



Chinese Medicine Industry Council of Australia Ltd

澳大利亞中藥行業聯合會

ABN 83 140 585 342

Suite 604, 309 Pitt Street, Sydney, NSW 2000 www.cmic-aus.org.au

31 March 2015

Review of Medicines and Medical Devices Regulation Secretariat
Department of Health
MDP 67
GPO Box 9848
CANBERRA ACT 2601
Email: medicines.review@health.gov.au

Dear Review Secretariat,

RE: Submission on the Expert Review of Complementary Medicines Regulation (Chapter Nine)

The Chinese Medicine Industry Council of Australia Ltd (CMIC) is the peak body representing suppliers of Chinese Herbal Medicines (CHM), an integral part of Traditional Chinese Medicines (TCM) which are majority regulated as Complementary Medicines in Australia. CMIC plays a key role in bridging the regulators and the industry to facilitate the efficient and effective management of CHM supply in Australia, and in return to benefit all parties in particular the patients. CMIC's values are Safety, Quality, Efficacy, Availability and Affordability.

CMIC welcomes the Expert Review of the Medicines and Medical Devices Regulation, in particular, CMIC thanks for the opportunity provided for the submission to the review of Complementary Medicines Regulation.

CMIC acknowledges that current regulation system for complementary medicine is generally effective and acceptable but CMIC agrees there are improvements required to enhance a streamlined regulatory framework without undermining the safety and quality of complementary medicines, to ensure the patients in Australia have a good access to high quality complementary medicines when needed and to ensure the complementary medicine industry in Australia is continuingly well positioned to be competitive in global market.

In general, CMIC supports the review and would like to provide the particular comments in the areas outlined below for the review panel's consideration.

THEME 1: DUPLICATION OF REGULATORY PROCESSES

Issue 1 - Requirement of TGA assessment of ingredients approved overseas



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CMIC supports the principle of a streamlined process that TGA eliminates the process of re-assessing the ingredients which have already approved or have had a long history of use in overseas.

CMIC suggests there should have separate systems to accept the well established overseas ingredients without TGA further re-assessment or re-approval. It is suggested that CHM which have a long history of tradition use and have been included in the Chinese Pharmacopoeia should be recognised by the TGA without any further re-assessment or re-approval, and Chinese Pharmacopoeia is to be used as a default standard for TCM. In addition to TCM, other well established ingredients which have already been accepted by reputable overseas health authorities according to their appropriate review systems (e.g. Health Canada for Natural Health Products, NHP) should be excluded for re-assessment or re-approval, and the NHP monographs can be used as a reference.

Traditional Chinese Medicines (TCM) have been used for thousands of years, and among near 6000 kinds of Chinese Materia Medica substances included in the “Zhong Yao Da Ci Dian” (*The Great Dictionary of Chinese Materia Medica*), approximately 600 have been well established in terms of safety and efficacy and included in the Chinese Pharmacopoeia.

Chinese medicine practices and CHM industry have been growing rapidly in Australia. Apparently, the Traditional Chinese Medicine Practitioners are recognised and managed by the Chinese Medicine Board of Australia (CMBA) under Australian Health Practitioners Regulation Agency (AHPRA) and there are many more graduates year after year from the universities and colleges where provide formal TCM education including undergraduate and/or post-graduate degrees such as RMIT University, University of Technology Sydney, University of Western Sydney and the Sydney Institute of Traditional Chinese Medicine. However, the challenge the industry critically facing is the availability of CHM substances and products due to the regulation limits (e.g. the ingredient pre-approval process, the inconsistent scheduling requirements/status for a same herbal substance compared to its status in overseas such as in Canada, USA, China, etc.). There are many good CHM substances and products commonly used in China and other regions/countries such as Hong Kong, Macau, Malaysia and Singapore that are not available to be used in Australia due to the regulation restriction and the time and costs involved in the ingredient approval process, etc., and the downside of this is the Australian users may then turn to source the unapproved products online from overseas, or even physically go to overseas to buy the products as tourists, it then therefore exposes the Australians to the products which might not be regulated/approved by the TGA or even by an overseas regulator (e.g. counterfeit products), posing a significant risk in product quality, safety and efficacy and associated public health, and further, negatively impacting the proper system in managing the industry.



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CHM has a long history of use with enriched experience of the known ingredients and formulation, the evidence of the traditional and scientific evidence of the TCM use is collected in the Chinese Pharmacopoeia including the knowledge and experience of the aspects of product quality, efficacy and safety. At the moment, three pharmacopoeias (British Pharmacopoeia, United States Pharmacopoeia and European Pharmacopoeia) are recognised by the TGA as default standards for all medicines including prescription medicines, Over the Counter medicines (OTC) and complementation medicines, but the fact is that, all these three pharmacopoeias have very limited monographs for herbal medicines especially CHM. Although CHM evidence cited in the Chinese Pharmacopoeia is accepted as reference by the TGA on the case by case basis, but there is no systemic adoption of its references for herbal substances included in the Chinese Pharmacopoeia in Australia.

The current system poses a loophole of “no standard” for Chinese herbal substances in this country, leaving consumers or patients in Australia with a high risk in seeking authenticated herbal species.

Since Chinese Pharmacopoeia is the only and the most comprehensive one in the world with in-depth practical knowledge of traditional Chinese herbal medicines, it is suggested to use the Chinese Pharmacopoeia as a 'trusted' source to determine whether an ingredient/formulation of TCM would need a re-approval as a complementary medicine. By doing so, it will not only help streamline the process but also facilitate the availability of herbal products to be used for the significantly increased numbers of registered TCM practitioners and their clinical practice in Australia, this will reduce the chance that people intend to get unapproved products online or from overseas and help minimise the health risks to the Australian public, and in long term, help strengthen our regulation system and enforce the compliance in our market.

Issue 2 - Interface between advertising and listing evidence requirements

CMIC agrees there are some degrees of overlapping between the TGA evidence requirements and the advertising pre-approval process, and CMIC supports the harmonisation.

As part of the eBS listing requirements and the compliance requirements, the sponsors of a listed product are required to hold evidence to support the therapeutic indications and claims as per TGA *Guidelines on the Evidence Required to Support Indications for Listed Complementary Medicines*, the eBS also have in-built coded indications and a function to 'detect' the restrictive wordings for free text claims. CMIC recognises that pre-approval of an advertisement containing only the eBS listed indications/claims for a product is a repetition to the listing evidence requirements and should be removed. Should the compliance of the



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listing evidence be in doubt, it should be stringently enforced before the indications/claims are allowed to be entered into the eBS or the AUST L is generated.

CMIC suggests some forms of compliance enforcement on listing evidence requirements before an AUST L is generated, and an advertisement is not required to be pre-approved if only the eBS listed indications/claims are advertised.

THEME 2: REGULATORY REQUIREMENTS ARE NOT COMMENSURATE WITH RISK

Issue 1 - Interface between complementary medicines and pharmaceuticals

In CMIC's view, herbal medicines and dietary supplements such as vitamins and minerals are slightly different, for example a TCM is a traditional medicine which has been used for thousands of years as remedies for disease prevention and treatment, it is more appropriate to maintain herbal medicines as complementary medicines while the others may be considered as dietary supplements or equivalent.

CMIC would also like to point out that the current registered complementary medicine registration system might be a burden to introduce good complementary medicines to the country. The current registered complementary medicine registration system is equivalent or more restrictive than OTC medicine registration system; it does not reflect the nature of a complementary medicine which is low risk in general. We support a full review of the registered complementary medicine registration system.

At the moment, there are two sub-registration systems for complementary medicines, namely listed (AUST L) and registered (AUST R) complementary medicines. For the registered complementary medicine registration application, a system is similar to OTC medicine application is implemented which requires quality, efficacy and safety data to be submitted and reviewed. CMIC respects the registered complementary medicine registration system, but thought a further improvement is required to allow recognising that herbal medicines are lower risk in general compared to pharmaceuticals (Prescription and OTC medicines), and additionally, we suggest the traditional evidence is to be accepted as efficacy data for registered complementary medicines (e.g. those described in the Chinese Pharmacopoeia are the thousand of year practical experience).

Issue 2 - Threshold for therapeutic goods

As discussed in the above, CMIC supports some of the ingredients are more dietary supplement originated and they should be exempted from listing requirements but retain the



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herbal medicines within the complementary medicine category with a more streamlined requirements for registered complementary medicine application process.

Issue 3 - Interface between complementary medicines and foods

See above.

Issue 4 - Evidence requirements

CMIC supports the current evidence requirements but would like to see an improved system to capture the points as described in the above.

- The listing process is to be harmonised with the advertising pre-approval requirements - an advertisement contains only the listed indications/claims is not to be required for advertising pre-approval.
- Traditional evidence in Chinese Pharmacopoeia is to be accepted for both listed and registered complementary medicine registrations.

Issue 5 - Compliance with GMP

CMIC does respect the TGA's pharmaceutical GMP requirements for complementary medicines but concur with the industry that the current requirements may be too stringent for low-risk medicines. One particular example is the regular inspection interval of 2-3 years for some overseas countries which adds excessive burdens such as time and costs to the sponsors/manufacturers. It would probably be more appropriate to introduce a longer inspection interval (e.g. 5 years) for lower risk medicines.

Issue 6 - Pre-publication approval for advertising

CMIC's members acknowledged the confusions of current pre-publication approval for advertising such as multi-organisation involvement, above the line vs below the line categories and evidence re-assessment for eBS listed indications/claims, etc. CMIC supports a reform of the current advertising approval system to introduce a simplified process.

As outlined in the above, one key area to be considered is the harmonisation of the listing evidence and the advertising pre-approval, CMIC strongly suggests to have a mechanism that an advertisement carries only the listed indications/claims is not to be reviewed and approved again.



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THEME 3: COMPLEX REGULATORY FRAMEWORK

Issue 1 - Lack of understanding of requirements for listing

As a peak body representing CHM industry which is essentially part of alternative therapies, CMIC acknowledges the importance of understanding the regulation requirements in particular when considering the majority of our members are from non-English speaking background. CMIC plays a key role in bridging the regulators and the industry to facilitate the efficient and effective management of CHM supply in Australia, we wish to work closely with the TGA to help understand of the regulations by our members by running regular meetings and training with the regulators or accredited regulatory consultants/agents.

CMIC supports an accreditation and licensing scheme for product listing but wishes it is a fair and simplified system to ensure that the alternative medicine groups like us are not disadvantaged. A suggested approach, for example, is that the government may grant such a licence without additional costs to an accredited member of a professional body from which education, training, assessment and co-regulation are carried out.

Issue 2: Poor consumer understanding

The majority of CHM medicine customers are Chinese from non-English speaking background, it is very important that the right regulatory and product messages are delivered to these customers by means of education and training. It's of concern that apparently there is not much has been done in terms of helping retailer customers to understand the regulation of complementary medicines, for example what does AUST L really mean to them, we believe the majority of them would not have a clue and some may think it's TGA approval number similar to prescription or OTC medicines. We thought the issue is across the board within the general public for complementary medicines, not necessary the TCM users only.

Again, CMIC is willing to work together with the regulators in promoting the consumer awareness of the regulation.

THEME 4: INADEQUATE DETERRENDS

CMIC realises there are extra steps to take in order to strengthen the post market surveillance. The CMIC feels the current post market surveillance activities may not be enough for those players who dare to take the risks to import or smuggle unlisted/unregistered or even counterfeit products, and in the mean time we thought the requirements have very limited flexibility for the companies that committed for compliance. Therefore, it is suggested to strengthen the post market surveillance to allow for a level of playing field.



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Summary:

CMIC appreciates the opportunity to contribute to the review, and to provide a numbers of comments for stimulating the review:

- CMIC acknowledges that current regulation system for complementary medicine is generally effective and acceptable but CMIC agrees there are improvements required to enhance a streamlined regulatory framework without undermining the safety and quality of complementary medicines.
- CMIC supports the principle of a streamlined process to eliminate the process of re-assessing the ingredients which have already approved or have had a long history of use in overseas. CMIC suggests overseas reputable standards/monographs such as Chinese Pharmacopoeia, Canadian NHP monographs are to be adopted or referred.
- CMIC supports the harmonisation of TGA evidence requirements and the advertising pre-approval process to avoid overlapping.
- CMIC feels herbal medicines should be retained within complementary medicine category but dietary supplements are to be exempted.
- CMIC suggests a simplified registered complementary medicine registration system to allow streamlined approval of good complementary medicines.
- CMIC respects the TGA's pharmaceutical GMP requirements for complementary medicines but welcomes a slight variation on the requirements for low-risk medicines, suggesting to extend the overseas GMP inspection interval to 5 years.
- CMIC strongly supports to increase the regulation understanding for sponsors and customers, and will be willing to work together with the regulators for the awareness of regulation within the TCM industry.
- CMIC supports to tighten up the post marketing surveillance activities, especially for unlisted/unregistered products and counterfeit ones.

CMIC would be very happy to discuss the comments in more detail should that be required.

Yours Sincerely,

A handwritten signature in black ink, appearing to be 'Max Ma', written in a cursive style.

Max Ma,
President, CMIC