a prescription can comply with the guidelines. Practitioners do not have to use this format, but these examples show how they can be laid out to contain all the required information. Prescriptions may be handwritten or printed as long as they contain the information required by the guidelines.

Prescription 1: 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

123 Evergreen Ave, Morningmeadow, NSW, 2000

Phone: 02 1234 5678 Mob: 0400 123 456

Patient: Ms May Citizen

Date: 1 June 2022

Ingredients	**(g)**	
Dang Shen	**9g**	党参
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

Directions for use:

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 for six days or until finished.

Do not use metal utensils in the preparation or storage of the ingredients. Store in a cool, dry place.

Number of packets: 3

Expiry date of prescription: 1 month from date of prescription

Number of repeats: 1

Warning: If symptoms persist or you experience any unexpected symptoms contact the Chinese medicine practitioner or a medical practitioner.

Practitioner signature:

Prescription 2: Individualised formula – herbal granules. Nomenclature of herbs in *pin yin*.

Dr White Tiger – Gentle Chinese Medicine Clinic – Registration number: CMR: 00012345

123 Evergreen Ave, Morningmeadow, NSW, 2000

Phone: 02 1234 5678 Mob: 0400 123 456

Patient: Ms May Citizen

Date: 1 June 2022

Ingredients	**(g) 5:1**	**Directions for use:**
Dang Shen	**9g**	Mix the granules well before use. Dissolve 3 grams of the mixed granules in half a cup of boiling water and let it cool slightly. 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. Store in a cool, dry place.
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**	

Expiry date of prescription: 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.

Practitioner signature:

Examples of labels

The following examples show how labels can comply with these guidelines. Practitioners do not have to use this format, but these example labels show how they can be laid out to contain all the needed information. Labels may be handwritten or printed, 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 of processed herbs. Nomenclature of herbs in *pin yin* with the addition of Chinese name.

	Ingredients	**(g)** **5:1**	**Patient:** Ms May Citizen **Dispensed Date:** 3 June 2022 **Dispenser:** Mr 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:** 1 June 2022 **Take within:** 14 days **No. of repeats left:** 0 **No. of packets:** 3
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**	

Directions for use:
Empty the contents of a packet of the medicine into a claypot.
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 for six days or until finished.

Do not use metal utensils in the preparation or storage of the ingredients. Store in a cool, dry place.

Warnings
Keep out of reach of children.
If symptoms persist or you experience any unexpected symptoms, contact the Chinese medicine practitioner or medical practitioner.

Dispenser signature:

Label 2: Individualised formula – herbal granules. Nomenclature of ingredients is in *pin yin*.

	Ingredients	(g) (All 5:1 Concentration)
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**

Ms **Patient:** Ms May Citizen

Dispensed Date: 02 Dec 2019

Dispenser: Mr 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

Take within: 7 days

No. of repeats left: 0

Directions for use:
Mix the granules well before use.
Dissolve 4 grams using the 1g spoon supplied (or half a teaspoon) of the mixed granules in half a cup of boiling water and let it cool slightly.

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. Store in a cool dry place.

Warnings
Keep out of reach of children.
If symptoms persist or you experience any unexpected symptoms, contact the Chinese medicine practitioner or medical practitioner.

Dispenser signature:

Appendix 3: Management and operation of a Chinese herbal medicine dispensary and supervision of dispensary assistants

This is only general guidance. When specific risks arise practitioners should seek 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 accordance with any 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).
- Chinese medicine practitioners need to meet their ethical obligations in regards to CITES and any relevant requirements.
- Chinese herbal medicine 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 enabling urgent contact of patients should be available.
- 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.
- Accurate equipment should be used for measuring and weighing of herbs, etc.
- Protective masks and safety glasses should always be worn when doing certain preparation tasks, such as grinding of substances that result in the production of any inhalable airborne particles or particles that may enter the eye. This is for the health and safety of staff.
- Establish procedures that help ensure the accurate dispensing of prescriptions.
- Create procedures that prevent prescriptions from being confused, mixed up or mislabelled.

Storage of Chinese herbal medicines – general advice

- Establish storage procedures that ensure the quality of Chinese herbal medicine ingredients is maintained and contamination is prevented.
- Chinese herbal medicine ingredients are to be stored in clean, dry containers that protect from insect and rodent attack.
- Chinese herbal medicine ingredients are to be periodically inspected and any signs of mould, discoloration, insect attack or other deterioration in the product, it should be discarded.
- When Chinese herbal medicine ingredients are transferred from the storage vessel into the containers from which they are dispensed, they should be checked for any foreign matter. Any foreign matter must be removed and discarded. If it cannot be completely and safely removed, the entire batch is to be discarded.
- Good practice in the storage of Chinese herbal medicine ingredients includes regular cleaning of storage containers and careful management of refilling.
- Chinese herbal medicines are to be kept out of reach of children and infants.
- Methods of storage will vary according to the particular ingredient. In general, it is advisable to keep the herbs in cool, dry conditions away from direct sunlight. Some Chinese herbal medicine ingredients are best stored in airtight containers, while others may require a degree of ventilation or periodic exposure to air to ensure they remain dry and do not become mouldy.

Labelling of Chinese herbal medicines in storage

- Chinese herbal medicines 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 the guidelines).
- Chinese herbal medicines that are easily confused due to similarity in appearance or name should be kept in separate locations to reduce the possibility of error. Care should be taken in labelling these Chinese herbal medicine ingredients in order to clearly distinguish them.
- If the identity of the ingredients supplied is in doubt, it should be returned to the wholesaler and not dispensed to patients.

Handling Chinese herbal medicines

When handling Chinese herbal medicines 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 Chinese herbal medicines 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 medicines are to be accurate and cleaned regularly
- utensils used in the processing of Chinese herbal medicines are to be kept clean.

Inventory record keeping

A record is to be kept of the inventory of herbs available. Ideally this inventory includes the:

- name of the Chinese herbal medicines 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 helped by suitably trained, unregistered persons (dispensary assistants) to dispense medicines, in accordance with the guidelines. The practitioner is responsible for the proper training of these assistants.

A registered practitioner is to be always available 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. This includes:

- 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 a Chinese medicine practitioner may delegate to dispensary assistants include:

- preparation of medicines to be dispensed, including identification, weighing, and Chinese herbal medicine 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 similar tasks.

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

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

- allowing a dispensary assistant to offer an 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
- 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 4: 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.

This 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 by either:

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

Reporting adverse events

All reports should contain the following data:

- patient information (initials only, date of birth and age)[16]
- reporter information (name, address, phone number)
- a description of the reaction
- any herbs or 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.

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