Consultation submission cover sheet

This form accompanies a submission on:

The document 'Evidence required to support indications for listed medicines (excluding sunscreens and disinfectants)'	
Name and designation	Max Ma, President
Company/organisation name and address	Chinese Medicine Industry Council of Australia Ltd
Contact phone number	

I would like the comments I have provided to be kept confidential: *(Please give reasons and identify specific sections of response if applicable)*	☐ Yes ☒ No
I would like my name to be removed from all documents prior to publication and not be included within the list of submissions on the TGA website.	☐ Yes ☒ No

It would help in the analysis of stakeholder comments if you provide the information requested below.

I am, or I represent, a: *(tick all that apply)*

Business in the therapeutics industry *(please tick sector):*

☐ Prescription medicines ☒ Complementary medicines ☐ OTC medicines

☐ Medical devices ☐ Blood, tissues, biological ☐ Other

☐ Sole trader ☐ Business with employees

☐ Importer ☐ Manufacturer ☐ Supplier ☒ Industry organisation

☐ Government ☐ Researcher ☒ Professional body

☐ Consumer organisation ☐ Institution (e.g. university, hospital)

☐ Regulatory affairs consultant ☐ Laboratory professional

☐ Health professional – *please indicate type of practice*:

☐ Other - *please specify*:

It would help in the analysis of stakeholder comments if you provide the information requested below.

Comments

An assessment of how the proposed change will impact on you. That is, what do you see as the likely benefits or costs to you (these may be financial or non-financial). If possible, please attempt to quantify these costs and benefits.
Considerable adverse impact with high cost and little benefit.
Whether or not you support the revised Evidence Requirements. If not supported, please provide reasons why.
Not supported, because lack of consideration of the uniqueness of Traditional Chinese Medicine. see previous and attached submission.
Any additional information on issues not asked in the above questions. If your comments relate to specific parts of the document please provide the page number and reference.

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11 July 2012

Ms Trisha Garrett

A/g Head

Office of Complementary Medicines

Therapeutic Goods Administration

Dear Ms. Garrett,

RE：Submission for the TGA consultation on the document of “evidence required to support indications for listed medicines”

We thank you for your letter dated 30 May 2012 regarding the matter for the proposed change for the evidence requirement for listed medicines. After that, we called several meetings among our directors and stakeholder members discussing this proposal. After a period of time in the review, we hereby take the pleasure to lodge our submission as below for your considerations.

CMIC is the largest national body representing the suppliers of Chinese medicine in Australia. We aim to play a role to bridging the regulators and the industry to facilitate the efficient management in Chinese medicine, and in turn to benefit all the related parties including the public. Our main values and principles are: Safety, Quality, Efficacy, Availability and Affordability.

We support any reforms to increase the credibility and efficacy concerns from the public for listed medicines; we should, however, be very aware of the nature and characteristics of complementary medicine including Chinese medicine, be cautious about the implementation of reforms and its influence on the sustainable development of the whole industry.

In general, we have the following preliminary concerns and views:

1. This is a big change to the current practice and in general, conflicting with the past arrangement, which indicates the proposed policy, is not in consistent with the principle in the past 20 years;

2. The proposed change attempt to use the OTC standard and western medicine concept to assess and manage the complementary medicine including Chinese medicine for the next step in Australia, which is neither in line with the nature of this kind of medicine , nor in consistence with other international jurisdictions, like Canada, Singapore, Hong Kang, Malaysia, etc.

3. Too stringent and over complicated for low risked medicines for which the TGA has pre-assessed the safety of ingredients and the quality assurance by costly GMP auditing and accreditation process that has already imposed an incredible financial burden to sponsors in the market;

4. We should review whether the current standard has been well maintained and any loopholes need to be fixed, and based on existing regulatory framework, TGA should consult the stakeholders in what way the efficacy issue could be improved before the actual implementation and allow longer time period for stakeholders to provide practical suggestions and feedback.

5. We strongly oppose the proposed change, based on the following considerations:

5.1 The proposed change will greatly increase the cost for listed medicines and will also limit a range of effective complementary medicine which could not provide the evidence as proposed, and ultimately it is in contradiction with the national medicines policy of “Accessibility” and will greatly impose a negative impact on the Availability and Affordability, and in turn fundamentally affect the interest of public consumers.

5.2 The proposed change seems to be less practical or less reasonable. TGA should consider the feasibility for complementary medicines. For instance, how to find out some many studies exactly the same with the proposed products based on the similarity of Australian populations. Besides, it is inappropriate to calculate clinical significance and it is quite subjective to find a historical record more than 75 years, but not 74 years, or 63 years etc, and rather than an university text book.

5.3 Regarding the list of TGA accepted monographs and authoritative texts, as outlined in Appendix 1, we believe that a more comprehensive list is necessary. Currently, the main source for traditional evidence for traditional indications in the context of Traditional Chinese Medicine (TCM) is the Chinese Pharmacopoeia. This text has several limitations:

a) It does not contain all of the commonly used traditional or classic formulations.

b) The formulations that it does contain are mostly described in a single dosage form (i.e. pills or boluses made of finely powdered herbs with honey or rice-water as excipient).

In the contemporary practice of Chinese herbal medicine, the predominant dosage form is that of herbal extractions. Therefore contemporary texts describing Chinese herbal formulations in this dosage for are also necessary. There are several high quality English and Chinese language literatures or text books that provide information on a larger range of traditional Chinese herbal formulas, each well researched and referenced that would be suitable to be included on the TGA accepted list. These provide a readily accessible source of the historical uses of Chinese herbal medicines, with specific relevance to contemporary TCM practice.

5.4 The proposed change will tremendously increase the cost for applying a new medicine and maintain the existing listing products in ARTG, which is apparently beyond the capacity for small business sponsor’s survival in Australia, along with the business closedown and unemployment increase many products will be delisted from ARTG. However, most of listed products have been in the market for many years and consumers’ continuous use is the strong evidence that product’s efficacy has been recognized and proved by the market. Otherwise those “non-effective” listed products will be washed out by the market.

5.5 The proposed change will only lifting the threshold for normal sponsors, but do little for fair competition and do NOTHING for existing not-compliant sponsors who even do not pay single dollar of regulatory cost to supply their products. TGA should re-enforce the market surveillance function and scrutiny for the current application evidence to ensure the competition is fair, and the current arrangement for evidence is not compromised.

5.6 Rather than provide support and clarity to the sponsors, this proposed change will significantly affect the current sponsors and the sponsors in the future. The sponsor will try hard to find out and rely on a TGA prescribed “Expert” to assess their medicine, rather than themselves are responsible for their medicine. And in many situations, “practitioners” may not necessarily well understand the “pharmaceutical manufacturing process and its correlation with efficacy apart from formulation”. These are two different professions.

5.7 It is impractical to review every indication with every evidences held. For instance, it is quite impossible to find an evidence to substantiate the indication of “increase general wellbeing”?

5.8 It is not reasonable that listed medicines can NOT refer to a disease that needs to diagnose, treat or manage by a practitioner. This change not only differs the current requirement that cannot make high claims and advertising code controlled serious diseases, but also will confuse the sponsors and limited the listed products not being available to practitioners.

5.9 The change make traditional medicine including Chinese medicine in a very difficult position to provide required “scientific evident” for a Scientific Indication. This is totally different from existing evidence framework without convincible explanation.

5.10 The draft change makes another unfair and unreasonable proposal that listed traditional medicine/indication can NOT mention some wording, like immune system, antioxidant, glucose level, providing natural Vitamins, minerals, etc. This is groundless. Actually TGA should assess whether the traditional evidence can demonstrate the same effect.

5.11 The proposed change will also impose a great impact to Traditional Chinese Medicine groups, because not every classic formulas or clinically validated formulas are documented with the required format , including indications, dose, administrations , year of evidence, similar Australian populations etc, even if in Chinese pharmacopeia.

5.12 The proposed Relevant Publications in Appendix 1 makes Chinese medicine in a great disadvantage situation to search and collect the “Evidence”. In fact, Chinese medicine has its own concept and mechanism to substantiate the evidence which is totally different to the proposed change.

5.13 The proposed change classify the medicine into “Scientific indication” and “Traditional indication”, and claim “scientific indication are efficacy-based and directed to the general Australian population, while Traditional Indication, refers to a tradition of use within a particular paradigm”. This will potentially mislead or confuse the public that Traditional medicine are “Not efficacy based”, or “may not effective on Australian people”. This could lead to a discrimination or exclusion to listed medicine with Traditional Indications in the market place.

We believe that the requirements for reporting ‘traditional evidence’, as outlined in Section 2.2.3 are too stringent and may in fact hinder the overall regulatory objectives as summarized in your letter of 30th May, 2012, i.e. ‘to protect public health and safety while allowing easy access for consumers to complementary medicines and ensuring a relatively low regulatory burden on suppliers of these products’. There are two areas that concern us: a) the characteristics and qualifications of the TCM expert. b) TGA accepted monographs and authoritative texts.

5.14 From 1 July 2012, among 14 professions, Chinese medicine has been included in the National Healthcare Practitioners Registration Scheme. Rather than 3 years of tertiary degree, “Registered Chinese medicine practitioners” and “TCM diploma degree or above” should be recognized as “Expert” in case the proposed “Expert report form” does need.

6. CMIC alternative proposals:

1. The current proposal should be withdraw or greatly amended and simplified;

2. In case TGA insist to create a new mode like this to manage complementary medicine, it should be classified as total different mode in between the Registered Medicine and Listed Medicine, maybe called (Efficacy) Assessed Medicine, - AUST A xxxx, providing an option for both sponsors and consumers.

3. The best option is that TGA should make some improvement based on the existing evidence requirement framework for listed medicine, including:

3.1 Increase the random check rate for evidence hold by sponsors;

3.2 Scrutiny enforcement in review of the evidence provided by the new applicants

3.3 Work closely with the industry, and give incentives to those who provide clues for poor or unqualified products that may damage the credibility of listed products.

3.4 Re-enforcement for the post market surveillance activities. Heavy fines should be applied to those playing bad or illegal traditional medicines in the market to protect Australian's public interest.

Should anything we could do further regarding this change, please feel free to let us know.

Yours sincerely,

Mr Max Ma JP

President, CMIC