AACMA SUBMISSION

Proposed TGA Complementary Medicine Reforms

Preamble

The AACMA understands and welcomes the need for regulation reforms for complementary medicines.

As these reforms will have an impact not just on public safety but also on the Chinese medicine industry as a whole (including Registered Chinese medicine practitioners, Registered Chinese herbal medicine practitioners, importers / sponsors / manufacturers of Chinese herbal medicine, and suppliers) it is vital that the reforms are fair to all parties. They should be easy to implement for all parties mentioned, including for the TGA as the regulatory body.

The AACMA response is directed to the Independent Review Panel's recommendations 33, 38, 39 and 43, as well the government's response to these recommendations.

The adoption of Recommendation 38 may limit to the practise of a Chinese herbal medicine practitioner. It would impose unrealistic expectations on sponsors to prove the efficacy of single herbs, particularly when it is the synergistic use of Chinese herbs that create the effect: single herbs are not commonly used in isolation.

Recommendation 39 requires sponsors / manufacturers of Chinese herbal medicines to be PIC/S GMP compliant. This is already the case for most practitioner only herbs, but not for over the counter remedies. The AACMA recommends that PIC/S GMP be adopted as the standard for all Chinese herbs.

The government's response to Recommendations 33 is endorsed by AACMA. It is in the interests of public safety that these over the counter products continue to be regulated within the therapeutic goods framework. This also means that all claims made by sponsors for their over the counter remedies should have proof of such claims and be easily accessed by the public on their websites or on a website deemed appropriate by the NRA.

A three-tiered regulation is the obvious choice for Chinese herbal medicine as prescribed by Registered practitioners, and is endorsed by the AACMA as the best regulatory option. This would differentiate between Aust L, Aust R and practitioner only herbs.

Introduction and Background

Public Safety is paramount in the provision of any health care and the AACMA welcomes the current Complementary Medicine reforms by the TGA and the ability to provide informed feedback.

Chinese Herbal Medicine has been a registered modality under the National Registration and Accreditation Scheme (NRAS) since July 2012.

The guidelines set down for Chinese medicine practitioners by the Chinese Medicine Board of Australia (CMBA) with support and oversight from the Australian Health Practitioner Regulation Agency (AHPRA) state that Chinese Medicine Practitioners hold a minimum 4 year Bachelor Degree or equivalent to be able to be registered to practise.

Chinese herbal medicine practitioners are Registered under these qualifying guidelines making them highly trained to be able to diagnose and then prescribe Chinese herbal remedies with a minimal risk if any, to patients

The high level of training and continued professional development required to maintain Registration for the Registered practitioners is a safe guard for the public who are treated by these practitioners and therefore minimises any risk.

Chinese Herbal Medicines

Traditional Chinese medicines have centuries of effective use in China and the rest of the world.

The very essence of Chinese herbal medicine is the synergy produced by the combination of the herbs that are prescribed to affect a positive outcome for the person being treated.

These suggested reforms approach Chinese herbal medicine from a western scientific perspective. Whilst we acknowledge the independent review panels' collective experience and the informed feedback received from stakeholders, this perspective doesn't fully reflect the subtleties of Chinese herbal medicine.

The cover letter attached to the report to the Minister for Health at the time, states that this review is *"cognisant of the growing trend toward self-medication and the increasing use of complementary medicines by consumers to actively protect and manage their own health. This is predicated on the assumption that all therapeutic products on the Australian market have been assessed for safety, quality and efficacy"*

This statement suggests that the recommended reforms are mostly designed with the over the counter remedies in mind where the consumer is either self-informed or advised by a retail assistant in a pharmacy or health food store.

That the intent was to safeguard the public from these remedies, without the realisation that Chinese medicine as prescribed by Registered Chinese medicine practitioners prepared by manufacturers who abide by the GMP and PIC/S standards and in countries who are signatories to the CITES international treaty would also be affected.

Suggested Reforms and Responses

Recommendation Thirty-Eight: *The Panel recommends that the NRA establishes the list of Permitted Indications, from which sponsors must exclusively draw, for listed medicinal products in the ARTG.*

Response: The adoption of this recommendation may limit the ability of a Chinese herbal medicine practitioner to practise, as sponsors/manufacturers of Traditional Chinese medicines that are practitioner only products and not available for over the counter sales would be prohibited from using single herbs in a formula unless each herb has scientific proof of its action and efficacy.

The need to scientifically prove each individual herb included in a formula would be akin to proving the effect of an egg when poached or in a cake or scrambled or in a soufflé. The point is just by adding heat to an egg without any other additions, the protein is denatured and it is immediately altered from its natural state. The addition of flour or milk or flavourings makes it a completely different entity to the original egg.

It's the combination that provides the effect and not just one herb in isolation.

Reiterating that the sponsors/manufacturers of these practitioner only Chinese herbal remedies already comply with the GMP and PIC/S standards and the countries where manufacture occurs are signatories to CITES.

Recommendation Thirty-Nine: *The Panel recommends that there be three options by which sponsors may seek entry into the ARTG of complementary medicinal products and other listed medicinal products for supply in Australia.*

Option One - Listing in the ARTG following self-declaration by the sponsor of the safety and quality of the product in circumstances where:

A. *the product contains only ingredients that have been previously approved by the NRA for inclusion in listed medicinal products; and*

B. *the ingredients, including proposed dosage where applicable, route of administration, and duration of use where applicable, comply with listing notices or similar documents issued or endorsed by the NRA; and*

C. *the ingredients comply with any compositional guidelines or other compendial standards issued, adopted or approved by the NRA; and*

D. *the product is manufactured in accordance with PIC/S GMP; and*

E. *the sponsor only seeks to make claims regarding the indications for use of the product selected from the list of Permitted Indications (Recommendation Thirty-Eight refers); and*

F. *the sponsor holds evidence to support these indications, consistent with requirements outlined in the evidence guidelines issued by the NRA from time to time.*

Option Two - Listing in the ARTG following a self-assessment of the safety and quality of the product, and following assessment of the efficacy of the product by the NRA, in circumstances where:

A. the product contains only ingredients that have been previously approved by the NRA for inclusion in listed medicinal products; and

B. the ingredients, including proposed dosage where applicable, route of administration, and duration of use where applicable, are compliant with listing notices or similar documents issued or endorsed by the NRA; and

C. the ingredients comply with any compositional guidelines or other compendial standards issued, adopted or approved by the NRA; and

D. the product is manufactured in accordance with PIC/S GMP; and

E. the sponsor seeks to make health claims that fall outside the list of Permitted Indications but which are still appropriate for listed medicinal products; and

F. the sponsor can provide evidence acceptable to the NRA to support the safety and efficacy of the product for the proposed indication(s), commensurate with risk. This may include the submission of an un-redacted evaluation report(s) from a comparable overseas regulator.

Option Three - Registration of a complementary medicinal product in the ARTG following an assessment by the NRA of the product for safety, quality and efficacy in accordance with existing requirements for registration of complementary medicines

Recommendation 39 Option one (C) is not specific on which compendial standards will be the guide to compliancy.

Will it be the Materia Medica of Chinese Medicine such as the Bencao Gangmu or based on a western pharmaceutical perspective?

It is perfectly reasonable for Chinese herbal medicine to be guided by its traditional base using Chinese medicine pattern differentiation and diagnosis to construct an effective treatment regimen according to the treatment principles indicated by the diagnosis.

This means the use of all the necessary approved tools of the trade including a full Chinese herbal pharmacopoeia that is produced safely and ethically and prescribed by appropriately trained, qualified and Registered Chinese medicine practitioners and Chinese herbalists.

Options 1 and 2 (D and E) state that the product be manufactured in accordance with the PIC/S GMP

This is already the standard of Chinese herbal medicines whether prepared or single herb or formula herb granules that are currently available for practitioner use only.

The sponsors/manufacturers make no claims regarding these medicines except the potential indications for use according to Chinese medicine diagnosis and treatment principles and not the biomedical or patho-physiology of a western medicine diagnosis.

Recommendation Thirty-Three: *The Panel recommends that listed medicinal products, including complementary medicinal products, and the ingredients for use in such products, continue to be regulated within the therapeutic goods framework*.

The AACMA agrees with the government response and endorses this recommendation. It is definitely in the interest of public safety that the TGA continues to regulate these products within the therapeutic goods framework with particular attention to over the counter remedies that are not prescribed by a Registered Chinese medicine practitioner.

Recommendation Forty-Three: *The Panel recommends that where a medicinal product is listed in the ARTG, the sponsor be required to publish on the sponsor's website or, if the sponsor does not have a website, on another website nominated by the NRA, the evidence that it holds to support all indications included in the ARTG entry*

The general public is unable to self medicate with Chinese herbal medicines that are practitioner only products such as single and formula granules as these sponsors only allow Registered practitioners to access their websites and to purchase their product.

The AACMA agrees with the government response and absolutely endorses the recommendation for the need of proof of claims made by sponsors and the supporting evidence to be publically available for over the counter medicines that are freely available to the public.

The AUST L listing that is granted to many over the counter remedies doesn't perform the task of public protection.

There is no requirement to show evidence of efficacy and there appears to be little ability to regulate these products.

The AACMA agrees with the AUSTL listing for products that have a very low risk to the public when self-selected at supermarkets, pharmacies and health food stores but still endorses the recommendation that any claims made by the sponsor are validated and that the products have been manufactured in a TGA authorised facility to a PIC/ S GMP standard.

The AUST R category should be retained as is for what is regarded as high risk medications requiring prescription or for lower risk medication that demand appropriate labelling to ensure public safety. The AACMA sees the proposal of a third tier of regulation as the obvious choice for Chinese herbal medicine as prescribed by Registered practitioners.

The reasons supporting this recommendation are:

- The required standard of the GMP and PIC/S will be adhered to and as this is a worldwide standard and accepted and approved globally, Chinese herbal medicines from countries that also maintain these standards will be compliant.
- The traditional aspect and prescription of Chinese herbal remedies according to Chinese medicine diagnosis and treatment principles is the foundation on which prescribing herbs is based and applying the same protocols applied to pharmaceuticals where drugs are used in isolation unlike Chinese herbal remedies that use the synergistic effect of all component herbs to provide an effective treatment is not appropriate or valid
- The historical use of these traditional herbal medicines over centuries is an indicator of evidence-based efficacy.
- As these are traditional medicines using several herbs, proof of effectiveness is measured on each individual case. The sponsors of these medicines would find it prohibitive to prove efficacy of each individual herb in a formula using the scientific method employed for western pharmaceuticals. Proving the effectiveness of each herb individually has no real value when used in a formula as it is the synergistic effect of the herbs that is so important in Chinese medicine.
- With a third tier of regulation for sponsors of Chinese herbal medicines, the TGA will have more control to monitor the use of prohibited Schedule 9 substances such as the Aristolochia species
- There will be increased safety for the public if Chinese herbal sponsors recognised by the TGA are providing the product for the Australian market
- A register for adverse events would also be necessary for Chinese herbal remedies that are regulated in the proposed third tier.

Summary

AACMA understands and welcomes the need for regulation reforms for complementary medicines.

The current recommendations seem to be directed to protect the public from over the counter preparations that make unsubstantiated claims about their effectiveness.

The AACMA endorses the government responses to the Review of Medicines and Medical devices in particular recommendations 38 and 39 and 33 and 43.

The AACMA recommends a third tier of regulation to cover a category of Chinese herbal medicines that are prescribed by registered Chinese medicine practitioners and not available to the general public as over the counter products, in particular the internationally recognised PIC/S GMP standard.

Thank you for the chance to offer feedback on this important issue.

It isn’t just public safety that is being decided here but also the livelihood of Chinese medicine practitioners and the manufacturers and suppliers of Chinese herbal medicines.

As the leading professional association for Chinese medicine practitioners representing its members for 44 years, the AACMA is pleased to be involved in this regulatory process and welcomes any further chance to offer information on this.

Please contact the AACMA National Office on 07 3457 1813.

Yours sincerely,

The AACMA Board