Public Consultation – *Draft Guidelines for safe Chinese herbal medicine practice:*

Submission

> *"The aim of the guidelines is to provide clear guidance on the writing of prescriptions, labelling and dispensing of medicines to support safety and quality in Chinese medicine practice". [Draft Guidelines page 3]*

This submission acknowledges the right of the patient to be provided with relevant information concerning their treatment, and the need for good two-way communication between members of the Chinese medicine profession and other health professionals sharing the care of our patients. It therefore endeavours to address concerns of all stakeholders: those using Chinese medicine services (patients), those delivering Chinese medicine services and products (practitioners and dispensers), and those contributing to the regulatory process.

The Draft Guidelines' chief focus is herbal nomenclature used in prescriptions and labels. At the end of this submission I will address concerns about nomenclature raised in Appendix 5 and about Dà Jì (大薊 Cirsii Japonici Herba sive Radix) / Dà Jǐ (大戟 Knoxiae or Euphorbiae Radix) on page 10 by providing information, context and perspective.

The submission relates principally to labels and prescriptions and proposes practical solutions which should be acceptable to all, and also addresses how professional associations can do more to ensure guidelines are complied with. I find the recommendations for dispensing practice and dispensing qualifications to be reasonable, with the exception of self administration and repeat prescriptions. **The most significant points relate to Herbal Nomenclature for labels on page 3 and The Glossary on page 4 and Self-administration, repeat prescriptions on page 6.** A summary appears on page 7.

The Guidelines state that the driving force behind the registration of Chinese medicine and the establishment of associated guidelines was a perceived risk of potential harm to the public. It also states that some 15% of complaints received by the former Victorian registration board involved Chinese herbal medicine practice *[Draft Guidelines page 3].* HOWEVER, it is my belief (based on personal experience and discussions with others) that complaints issued not from a deficit in labelling guidelines but from a failure to meet reasonable professional standards as set out in current practice and labelling guidelines. In some cases ingredients were not stated, or the practitioner's name and contact details were not available, or the practitioner failed to respond adequately when contacted. This constitutes unprofessional behaviour. Such practitioners are in the minority but get a bad name for our profession.

Those incidents might well have raised questions about herbal substances, but the problems actually arose not out of inadequate guidelines, but out of non-compliance with guidelines and professional standards. The imposition of additional requirements cannot logically offer a solution when there was non-compliance with even the most fundamental requirements in the first place. It is therefore in the interest of both the profession and the public to establish suitable, practicable guidelines.

Proposed Guidelines:

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

- *the use of correct herbal nomenclature*
- *standardised prescription writing (inclusive of relevant information)*
- *accurate and informative labelling, and*
- *precise and professional dispensing of medicines.*

Herbal Nomenclature:

The Draft Guidelines state [Par 1 Page 9]:

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

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

Under the earlier CMRBV guidelines it was permitted to use Chinese characters without pinyin. This is appropriate for prescriptions written as part of the patient record but is clearly inadequate for communication with a non-Chinese speaker, and not appropriate for labels. The recommendation to include the pinyin is not difficult and ensures that prescriptions and labels are accessible by all. It is noted that other nomenclature such as the botanical or pharmaceutical names can be used as an alternative. Most of our profession would prefer pinyin.

The Draft Guidelines have been conscientiously prepared, but with so much information presented, there are a couple of things which lend themselves to an interpretation which would fail to win the support of the profession.

1. Because the stated objective is safety in Chinese herbal medicine practice, the proposal for the use of the botanical name presupposes or implies 1) that this will ensure safer delivery of services and b) therefore, without the botanical name Chinese herbal practice is unsafe. With the one exception of Da Ji, this is not so. The core issue for safety is the established standards of practice requiring satisfactory qualifications, training and appropriate examination and diagnostic procedures. These ensure the safe delivery of Chinese medicine and ensure that only appropriate substances will be prescribed.

2. When reading different sections of the Draft Guidelines, confusion arises as to whether the labelling requirements demand that the pinyin is clarified by the botanical/pharmaceutical name in **all** instances, or **only** where there is potential for ambiguity - namely in the case of Dà Jì (大蓟 Cirsii Japonici Herba sive Radix) / Dà Jǐ (大戟 Knoxiae or Euphorbiae Radix).

Herbal Nomenclature for prescriptions:

In regard to the herbal nomenclature for prescriptions, paragraph 1.1 of the Guidelines states:

"*Individual herbs must be written using <u>any one of the botanical name, pinyin name or pharmaceutical name.</u> Other forms of nomenclature may be used in addition to these (e.g. Chinese characters) where it is an accurate translation of the name and enhances patient safety and compliance."*

Appendix 3 in the Draft Guidelines contradicts this by showing a sample of a prescription showing <u>both the Chinese characters and pinyin.</u> The footnote states:

1. *Example shows pinyin (together with Chinese characters), but <u>botanical</u> name can be used instead. <u>Chinese characters are optional unless necessary to remove ambiguity</u>.*

The general intention makes good sense, is practicable, and corrects the earlier deficit of permitting Chinese characters without pinyin or other explanatory nomenclature. HOWEVER the 1st undrlined statement is at odds with the sample in Appendix 3, and the footnote causes further confusion. Apart from that, the botanical name used alone indicates only the source plant - it does not indicate plant parts or preparation method - it is the pharmaceutical name which informs as to plant part and whether prepared or not. The botanical name is only useful to clarify ambiguity in the case of Dà Jì / Dà JǏ . The Chinese name (characters or pinyin) has the capacity to provide more exact information than the botanical name. Perhaps the footnote should read:

1. *"Example shows pinyin, but the botanical name, pharmaceutical name, or Chinese characters can be added where the pinyin presents potential for ambiguity".*

Herbal Nomenclature for labels:

In regard to the herbal nomenclature for labels, paragraph 1.2 of the Guidelines [page 10] states:

"When using pinyin <u>and</u> there is a possibility for the use of pinyin alone to result in confusion, the pinyin must be used together with another name, such as the botanical name, pharmaceutical name or Chinese characters".

The underlined word "and" is presumably intended to mean **<u>not</u>** that all herbs written in pinyin must be used together with another name, but **<u>only</u>** when there is a possibility for the use of pinyin alone to result in confusion. The cited example of Da Ji is in fact the only potential example.[1] The sentence would be clearer I it read:

"When using pinyin <u>and when</u> there is a possibility for the use of pinyin alone to result in ….

There is potential for confusion here: it arises in part because throughout the document there is heavy emphasis on the botanical and pharmaceutical names and this gives the impression that they are preferred or may be a mandatory addition to the Chinese name for **<u>all</u>** herbal ingredients. This one small word "and" appearing only in the paragraph above does not stand up to the weight of the repeated recommendations to use the botanical name throughout the many pages of the Draft Guidelines. The inference that **<u>all</u>** herbs would have to be doubly listed is supported by **Appendix 4** where the sample label shows that <u>all</u> herbal ingredients written in pinyin are accompanied by the

[1] It should be noted that:

- **Dà Jì** (大薊 Cirsii Japonici Herba sive Radix) is to stop bleeding – particularly in haematuria. **Dà JǏ** (大戟 Knoxiae or Euphorbiae Radix) is a harsh cathartic.
- I have not heard of anyone using **Dà JǏ** (大戟 Knoxiae or Euphorbiae Radix) in the contemporary clinical setting and could find no distributor selling this in Australia, but guidelines should be in place for this herb, even if for no other.

Latin name, and also by **Appendix 5** which describes how the Chinese nomenclature is confusing from the botanical point of view - even though not confusing to someone knowledgeable about what each Chinese name really refers to. (Please see the appendix to this submission which offers perspective and context to some of the concerns raise in Appendix 5 of the Draft Guidelines.]

Chinese medicine practitioners have a justified preference for the Chinese name so the reality is that they will be forced to write both the pinyin plus either the botanical name, pharmaceutical name or Chinese character. If the requirement were to add the lengthy and unfamiliar botanical or pharmaceutical name to **all** herbal ingredients in a prescription (as opposed only to those that had potential for ambiguity), it would not only be onerous and time-consuming but would also result in cumbersome reader-unfriendly labels. With formulas ranging from 10 to 30 herbs, it would add some 10-15 minutes to each consultation - for many practitioners this could add up to an extra 2 hours each day.

The Draft Guidelines would do well to clarify this issue and should state clearly that the statement "*pinyin must be used together with another name* is a requirement only where there is ambiguity as in the case of Da Ji. To write double nomenclature for the one relevant instance of Da Ji is reasonable, but to apply it broadly to all herbs in the prescription on the label rather than specify it as a requirement only in the case of ambiguity would be onerous and unjustified.

The Glossary:

Concerns of patients or shared-care practitioners of other modalities can be resolved by providing a glossary (pinyin to pharmaceutical name) for reference. Chinese medicine practitioners should provide the glossary to their patients. It can be attached to or enclosed with the herbs. A glossary should also be accessible on the AHPRA website for easy reference in hospitals, by the patient or by other health professionals. Western health professionals and hospitals also have a duty to ensure that the document is available as an easily accessed resource, just as they might do with a Merck manual. Labels should be kept as simple and clear as possible. If this document is made available in this way, there is no need for cumbersome and onerous labelling.

A glossary should comprise the most relevant nomenclature (ie pinyin, Chinese characters and pharmaceutical name – not the common name), and should be simple and clear:

- The herbs should be listed in alphabetical order of the pinyin name to enable a search for the pharmaceutical or botanical name.
- The list should be comprehensive, and include the ambiguous Dà Jì / Dà Jǐ and also include restricted herbs, especially those of high toxicity such as Ma Qian Zi (strychni semen), Lei Gong Teng, all the 'aristolochia herbs' (Guang Fang Ji, Ma Dou Ling, Guan Mu Tong, etc).

In order to assist the Board, I have attached to this submission an extensive yet straightforward glossary based on Bensky, Clavey and Stoger. It lists some 800 herbs alphabetically according to the pinyin, giving both the Chinese characters and the pharmaceutical name.

The glossary endorsed by the Board is unfortunately not completely accurate, nor comprehensive, and is therefore not an authoritative cross-reference between different systems of nomenclature as suggested in the Draft Guidelines:

a) At the time of this submission the herbs are not ordered by the pinyin name thus disenabling a search for the pharmaceutical name
b) It does not include many restricted or otherwise contentious herbs which should be included (such as Ma Qian Zi, Zhi Fu Zi, Ma Huang, Guang Fang Ji, Mu Tong, Lei Gong Teng etc)
c) It does not include **Dà Jǐ** 大戟 **Knoxiae or Euphorbiae Radix** which is a cited example of potential ambiguity and as such an essential entry to such a glossary
d) It uses the Chinese common name "Jiang" to refer to two herbs Sheng Jiang and Gan Jiang whose properties and actions are different and ails to give the correct pharmaceutical name to distinguish them
e) It omits a number of herbs which are used by contemporary practitioners.

In shared health care, health professionals other than Chinese medicine practitioners should be able to know what substances were ingested. However, neither the patient nor another health professional is better informed by the pharmaceutical/botanical name than the Chinese name: the Latin name does not help the patient or shared health professional understand the actions and the purpose of the herb in the formula.

Both the pinyin name and the pharmaceutical name can be entered in a search engine: entering the pinyin will find information relevant to the herb's use in Chinese medicine; the results of entering the botanical or pharmaceutical name will find information more relevant to the herb's Western use. This is often significant. "Huang Qi" for instance, represents a much greater range of action to the Chinese medicine practitioner than "astragalus" does to the naturopath or layperson

Many health professionals keep a Merck manual and other resources on hand as reference tools. Similarly, a Chinese glossary of the Pinyin – Pharmaceutical herbal names should be retained by all health professionals and be accessible in hospitals and clinics. For shared care to work well for the patient's benefit there must be mutual respect and two-way communication between Western and Chinese practitioners.

Herb-drug interactions:

The potential for herb-drug-food interactions must never be dismissed and has often been cited as a significant risk. However, it has been shown that the risk is associated with taking the substances at the same time or within minutes of each other, and that those adverse events can be avoided if the herbs are taken at least one hour before or after taking other medications. (Many people are not aware that even grapefruit juice can affect Western medications and must not be taken at the same time.) In September 2013, Health World sponsored a seminar on this issue presented by Prof Kevin Ergil. It was extremely well presented and explained the underlying pharmokinetics and pharmodynamics with great lucidity. He also provided great online resources where the practitioner can do a quick and easy search on the interactions of a particular Western drug with any Chinese herb, entering pinyin. I highly recommend this seminar to all who share the care of a patient taking different medications.

The general recommendation is to advise patients to take their Chinese herbs 1 hour before or after other medications. Using the Latin name will not prevent interactions, and should interaction be suspected, the pinyin can be referenced against the glossary as discussed above.

Self-administration, repeat prescriptions [4.8 of the Draft Guidelines]

I agree with point 1 which allows the dispensing of packaged "patent" medicines providing the stated cautions are adhered to. I do not agree with point 2 which allows a patient to have a customised prescription filled on the patient's initiative. This practice undermines the practitioner. The person should see a practitioner.How can a dispenser working out of a shop determine over the counter whether the formula was written for that person? Many people hear that a friend responded to a certain herb or prescription and believe that it will do them good too when in most cases it is not suitable. In most cases it would be very difficult for the dispenser to ascertain that the medicine is for the purpose and person stated, or if it is still suitable. Paragraph 4.9 states that the dispenser must not make a diagnosis – but in order for the dispenser to "determine that the medicine is indicated for the condition the consumer requests it for" they must make a diagnosis because herbal prescriptions are not based on a "condition" but on a differential diagnosis which might change for the individual within a few days. A patient-initiated request for a prescription to be filled is in fact therefore a request or a diagnosis as proscribed in 4.9.

Transition and Review:

Questions 14 and 15 of the consultation question ask about the transition and review period respectively:

14. Do you agree with the proposed 12-month transition period and if so is this period adequate?
15. Should the review period for the guidelines be two, three or five years?

In regard to the transition period, 12 months should be adequate providing notification is properly given as I am confident it will be.

On page 19 of the Draft Guidelines it states: *"These guidelines will be reviewed at least every three years."* I agree with this timeline. Three years is probably adequate, but there needs to be flexibility if problems are identified. It gives time for the new guidelines to be grasped and systems employed. It also gives time for complaints or bugs to surface. I recommend adopting conservative guidelines which can be easily accepted and easily implemented. If they should prove inadequate then it is easy to justify stricter guidelines at the end of the three year period.

Conclusion:

In Australia, patients are accustomed to being given information about their treatment, and have a right to access medical reports to show other health professionals when appropriate or required. They have a right to know the formula ingredients and to have good communication between their various health professionals. Apart from the issue of patients' rights, our profession aims to have respectful and cooperative engagement with others in the health profession. Concerns of patients and other stake-holders should therefore be considered and accommodated where appropriate.

Guidelines should be reasonable and achievable. The inclusion of the pharmaceutical or botanical name is helpful only when there is ambiguity. **The only potential for ambiguity is in the case of Dà Jì (大薊 Cirsii Japonici Herba sive Radix) and Dà Jǐ (大戟 Knoxiae or Euphorbiae Radix).** In practical terms it is more important to instil in practitioners the usefulness of the current guidelines. I believe the vast majority of practitioners are compliant and understand the value of providing their contact

details, and of providing information regarding the ingredients and administration methods of the prescription.

The potential for confusion without the use of additional nomenclature is true only in the case of Da Ji. Potential risk resides not in the use of pinyin but in the failure of some to comply with current labelling guidelines, and their failure to be contactable or co-operative. Such practitioners will not be made more co-operative by the addition of further guidelines. Any risk posed by restricted herbs is already addressed by the SUSMP schedule.

Role of professional associations

I believe that AHPRA, the CMBA and above all the former CMRBV have already put in place satisfactory regulatory requirements, including the recent requirement for a minimum of 4 CPE points to be earned in the area of professional issues. The ball is now in the court of professional associations to help enforce the standards and guidelines by providing education - not simply by stating the regulatory requirements and guidelines to their members, but by advising their members persuasively of the importance of the current guidelines, both for the public and the profession, emphasising the need to comply, and providing useful resources (such as the glossary).

SUMMARY:

- Pinyin should be the standard.
- Where Chinese characters are used they should be accompanied by pinyin (not difficult for Chinese speakers) in patient information such as prescription chits or labels in order to facilitate intelligible communication with the patient and other health professionals sharing the patient's care.
- Where there is potential for ambiguity or confusion (eg Da Ji) the ambiguity should be removed by adding the pharmaceutical or botanical name in both patient information (labels) and in prescriptions which are outsourced to a dispenser.
- Chinese medicine practitioners should provide a glossary to their patients in either electronic form or as hard copy according to the convenience of the patient.
- Western practitioners and health institutions should have a glossary at hand, just as they might do with a Merck manual and other reference resources.
- AHPRA could have a comprehensive and easy-to-read glossary on its website for access by all, including the public and practitioners of Western medicine. (See attached sample).
- Professional associations could run programs to teach practitioners the importance of compliance not only for the benefit of the patient but also for the benefit of our profession.

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RESPONSE TO NOMENCLATURE CONCERNS RAISED IN THE DRAFT GUIDELINES

Chinese name vs botanical name vs pharmaceutical name

The first issue is the proposal to use the botanical rather than the pharmaceutical name. In regard to the Herbal nomenclature for labels, paragraph 1.2 of the Guidelines states:

> *"The botanical name is the only name which clearly indicates the actual species used, therefore in the interest of patient safety the botanical name must be used when labelling medicines.*
> *When using the botanical name, the plant part and any processing the herb has undergone must be specified, as they may result in different pharmacological properties and outcomes."*

The underlined statement is incorrect:

1. The botanical name is **not** the only name which clearly indicates the actual species.
2. The pharmaceutical name indicates not only the species but also the plant part and in most cases whether prepared or not.
3. Many Chinese herbs are not botanicals but are minerals or of zoological origin when clearly a botanical name is not available.

A better recommendation would be that the nomenclature used (whether botanical, pinyin, or other) must indicate the plant part and any processing or otherwise that information needs to be added.

Appendix 5 raises concerns about Chinese herbal nomenclature (Chinese characters or pinyin), suggesting there is risk of confusion. An explanation of these concerns follows here:

1. The **botanical name** indicates only the source plant. It does not indicate the plant part, nor does it indicate whether prepared or not.
2. The **pharmaceutical name** indicates both the species of the source plant and the plant part. It also indicates whether it has been prepared or not – but does not indicate the preparation method.
3. The **Chinese name** (pinyin or characters) indicates the source plant or plants where more than one species has the same actions and properties. This is clinically practical. The Chinese name also indicates the **plant part**, and not only whether prepared or not but the preparation method**,** and the substances used in preparation**. The Chinese name should be written in pinyin for accessibility by non-Chinese speakers.** This is not difficult for those accustomed to writing prescriptions using Chinese characters.
4. There is only a safety issue in the case of ambiguity. The Draft Guidelines (page 10) cite the example of Dà Jì (大蓟 Cirsii Japonici Herba sive Radix) / Dà Jǐ (大戟 Knoxiae or Euphorbiae Radix) – but this is the only instance of potential ambiguity (Please see the attached list of 800 herbs).

NB: In comparing the botanical and pharmaceutical names, note that the pharmaceutical name for Pu Gong Ying (dandelion) is Taraxaci Herba indicating that the whole plant is used including the leaves and stems. Its botanical name is taraxacum mongolicum which can equally refer to the root alone used as a coffee substitute. The root does not have the same properties as the leaves and stems which are highly effective in clearing infections and inflammation.

Same plant – different names

Some herbs are sourced from the same plant but bear different names. **This properly reflects the fact that they have different properties and actions.** The reason is generally that they come from a different part of the plant (eg flower, stem, bark, root) or that one is raw and the other cooked, or that they have undergone different preparation methods such as baking or roasting, soaking or spraying, or been prepared with honey or ginger, or bran or wine. Or that they come from a particular region known for producing high quality. None of these things is expressed in the botanical or pharmaceutical name. **Some herbs are sourced from different species but have the same properties and actions and therefore it is useful that they bear the same name.**

Examples of the above follow here – the pharmaceutical, not the botanical name is given:

1. **Sheng Di Huang** 生地黄 **Rehmannia Radix** vs **Shu Di Huang** 熟地黄 **Rehmannia Radix Preparata:** The botanical name is the same. The former is unprepared and the latter has undergone preparation which significantly changes its properties. Both the Chinese name and the pharmaceutical name reflect that.
2. **Sheng Jiang** 生姜 **Zingiberis Rhizomatis Recens** vs **Gan Jiang** 干姜 **Zingiberis Rhizoma:** The first is the fresh form, the second is dried. The properties and actions are quite different and expressed clearly by the pinyin.
3. **Chen Pi** 陈皮 **Citri Reticulatae Pericarpium** vs **Qing Pi** 青皮 **Citri Reticulatae Viride Pericarpium:** The botanical name is the same. The first is aged peel. The second is not aged. These characteristics are expressed in both the Chinese and the pharmaceutical name.
4. **Zhi Qiao (Zhi Ke)** 枳壳 **Aurantii Fructus** vs **Zhi Shi** 枳实 **Aurantii Fructus Immaturus:** The botanical name is the same. The first is the dried ripened fruit. The second is green and unripe. This is expressed in both the Chinese and the pharmaceutical name.
5. **Bing Lang** 槟榔 **Arecae Semen** vs **Da Fu Pi** 大腹皮 **Arecae Pericarpium:** These are different parts of the same source plant – the first is the seed, the second is the husk. Other examples are:
    - Gui Zhi 桂枝 Cinnamomi Ramulus (twig) vs Rou Gui 肉桂 Cinnamomi Cortex (bark)
    - Gua Lou 瓜蒌 Trichosanthis Fructus (fruit) vs Tian Hua Fen 天花粉 Trichosanthis Radix (root)
    - Su Geng 苏更 Perillae Caulis (stem) vs Su Zi 苏子 Perillae Fructus (fruit)
6. **Where the pinyin can indicate more than one specie**s: The reason for this is that the properties and actions are the same. This is not a reason to avoid the Chinese name. Rather, it is a good reason to use it. It shows that the included species are all safe and suitable. Ambiguity would be an issue only if the properties and actions were different.
7. **Common names:** In most cases common names give rise to confusion and inaccuracy and should not be used. However, common sense and clarity must rule. There would be nothing wrong in writing “ginger juice” instead of “Zingiberis Rhizomatis Succus” for “Jiang Zhi”.

Dà Jì 大蓟 **Cirsii Japonici Herba sive Radix** and **Dà Jǐ** 大戟 **Knoxiae or Euphorbiae Radix.**
The issue of these two herbs is raised in Par 1.2 on page 10 of the Draft Guidelines. Although it is good practice in this case to clarify proactively by adding the botanical or pharmaceutical name, points to note are:

- This is the only instance o the pinyin being ambiguous.
- The tones and characters are different but although either could be used to differentiate them, this would be difficult and not of practical use.

- If history notes are recorded correctly and include the treatment principle, there can be no confusion because the actions of the herbs are so different. The first, **Dà Jì** (大薊 Cirsii Japonici Herba sive Radix) is to stop bleeding – particularly in haematuria. The second, **Dà Jǐ** (大戟 Knoxiae or Euphorbiae Radix) is a harsh cathartic.
- It is the dispenser's duty is to ask the prescribing practitioner or clarification and not guess but best practice would be to clarify proactively.
- I could find no distributor in Australia who stocks **Dà Jǐ** (大戟 Knoxiae or Euphorbiae Radix) and have not heard of anyone using in the contemporary clinical setting – however, guidelines should be in place for this herb.

In shared health care, health professionals other than Chinese medicine practitioners should be able to know what substances were ingested. However, neither the patient nor another health professional is better informed by the pharmaceutical/botanical name than the Chinese name. The Latin name does not help the patient or shared health professional understand the actions and the purpose of the herb in the formula.

Either the pinyin name or the pharmaceutical name can be entered in a search engine. Entering the pinyin is more likely to find information relevant to the herb's use in Chinese medicine. The results of entering the botanical or pharmaceutical name tend to be more relevant to the herb's Western use. This is often significant. "Huang Qi" for instance, represents a much greater range of action to the Chinese medicine practitioner than "astragalus" does to the naturopath or layperson. For this reason, the pinyin has practical and clinical significance.

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