20 August 2012

TGA Labelling and Packaging Review
PO Box 100
Woden
ACT 2606

Via Email: labellingreview@tga.gov.au

RE: CMIC Submission -TGA Medicine labelling and Packaging Review Consultation Paper (MLAPRCP)

Dear Review Panel

The paper addresses the important issues very well and offers solutions to substantially improve the safe use of products purchased from a supermarket or a pharmacy without a prescription, or products purchased following a consultation with a health professional, usually with a prescription.

However, we believe that the proposed changes to labels and packages are specifically relevant for pharmaceutical drugs and have limited, if any, relevance for Traditional herbal medicines. The current labeling requirements for multi-ingredient Chinese herbal medicines, TGO 69, adequately address all of the issues identified in the MLAPRCP. Specifically:

1. “Information about the active ingredient(s) contained in the medicine is not always easy to find.” The name and quantity of all active ingredients are displayed on the product label in letters of the minimum specified height. We have not received any complaints about this issue.

2. “Use of the same brand name for a range of products with different active ingredients resulting in look-alike medicine branding (this is known as brand extension or trade name extension)” This does not occur in the Chinese medicine industry. Traditional formulations marketed by different sponsors retain the traditional name and are clearly distinguished by the individual sponsor’s specific company logo and colours. Moreover, any differences in quantities of active ingredients between products are clearly displayed on each label.

3. “Medicine names that look-alike and sound-alike that can lead to use of the incorrect medicine.” In our opinion, names of Chinese herbal formulas are quite specific and even in cases where names are similar (e.g. Liu Wei Di Huang Wan and Ba Wei Di Huang Wan) the degree of specialist knowledge required to recognize and work with these medicines would ensure against the sort of confusion that may be encountered by a non-professional. Thus, Chinese names in pin yin should not be included under this point. Moreover, the vast majority of Chinese herbal medicines that are marketed in Australia have dual
names, i.e. both pin yin as well as English, leading to very clear differences in medicines with similar Chinese (or English) names. In our experience this is not a safety issue for Chinese herbal medicines.

4. “Medicine containers and packaging that looks like that of another medicine.” This is not a safety issue for Australian Chinese herbal medicines, as they are adequately distinguishable from other medicines. We have not received any complaints regarding this issue.

5. “Lack of a standardized format for information included on medicines labels and packaging”. We have found that the current labeling requirements of TGO 69 are sufficient to enable both dispensers and end users to identify the active ingredients, dosage and indications of a medicine. We have not received any complaints in regard to this issue and we believe that the current standards are satisfactory.

6. “Dispensing stickers that cover up important information.” Not relevant to Chinese herbal medicines.

7. “Information provided on blister strips.” See comments to point 5, above.

8. “Information included on small containers.” See comments to point 5, above.

9. “Information provided in pack inserts.” See comments to point 5, above.

Although it is arguable that the present format for information included on medicines labels and packaging could be improved by having a uniform template for all medicines, there are two important points in regard to Chinese herbal medicines:

a) The current system for complementary medicine is sound and has not led to any safety concerns.

b) The recent change of the AAN list in terms of the herbal names has necessitated the re-molding and re-printing of new labels for almost all the Chinese herbal products on the ARTG, the cost of which is borne by individual sponsors. At the present time, a second round of label changes would place a considerable additional financial burden on sponsors, which does not appear to be justifiable, or necessary.

In summary, our position is that the proposed changes should only apply to OTC and prescription medicines and that it should not include Complementary medicines, specifically traditional Chinese herbal medicines.

Should anything you’d like to hear further for the review, please feel free to let us know.

Kind regards

Max Ma

For and on behalf of
Chinese Medicine Industry Council of Australia Ltd (CMIC)