AACMA
AUSTRALIAN ACUPUNCTURE & CHINESE MEDICINE ASSOCIATION LTD
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The Project Officer
Office of Complementary Medicines
Therapeutic Goods Administration

Email: ocm@tga.gov.au

Re: Revised Draft Evidence Required to Support Indications for Listed Medicines

Thank you for providing the opportunity to lodge a submission on the *Revised Draft Evidence Required to Support Indications for Listed Medicines.*

About AACMA

The Australian Acupuncture and Chinese Medicine Association Ltd (AACMA) is the peak national professional body of qualified practitioners of acupuncture, Chinese herbal medicine and Chinese herbal dispensing. The Chinese medicine profession joined the National Registration and Accreditation Scheme for the Health Professions (NRAS) on 1 July 2012 and is regulated under the Australian Health Practitioner Regulation Agency (AHPRA) by the Chinese Medicine Board of Australia (CMBA). We represent over 2200 members nationally.

Requirements for scientific evidence

Whereas on the surface the evidence requirements appear to follow academic models, there are some major contradictions in the requirements that are, in our view, not academically sound. The scientific evidence requirements appear to be based on a view that complementary medicines are only used by people who are healthy and appear to be designed to negate the relevance of any studies that actually demonstrate efficacy in sick people.

Firstly, in terms of studies which may be included to demonstrate scientific evidence of efficacy, only studies that are undertaken on a healthy population can be included. It is common practice that a population sample used in testing an intervention should, as much as practicable, reflect the demographics of the target population so that the evidence is generalisable to that target population. Similar considerations would apply to a control group. By limiting acceptable studies to only studies on healthy people, the results would be generalisable only to healthy persons in the community. This would imply that the TGA considers listed medicines to be only suitable for people who are not ill and therefore akin to placebo in their action.

Secondly, there needs to be research done in order to cite the research. There is a limited funding pool and only a small proportion is allocated to complementary and traditional medicine research. By limiting acceptable evidence for listed medicines to studies done on healthy persons only, the effect will be to drive research funding away from the more important studies that assess efficacy in non-healthy subjects (which would be of much greater benefit to the community).

Thirdly, the requirement for a systematic review to be undertaken on every ingredient is highly resource intensive and will result in a significant cost burden on sponsors. That, of course, assumes that the research to be reviewed is there in the first place.

Indeed, the cost and resource impacts may well prove to be so prohibitive that large parts of the industry will simply collapse.

Requirements for evidence of traditional use

Most manufactured Chinese herbal medicine products used in Australia are based on classical formulas and evidence would be based on traditional indications and usage.

Most classical Chinese herbal medicine products are supplied via practitioner prescription/dispensing, Chinese herbal retail outlets and, to a much lesser extent, through health food stores and pharmacies.

The evidence guidelines for traditional use are too inflexible, are based on some untested and incorrect assumptions, and do not take into account the evolution of usage in different populations.

For example, in relation to populations on which traditional usage is based (more than 75 years of use), there is an incorrect assumption that only people from a Chinese cultural background use Chinese herbal medicine products. However, the target population is here, in Australia, which is a culturally and ethnically different population from pre-revolutionary China. A large proportion, if not the majority, of consumers of Chinese herbal products are not from a Chinese background.

Therefore, sponsors would have difficulty satisfying parts of the proposed new evidence guidelines for traditional use, based on the comparable populations requirement.

According to Part A, traditional evidence cannot imply efficacy. This is unacceptable and we totally reject this reasoning.

Relatively few classical formulas and few individual Chinese herbs have been subject to testing for efficacy, and even fewer tested for efficacy only on healthy subjects. Therefore it would be difficult for sponsors of Chinese herbal medicine to provide the level of evidence to support efficacy under these proposed guidelines.

We support the statement that mixing of two different types of traditional medicine ingredients does not of itself make the formula a traditional formula.

Justification for the increased regulatory burden on sponsors

There is no doubt that there are, and have been, some rogue operators who are making unreasonable claims and breaching advertising standards for listed medicines. However, rather than making the guidelines clearer for industry and ramping up enforcement and penalties, the TGA has responded to criticism by imposing significantly additional burden on already compliant industry.

A basic principle is that if additional regulatory burden is to be imposed, then there needs to be a public benefit test about whether the risk from not implementing the additional regulation outweighs the negative impact of that added regulatory burden.

In this situation, there is no significant public health risk associated with the current system of listed medicines that, if appropriately enforced, would justify such a significant added compliance burden on industry.

Unintended consequences on consumer and industry and professions

If the TGA guidelines are approved in their current draft form, there will be a significant and costly compliance burden placed on an already compliant industry. At the same time, the rogue operators will continue to flaunt the TGA standards unless enforcement is prioritised.

So the net effect will be a compliant industry struggling under the regulatory burden.

In these circumstances, it is inevitable that some legitimate and compliant sectors in the industry will collapse or walk away and their products will no longer be available to consumers. If suitable product is no longer available, consumers could well be driven to seek 'similar' product from less reliable and legitimate sources, such as from overseas via the internet where claims are less rigorously controlled, prices are cheaper, and safety questionable.

Summary

The draft guidelines for evidence need to be further reviewed and the negative and unintended consequences identified and further investigated. Obviously, consumer safety is a priority, and this could be achieved by less onerous and restrictive guidelines that industry can work with, coupled with increased enforcement for those not complying.

Please contact me at the AACMA office on 07 3324 2599 ext 13 if you wish to discuss the contents of this submission.

Yours sincerely

Judy James
AACMA CEO