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Review of Medicines and Medical Devices Regulation Secretariat
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Dear Emeritus Professor Lloyd Sansom AO

Re: Review of Medicines and Medical Devices Regulation Chapter Nine: Regulation of Complementary Medicines

Thank you for the opportunity to respond to the current review of regulation of complementary medicines. 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 a 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.

Chinese medicine is recognised as a medical practice by the World Health Organization (WHO). Chinese herbal medicine practice differs from complementary medicines such as homeopathy, naturopathy and aromatherapy. The World Federation of Chinese Medicine Societies (WFCMS) which is comprised of159 member countries and districts and the world's largest and foremost authority on Chinese medicine, recently signed an agreement with the WHO as a cooperating Working Party for Chinese Medicine including the setting of international standards in Chinese Medicine. The FCMA, a member of the WFCMS will represent Australia on this Working Party and will be in charge of the Oceania zone.

After reviewing *Chapter Nine: Regulation of Complementary Medicines*, on behalf of the FCMA, I would like to make the following recommendations; after which I provide our 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. A different set of criteria be established for the importation of Chinese herbal products;
3. A different set of criteria be established for the evaluation of the level of risk and toxicity of the Chinese herbal medicines.

Rationale

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

The FCMA believes that a separate "Chinese Materia Medica Expert" committee/panel to deal solely with Chinese herbal products would be more appropriate than a blanket committee to evaluate the safety of herbal 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.

An example of the lack of full appreciation by regulatory bodies regarding the different methods in the use of whole herbs and single isolated substances could be seen in the potency of a plant/pharmaceutical product, Ma Huang (*Ephedra* used as ephedrine). *Ephedra* as a plant has been used in Chinese medicine for 2000 years (noted in ancient medical texts) and its effects and side effects were already noted with a known antidote. Even as a raw herb, Chinese medicine practitioners are aware of the dosage not to be exceeded for treatments. In Western pharmaceutical use, only the active substance (ephedrine) is extracted and the concentrated form is noted to very potent and potentially lethal. For this reason, *ephedra*, a substance currently listed on Schedule 4 of the Poisons Standard 2015, is banned from use by Chinese medicine practitioners. This is a clear lack of understanding by a Committee attempting to regulate another profession/s.

We also believe that a committee to evaluate, say, naturopathy or homeopathy is still inappropriate as these complementary medicine practices generally use extracted single substances rather than whole herbs (in the case of homoeopathy, the amounts

are below Avogadro's number in terms of amount of the substance in the homoeopathic formulation).

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

- Specialist/s in Chinese materia medica
- Specialist/s in Chinese patent products
- Chinese medicine practitioner/s
- Representation from Chinese medicine association/s
- Relevant members from the Therapeutic Goods Authority (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. The FCMA would be pleased to be of assistance to the Office of Complementary Medicines.

Recommendation 2: A different set of criteria be established for the importation of Chinese herbal products

The FCMA believes that products imported into Australia should be of good quality and safe for use. We suggest that the TGA collaborate with the State Administration of Traditional Chinese Medicine of China (SATCM) to establish a specific set of criteria in relation to importation of proprietary forms of Chinese medicines. Regarding safety, we agree that for products that are manufactured, compliance with Good Manufacturing Practice (GMP) is mandatory.

With respect to raw herbs, these are currently screened by Australian Customs and the Australian Quarantine Inspection Service (AQIS) and fall outside the jurisdiction of the TGA which handles only proprietary forms of complementary medicines. It is suggested that regulation of the safety and quality of raw herbs be integrated under one jurisdiction that is, combined with proprietary forms of Chinese herbal medicines.

Recommendation 3: A different set of criteria to be established for the evaluation of the level of risk and toxicity of Chinese herbal medicines

The FCMA is concerned with the current way in which some Chinese herbal medicines are scheduled and regulated, in that it restricts the availability of the range of products that could be used by Chinese medicine practitioners even though all Chinese herbal medicine practitioners have been registered under the Australian Health Practitioner Regulation Agency (AHPRA). These restrictions affect the efficacy and efficiency of treatments given to those seeking assistance.

Due to the concept of food as medicine and medicine as food, we consider the current rescheduling of foods to be problematic for Chinese herbal practice. Chinese herbal

practice uses most products in their natural state. Many of the natural ingredients are normal food products which could be brought from Asian grocery stores such as Hong Qu (Red Yeast Rice). While these are considered safe to the general public, the TGA has banned their use by Chinese medicine practitioners. It makes no sense that while the public who has no knowledge of the medicinal use and safe dosages of these substances are given full access, Chinese medicine practitioners who have the knowledge are not given access. Red yeast rice is frequently used in general cooking and to enhance the flavor of food by chefs. These ingredients are safer in the hands of practitioners because of the controlled dosages being dispensed. Isolated constituents of herbs that could be potentially toxic in concentrated forms as used in western pharmaceuticals, may be no more toxic than foods when consumed at appropriate dosages in their natural form. Importantly when any single herbal product or formulations of several herbs are dispensed, Chinese herbal medicine practitioners are knowledgeable in the dosages to be used; therefore such herbs are already safer in the hands of practitioners than when used by the general public as foods. It makes little sense to ban practitioners from using herbs when dosages for dispensing are controlled. For this reason, we believe that it is necessary for a different set of criteria to be established for scheduling of Chinese herbal medicines. This illustration equates to, for example, Panadol being easily accessible to the public via supermarkets, yet, doctors not being allowed to prescribe it.

It is for the above reasons that we recommend that a separate and dedicated committee be set up to develop criteria appropriate and relevant to the way Chinese herbal medicines are used. This would mean that the current rescheduling of Chinese herbal medicines from Schedule 4 to Schedule 9 and the Appendixes of the Poisons Standard would be reviewed with renewed understanding of the safety of the herbs.

With regard to products that could be potentially toxic, consultation with a committee of experts in Chinese herbal pharmacopeia and collaboration with similar authorities overseas like the SATCM or the WFCMS, would be of much assistance and desirable.

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

Yours sincerely,

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