Federation of Chinese Medicine & Acupuncture Societies of Australia Ltd.
澳洲全國中醫藥針灸學會聯合會 (National Body)

FCMA

ACN: 104 651 523 ABN: 70 199 744 719
All correspondence:
6 Paisley Street
Footscray Victoria 3011
Australia
Tel: +61 3 9689 2678
Fax: +61 3 9689 0872
+61 3 9802 4261
Email: contactus@fcma.org.au
tchiangl@fcma.org.au
Web: http://www.fcma.org.au

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Complementary Medicines Reform Section

Complementary and OTC Medicines Branch

Therapeutic Goods Administration (TGA)

PO Box 100

WODEN ACT 2606

Dear TGA Officer

Re: Reforms to the regulatory framework for complementary medicines: Assessment pathways

Thank you for the opportunity to respond to the current Reforms to the Regulatory Framework for Complementary Medicines (Reforms). The Federation of Chinese Medicine & Acupuncture Societies of Australia Ltd (FCMA) is a national Chinese medicine association and has more than 700 Chinese medicine practitioners in all states and territories. As President of and a Chinese medicine practitioner, I represent the interest of our Chinese herbal medicine practitioners and would, therefore, like to respond solely from the perspective of Chinese herbal medicine practice.

The FCMA submitted a response to the Review of Medicines and Medical Devices Regulation (MMDR review) on 1 April 2015. The FCMA is disappointed that all of its recommendations proposed were not accepted by the expert panel. I wish the TGA would consider the concerns raised by the Chinese medicine sector; which is one of the primary health care providers in the Australian health care system. I would like to make the following recommendations; after which I provide rationale for the same.

Recommendations

Due to the fact that Chinese medicine profession is nationally regulated via statutory regulation, the FCMA recommends that:

1. A separate committee be established solely for Chinese herbal medicines;
2. Chinese Pharmacopeia or Chinese Materia Medica (Zhong Hua Ben Cao) should be adopted by TGA for evaluation of Chinese herbal medicine products;
3. Scientific evidence for evaluation of efficacy of a product be consistent with the level of regulation of medicines.;
4. All existing listed Chinese herbal products should be treated as grandfathered products.

Rationale

Recommendation 1: A separate committee be established solely for Chinese herbal medicines

One of the proposed reforms requires a sponsor's self-assessment and pre-market evaluation assessed by TGA for listed products via new pathway. The FCMA believes that a separate Chinese herbal medicine expert committee to deal solely with Chinese herbal products. The committee could provide advice for evaluation of evidence of effectiveness or efficacy for all levels of indications and claims, which would be more appropriate than a blanket committee to evaluate the safety of complementary medicine products. While members of more general committees associated with complementary and alternative medicine are generally familiar with western pharmaceuticals, they may not be familiar with Chinese herbal products. This is due to the unique way by which the products are understood to work and are used. In western pharmaceutics, the medicines are extremely highly concentrated with one active substance made either by extraction from a natural product or made synthetically. Therefore, these substances are extremely potent and in some cases, potentially lethal. Chinese herbal medicines are prepared either by extraction from whole natural herbs into decoctions, or finely grounded and compacted into patent pills, freeze dried as a powdered single herb or extracted commercially as a single liquid herbs. Whether herbs used singly or in a formulation, single active substances are not isolated and they contain all the substances from the plant, therefore the herbs are neither highly concentrated nor as potent compared to western pharmaceuticals.

We also believe that if the sunscreen and homeopathic products could be treated separately from the complementary medicines, there is no reason not to have

Chinese herbal medicine products regulated independently by a Chinese herbal medicine committee under the TGA.

For the above reasons we suggest that a committee to be made up of the following experts:

- Specialist/s in Chinese herbal medicine
- Chinese medicine practitioner/s
- Representation from Chinese medicine association/s
- Relevant members from the TGA or representatives from their complementary medicine review committee.
- A consumer representative or advocate
- Other members as deemed necessary

During the 1990's the FCMA was the key association involved in the review of regulation of Chinese medicine profession which ultimately led to the registration of Chinese medicine practice in the state of Victoria. During the earlier years, I was personally involved in the review of herbal products for importation into Australia; and was appointed by the then deputy Minister for Health as a member of the Complementary Evaluation Committee of TGA. Working as a bridge for efficient communication between Australian and Chinese authorities, I travelled many times to China and accompanied with the National mangers of TGA for the purpose of understanding Chinese herbal medicine and the administration system of Chinese herbal medicines in China. The FCMA would be pleased to be of assistance to the establishment of the Chinese herbal medicine committee.

<u>Recommendation 2: Chinese Pharmacopeia or Chinese Materia Medica (Zhong Hua Ben Cao) should be adopted by TGA for evaluation of Chinese herbal medicine products</u>

Chinese Pharmacopeia was compiled and authorised by the Chinese government. The 2015 version published in Chinese and in English has included 618 kinds of traditional Chinese medicinal substances (TCMS), 47 plant oils and extractions and 1,493 proprietary forms of Chinese herbal medicines (Zhong Cheng Yao). Chinese Materia Medica (Zhong Hua Ben Cao) was compiled by the State Administration of Traditional Chinese Medicine of China (SATCM) in 1999. It included 8,980 kinds of TCMS. Contents in scientific research such as pharmacology and toxicology of each TCMS are also recorded on the Chinese Materia Medica. We are surprised that both the Chinese Pharmacopeia and Chinese Materia Medica have not been approved by the TGA as key references for determination of permitted ingredients

and proposed permitted indications or assessment of Chinese herbal medicine products. The FCMA believes that products imported into Australia should be of good quality and safe for use. We agree that for products that are manufactured, compliance with GMP is mandatory. We suggest that the TGA could collaborate with the SATCM to establish a specific set of evaluation criteria in relation to importation of proprietary forms of Chinese medicines. This collaboration could be considered as one of the implements of China-Australia Free Trade Agreement (the Agreement) signed by the Australian and Chinese governments on 17 June 2015. The Agreement encourages the cooperation in the field of Traditional Chinese Medicine (TCM) services, as well as trade in TCM and complementary medicines.

Recommendation 3: Scientific evidence for evaluation of efficacy of a product be consistent with the level of regulation of medicines

Evidence requirements (correspond to questions 3.6 to 3.8) proposed by the Reforms requires "All studies should be compliant with International Council for Harmonisation (ICH), and European Medicines Agency (EMA) guidelines adopted by the TGA at the time of application, this includes adopted guidelines on clinical trials, Good Clinical Practice (GCP), ethical certification, non-clinical studies and bioequivalence, as outlined in Part D of the Australian Regulatory Guidelines for Complementary Medicines (ARGCM). Literature searches should likewise meet the criteria specified in the ARGCM." Whiles ICH, EMA and Part D of the ARGCM are applicable for newly registered complementary medicines; FCMA believes that it is absolutely inappropriate to use these criteria for listed complementary medicines. Therefore, we suggest evidence requirements should be consistent with the regulatory status (listed or registered) of the medicines. Further details of the methodology of accepted evidence for the proposed new pathway will be submitted in due course as agreed on the Permitted indication workshop with Chinese medicine practitioners on 24 March 2017 in Melbourne.

Recommendation 4: All existing listed Chinese herbal products should be treated as grandfathered products

The FCMA does not agree with the proposed transition arrangements (question 7.1 of the Reforms) for any existing listed Chinese herbal products as any such changes will inevitably result in huge impacts on those existing products. The majority of single Chinese herbs, herbal products and proprietary forms of Chinese herbal medicines has been used in the country and has been safely consumed. We recommend that all the current herbal products that are in use and are already listed; to remain so and be exempt from the transition period. We consider it fair that if a sponsor of a currently listed herbal product with low or intermediate level indication

wishes to change the level of indication, the new pathway for assessment applies. The onus would be on the sponsor to do so if the sponsor chooses to change the indication level in the event of new discovery regarding a single ingredient or the formulation.

I hope that you would kindly consider this submission. Please feel free to contact me if any for any more information is required.

Yours sincerely,

Professor Tzi Chiang Lin, PhD.

National President, FCMA.

Prepared by:

Professor Tzi Chiang Lin

Dr. Sherman Gu,

Officer, FCMA

Dr. Grace Tham

Chair, Policy review panel, Victorian branch, FCMA