Organisation response to the Chinese Medicine Board of Australia public consultation on the revised Guidelines for safe Chinese herbal medicine practice

Response from Chinese Medicine Industry Council

(Note: All responses have been reproduced as provided and have not been edited or otherwise altered.)

Question One: Are there any specific issues or effects from applying the current guidelines? If so, what are they?

Response provided to the question: Are there any specific issues or effects from applying the current guidelines? If so, what are they?
No. the current guideline was intensively consulted and amended before being announced and formally implemented. And after many years' internal trainings, practitioners are getting familiar with it, and no issues have been aware of, and no complaints have been received by the CMIC. As such, we can't see any reasons to change the main body, except some of the references that may need to be updated.

Question Two: Is the content and structure of the draft revised guidelines helpful, clear, and relevant?

Response provided to the question: Is the content and structure of the draft revised guidelines helpful, clear and relevant?
No. The revised guideline will impose a big impact on the industry, potential adverse effect and confusion could be expected. Especially the following areas are not acceptable: 1. The revised Guideline changed the current term of "Chinese herbal medicines" and "Chinese herbs" into "medicine" and "medicinal ingredients" in the main text contents, which are neither reasonable, nor in line with the document's title. Chinese herbs can be used as general retail products to meet the traditional use and belief for Australian ethnic groups or as food and soup ingredients for Asian Australians. It can only be regarded as an herbal medicine material when used under the theory of Traditional Chinese Medicine (TCM). The term of "Medicinal ingredients" should be used for manufactured herbal medicines which are listed on the Australian Therapeutic Goods Register (ARTG). In addition, many Chinese herbs have dual usages, one for therapeutic, one for food ingredients, like Dang Sheng, Fu Ling, Xing Ren (apricot kernel), Red dates, Orange peel, Cordyceps Mushroom and Ejiao. According to public released data by the Chinese government, there are more than 100 kinds of Chinese herbs being listed as a dual usage of food and therapeutic. As such, we oppose changing or upgrading the term of Chinese herbal medicine into " medicine " , or Chinese herbs into " medicinal ingredients". 2. The revised guideline added Clause 9 (page 17) "quality of medicinal ingredients" which simply and unreasonably judges the herbs quality based on labelled expiry date. We support to address the quality of Chinese herbs, but it comprises a wide range of controlling factors. If the CMBA intend to revise the guideline, it should delete this Clause 9 or allow the Chinese herbal medicine practitioners to make a judgment of the herbs quality before releasing for use, rather simply based on the labelled expiry dates which are actually not justified by exporters. Due to the import requirements for pre-packed Chinese herbs, it requires all packaging to have an Expiry Date on the label. To the best of our knowledge, these expiry dates labelled by exporters are just a "formality" rather than "real", because the shelf-life for each herb is not justified by "stability studies" (no such a requirement by exporter's jurisdiction as of today). In addition, for some herbs, such as Chen Pi, Ban Xia, etc, the quality increases throughout the time if stored correctly and so-called "the longer storage, the better quality" in Chinese medicine. On the other hand, some herbs should be dumped before the labelled expiry dates if not properly managed in transportation or storage. In conclusion, unlike manufactured Chinese herbal medicine, the practitioners/dispensers who sells and releases the herbs to customers should have the ability, liability and discretion to judge the final quality for use.

Question Three: Is there anything missing that needs to be added to the draft revised guidelines, if so please provide details?

Response provided to the question: Is there anything missing that needs to be added to the draft revised guidelines, if so please provide details?
Yes, some examples are as below: 1. Background on page 7, "The medicinal name in Chinese characters corresponds to the name in pin yin as found in the PPRC. However, the name does not always refer to a single species name, since one ingredient may be sourced from more than one species. This can result in confusion that represents a risk to public safety, for example there are several recorded incidents in which consumption of Chinese herbs has resulted in renal failure due to the toxin aristolochic acid and the events have been attributed to a lack of clarity in naming leading to confusion between herbs with similar names. If an ingredient is written as fang ji 防己, it can be mistaken as mu fang ji 木防己 (Aristolochiae seu Cocculi radix), or guang fang ji 广防己 (Aristolochiae fangchi), or han fang ji 汉 防己 (Stephania tetrandra S. Moore).".This example is no more valid. In Chinese pharmacopeia (Vol.1, 2015), "Fang Ji" refers to only one species, which is " Stephania tetrandra S. Moore". 2. "TGA Therapeutic Goods Order no. 69 — General requirements for labels for medicines as amended made under section 10 of the Therapeutic Goods Act 1989. Available at www.comlaw.gov.au/Details/F2009C00264" on page 18 is no more valid, and need to update as below: "Therapeutic Goods Order No. 92 - Standard for labels of non-prescription medicines": https://www.legislation.gov.au/Series/F2016L01287

Question Four: Taken as a whole, are the guidelines practical to implement and sufficient for safe prescription writing, labelling and dispensing of Chinese herbal medicines?

Response provided to the question: Taken as a whole, are the guidelines practical to implement and sufficient for safe prescription writing, labelling and dispensing of Chinese herbal medicine?
current version should continue without a need for major changes except some references. If needed, please make further amendment based on our justifications and comments as above.

Question Five: The Board is proposing a five-year review period of the guidelines. Do you agree?

Response provided to the question: The Board is proposing a five-year review period of the guidelines. Do you agree?
Yes, agree

Question Six: Do you have any other comments?

Response provided to the question: Do you have any other comments?
yes. As what the board did in 2015, the final version should be sent to some key stakeholders for a final review before release.