Chinese Medicine Industry Council of Australia Ltd
澳大利亞中藥行業聯合會
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The Section Manager

Complementary Medicines Reform Section

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By: online submission

Re: Critical Feedback and Recommendations from CMIC in regarding the TGA Consultation: Reforms to the regulatory framework for complementary medicines -- Assessment pathways

The Chinese Medicine Industry Council of Australia Ltd (CMIC) is the peak body representing the importers and the suppliers of Chinese Herbal Medicines (CHM), an integral part of Traditional Chinese Medicines (TCM). Practitioners of TCM are regulated by AHPRA via the Chinese Medicine Board of Australia (CMBA), while finished CHM products prescribed by practitioners and accessed for self-medication by the public are regulated by the TGA as part of Complementary medicines (CM) policy and guidelines.

CMIC's key values are Safety, Quality, Efficacy, Availability and Affordability. CMIC plays a key role in bridge-building between the regulators and industry to facilitate the efficient and effective management of CHM supply in Australia. It benefits practitioners, patients and the general public, as well as governments as a whole.

CMIC welcomes strategic reforms to improve the current CM assessment and management system by fixing loopholes based on safety, quality and efficacy concerns. However, it is important this strategic reform will not cause unduly dramatic turns and changes to existing established arrangements. At least, it should NOT sacrifice the interests of one interest for benefit of another interest, without good reason, or impose excessive or unnecessary burdens on the industry.

We acknowledge that the TGA has put in a tremendous effort in refining the system. However, from the perspective of the TCM and its therapeutic framework, we wish to point out our concerns, provide suggestions, and propose solutions for your consideration:

Concerns 1: kind of evidence for the proposed New Pathway.

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We support the scientific evidence from well-designed clinical trials to be used as a Method 1. However, a strong concern for the current proposal in Method 2 , which neither accepts herbal medicines nor accepts quality Traditional evidence.

This will put the Traditional herbal medicine, including TCM into a disadvantaged position, and potentially have a bias from the level of policy.

For your information, there are hundreds of TCM classical set formulas (Jiang Fang) created about 2000 years ago. Having been validated and refined during its long history of use, a significant amount of clinical practice and publications were developed by well-known ancient and modern Chinese physicians. These classical formulas are popularly used in the industry and profession. A portion of well-recognised formulas have been adopted into the Chinese pharmacopeia or approved by the Chinese government as finished products and/or compiled from university' textbooks that have been taught globally including in Australia up to the present.

These classic formulas serve like a bible well recognised by practitioners within the industry. Clinical effectiveness has been validated during a long time of practice and it is believed that practitioners and patients or consumers do need this kind of finished products in the market with a more definitive indications. However, many of them have yet done the modern double-blind clinical trials due to a range of factors which may include funding, patent right, motivations, incentives, or policies.

Solutions: Table 4 of evidence dossier requirements for the new pathway: the Method 2 in the new pathway should add in a category that **quality** Traditional evidence for traditional Chinese medicine will be accepted.

Category of evidence, Table 2

In Category C, should add in: one overseas government approval evidence plus one reference evidence from an overseas pharmacopeia; OR two overseas government approval evidence; OR two source of international (two different jurisdictions) tertiary educational textbook referenced classic formulas with justifications of quality control method including full steps of the manufacturing process.

Concern 2 : Permitted indication for TCM products

We understand and support the government's move to implement a pre-approved indication list for low indications to minimise the misuse or abuse in the free text system in eBS system.

However, considering the nature of the TCM and its complexity and characteristic for the presentation of the product indication, we believe it is very challengeable to create a complete FULL TCM indication list to choose from before a particularly formulated product created or put in place. Thus the options one and three for implementation of the permitted indications list seems impossible for TCM products.

Solutions: We appreciate your recent consideration to abandoning the exact wording of "coding" concept, and wish to accept the " word to word effect", and as such Option Two seems much closer to the need subject to all contents under the TCM indication elements to be fully accommodated.

Rationale:

A typical and complete indication for a TCM product is more definitive with the context of TCM theory, and it may comprise FOUR elements in the TCM indication, namely Symptoms (1), disease/conditions (2) , plus pattern differentiation: location of pathogenic (3), and nature of the pathogenic (4).

Eg: *Traditionally used in Chinese medicine to resolve phlegm to relieve a cough caused by lung-Yin deficiency or lung-heat presented.*

Each element may have tens or hundreds of kinds /types, thus leading to numerous different combinations for countless indications. Therefore attempting to create a full list of coded indications for TCM products requires enormous resources.

Therefore, a TCM-specific subcategory to be modified with extended Qualifier in Option 2 may help resolve the concerns subject to contents of FULL elements in FOUR areas in TCM terminologies are well developed and pre-installed into the eBS system.

To prevent any mistake, shortages or overlook, a green period of three years after a transitional period should be FREELY added in by the sponsors or at least by the TCM Industry body. This seems necessary and should be part of the new policy.

Concerns 3: new policy to apply existing products

Due to the fact of "cost-recover" system for Australian therapeutic goods, the proposed policy should apply to any NEW listing applications only , while the existing listed products should be maintained under the existing policy (similar to Grand-parenting medicine), though, case by case review for post-market assessment and rectification for non-compliances are still necessary.

In other words, to minimise the unnecessary burden to the industry, if the government wishes to repudiate the existing system which had been operating successfully until now, then it is not the fault of the industry. Someone has to take responsibility for shortcomings in the system and those who committed mistakes or abused the system should pay the labour cost of updates in the ARTG, including the related cost of re-labelling, rather than the industry that has been operating legally within the system.

Solutions: New policy and new pathway apply to new applications of new listing unless sponsors wish to upgrade their existing listed products to the level of the new pathway.

Concerns 4: Presentation of claimer statements

The proposed Option 1 and Option 2 for Claimer as a statement ON LABEL is likely making the medicine in the new pathway over outstanding in the market, and may potentially result in a misunderstanding or perception that this is the BEST effective medicine, thus putting into an unfair position for registered medicines and those medicines for which evidence is reviewed and approved as compliance by post market assessment.

Solutions: a Unique Visual Identifier to be established and named for the medicines under the new pathway. For instance, based on the risk level of indications, CM is to be classified into three tiers, namely Listing, Listing Plus and Registered. For Listing Plus, it is to be symbolized as AUST LP xxxxxxx. This is simple, consistent, standardized and easily recognizable by industry and consumers, and NO other statement for efficacy approval should be allowed on Label.

Concerns 5: Protection for new ingredients

We appreciate and support the TGA's initiative to provide incentives to sponsors who have been striving to successfully make a new ingredient to be included in the "permissible ingredients list", so that anybody could be freely to use while two (2) years exclusive right and or three (3) years dada protection as an incentive to be given to the developer as proposed.

CMIC believes TWO (2) years protection is not attractive enough or not economically worthy for a sponsor to spend as much as A$100k to develop a new ingredient. It is necessary to take into account of the time needed for a new listing, new design of packaging, lead-time in the manufacturing, shipping and pre-sales marketing, all of which may take more than a year. Also, the two years' protection is apparently insufficient. Meanwhile, once the ingredient is available, the formula can always be variable via certain level of modification. Therefore, three (3) years data package protection can provide little help or protection for the developer.

Solutions: the inclusion process and pathway of a new CM ingredient adding into " permissible ingredients list" should be enhanced by the following concept and ways:

1. The current "permissible ingredients list" is based on the product's ingredients which were available almost 30 years ago from grandfather medicines. It is not complete as it should because of the fact of undeveloped complementary medicine trading connections between overseas countries (like China) and Australia at that time.
2. The responsibility for the establishment and inclusion of a comprehensive FULL list of CM ingredients to serve the public is the responsibility of government, NOT the sponsors.
3. CMIC identified there are approximately 30 kinds of frequently-used TCM ingredients that are NOT yet on the permissible list. Thus it has hindered the supply for a range of effective TCM products to be available in Australia. It is in contradiction to the best interest of public consumers and patients in Australia, as well as local TCM practitioners.
4. To authorise CM professional bodies to raise a list of important ingredients list that should be included in the "permissible ingredients list" for awareness, consensus and project planning.
5. As recommended by the Expert Panel, to proactively seek comparable government to exchange or share the required technology and information for the raised or concerned ingredients for assessment. Thus it may help saving tremendous of time and resources.
6. For TCM product where TCM was originally invented, CMIC recommend that China should be regarded as a "comparable" government in terms of TCM technology and management.
7. Meanwhile, to encourage sponsors to invest in developing a new ingredient submission, five (5) years ingredient and data protection are necessary.

Concerns 6: Three years transitional period

In additional to the above, CMIC believe the proposed 3-year transition period seems to contradict the maximum product lifespan of 5 years to some extent. For instance, a new batch of already-labelled product with 5 years of expiry date will have to be removed from the market at the 3rd year when transition period ends, resulting in significant losses to sponsors.

Solutions: Five (5) years transitional period is reasonable if new policy applying to all products is finally determined.

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In general, when implementing the reform of panel's proposal, CMIC would like to draw your kind attention to the following areas which may assist in your consideration:

1. The TCM profession has been regulated under NRAS since 1 July 2012 as a part of Australian's healthcare professions' workforce. Therefore the product supply policy should be harmonised with and comparable to the nature and the need of this profession.

2. TCM product could be considered as a separate category similar to that of " sunscreens", for which special assessing criteria and arrangement to be considered under the new reform system.

3. TCM originated in China, the authentication and integration of TCM should be maintained to better serve the public. The new policies regarding the TCM products assessment need to be in line with the International practice of other jurisdictions such as China, Singapore, Canada, Malaysia, Hong Kang and international standards for TCM, such as ISO/TC249 or WHO.

4. The proposed Assessment Pathway where seriously affects the sustainability of TCM products, may have potential contradictions with the spirit or provisions of China-Australia Free Trade Agreement (ChAFTA) and need to be carefully addressed.

5. CMIC recommends that the TGA consider a long-term plan to improve in this important area by setting up a TCM committee under the TGA; to create a TCM assessment pathway and to develop guidelines for the management of listing/registration of TCM products based on TCM theories and rules, as well as the kind of scientific evidence. In this way, it can be harmonised with the needs of TCM practitioners who are regulated under AHPRA by the CMBA.

Dr. Max Ma

For and on behalf of CMIC

23 March 2017