10 April 2017

Dr Larry Kelly
Assistant Secretary
Medicines Regulation Division
Therapeutic Goods Administration
Department of Health
PO Box 100
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Dear Assistant Secretary

Response to the discussion paper on the reforms to the regulatory framework for complementary medicines by the Therapeutic Goods Administration (the discussion paper)

Thank you for the opportunity to respond to the discussion paper. This response is jointly provided by the fourteen National Boards in the National Registration and Accreditation Scheme, and the Australian Health Practitioner Regulation Agency which administers the Scheme in partnership with the Boards. The response includes some specific comments from the Chinese Medicine Board of Australia, which has a particular interest in the proposed reforms.

The National Law includes provisions for the registration of practitioners and various post registration monitoring mechanisms such as conditions or restrictions on registration, requirements for appropriate advertising of health services and notification (complaint and concerns) procedures.

There needs to be alignment between the regulation of health practitioners and the regulation of treatments[1] that they might use. A number of professions including Chinese Medicine rely on access to appropriate therapeutic goods to deliver services and support community health.

In general, the Boards and AHPRA support the proposed reforms and the underpinning principles. The current listing system which respects the consumer right of timely access to low risk products is retained and will be greatly strengthened by the removal of the free text field for indications and replaced by a more controlled approach to permitted indications.

We consider that the proposed additional pathway is a common sense approach to incentivising the industry towards an option for independent assessment of product efficacy and is commensurate with ensuring public safety in regard to more substantial product indications and therapeutic claims. The approach to evidence for therapeutic claims provides greater clarity and aligns well with current work across National Boards on similar issues relating to advertising of regulated health services.

Specific comments from the Chinese Medicine Board of Australia

Since 2012, the Chinese Medicine Board of Australia (CMBA) has been responsible for the regulation of Chinese medicine practitioners under the Health Practitioner Regulation National Law, as in force in each State and Territory (the National Law). In addition to supporting the general comments above, the CMBA offers the following specific comments on the proposed reforms.

[1] Including medicines and devices

Registered Chinese medicine practitioners generally prescribe herbal medicines which are formulated on a one-off basis for each patient based on that patient's particular needs. These extemporaneous products are exempt from both inclusion in the *Australian Register for Therapeutic Goods* and the GMP[2] manufacturing requirements of the *Therapeutic Goods Act* 1989. It should be noted that the CMBA is implementing *Guidelines for Safe Chinese Herbal Medicine Practice* (see CMBA *website*) which will come into full effect in November 2017.

There is also an increasing availability and use by practitioners of commercial Chinese herbal medicines in newer dosage forms such as tablets, capsules and granules. Some of these medicines are listed as 'practitioner dispensing-only' products which should be supplied only to practitioners without the uses being included on their labels because a dispensing label is attached by the practitioner when the product is supplied to the individual patient. The dispensing label includes information on the purpose (which might be an off-label use). Like the regulation of extemporaneously prepared medicines, this is considered a practical regulatory approach and an important recognition of the professional role and responsibilities of the practitioner.

In addition, Chinese medicine practitioners, especially acupuncturists, use devices such as acupuncture needles, cups, dermal hammers and electro-acupuncture machines/stimulators.

In the area of Chinese medicine, it is important to give adequate consideration to the underlying philosophy of Chinese medicine theory as well as the relevance and importance of the evidence based practice which has evolved from centuries of traditional use. In terms of permitted indications, the CMBA encourages the TGA to ensure that the regulatory approach adequately recognises the terminology used in Chinese medicine. The World Health Organisation has developed a set of common terminologies for Chinese medicine, many of them are fundamentally different from Western medicine. They are integral and crucial to the clinical decision making in the practice of Chinese medicine including the expression of the uses of treatments.

More specifically, the CMBA suggests that thought needs to be given to the application of 'alleviation' of disease/disorders/conditions when defining permitted indications. The examples given in the discussion paper for listed medicines are appropriately consistent with the alleviation of mild symptoms or disease yet there is the inference that an indication cannot claim alleviation of a disease. While the interpretation of 'cure' and 'prevention' are relatively clear, 'alleviation' is a graduated term which needs clarity in relation to its application.

The CMBA is also very supportive of encouraging more investment and innovation by the industry particularly where it results in a stronger evidence base. However, when considering the granting of market exclusivity, it needs to be recognised that many of the ingredients used in Chinese medicine are naturally occurring materials and most of the formulations are regarded as core traditional formulations of Chinese medicine.

The CMBA has recently developed a compendium of herbs and other materials used in Chinese Medicine to assist in consistent terminology in prescribing and dispensing. This may also be a useful resource for the TGA - see CMBA Nomenclature Compendium .

The CMBA appreciated the opportunity to meet with the TGA on 23 March 2017 to discuss aspects of the reforms that have particular implications for Chinese Medicine practitioners.

Conclusion

There are other areas of mutual interest for the TGA and the National Scheme such as encouraging reporting of any adverse events to treatments, encouraging appropriate advertising and informing importers of Chinese medicine products, which might include registered practitioners, of their responsibilities. We are keen to continue the close cooperation and communication with the TGA as we share very similar risk-based decision making in the interests of ensuring public safety and benefit.

[2] Good Manufacturing Practice

Please contact me if you wish to discuss any aspect of this response.

Yours sincerely

MARTIN FLETCHER
Chief Executive Officer