Submission on the consultation: Reforms to the regulatory framework for complementary medicines: Assessment pathways

Date: 28th March 2017

To:

Complementary Medicines Reform Section

Complementary and OTC Medicines Branch

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General comments
The presentation and format of the consultation paper, the topics being discussed, their interrelationship, and the lack of information with respect to some of the topics make it very difficult to provide meaningful feedback.

It is important that the proposed list of permitted indications, along with further details and clarity around what constitutes an intermediate indication, and the revised evidence guidelines be provided for review and comment as a matter of priority. It is only with this information that the proposals put forward can be appropriately sense checked.

Assessment Pathways for complementary medicines
Recommendation, 39, of the Review of Medicines and Medical Devices Regulation states “That there be three options by which sponsors may seek entry into the ARTG of complementary medicinal products and other listed medicinal products for supply in Australia.”

The consultation document states that “Introduction of the new pathway will bridge the significant gap that exists for industry between the evidence requirements, costs and timeframes for the existing listed and registered medicines pathways. This will allow greater consumer access to a wider range of evidence-based remedies to self-manage their health.”

Whilst the introduction of an additional assessment pathway meets the objective of recommendation 39, it does not provide any details about how the deliverables described in the above statements will be achieved.

As it has been proposed, the additional pathway has basically the same evidence requirements as the existing AUST R pathway, while on face value making the evidence requirements for the existing AUST R pathway less flexible. It also appears, based on the limited information provided, that there is a recalibration upwards for the existing AUST R category. This upward recalibration is not consistent with recommendation 39 which states “Option three - Registration of a complementary medicinal product in the ARTG following an assessment by the NRA of the product for safety, quality and efficacy in accordance with existing requirements for registration of complementary medicines.”

There are several factual errors, inconsistencies and ambiguities contained within Table 1. Eligibility criteria and the regulatory requirements for the three assessment pathways. The table states registered medicines includes those ingredients included (or meet the criteria for inclusion) in a schedule to the Poisons Standard, other than schedule 4, 8 or 9. This is incorrect, registered medicines can currently contain ingredients from the permitted ingredients list, or ingredients that are not included on the permitted ingredients list and that are not included (or meet the criteria for inclusion) in a schedule to the Poisons Standard, other than schedule 4, 8 or 9. There is also currently no restriction on registered medicines using only listable indications.

Due to the lack of clarity surrounding the new pathway, and the proposed changes to the existing pathways, it is suggested that a matrix be developed by the TGA that clearly describes and compares the current two tiered regulatory framework against the proposed three tiered regulatory framework. This should be developed and published for further consultation prior to moving forward with implementation of the new pathway.

It is our view that there will be very few applications submitted for evaluation through the new pathway. We therefore recommend that the TGA engage in further consultation to determine how the new pathway can be developed to increase transparency for consumers, provide additional flexibility for sponsors and support innovation. It makes absolutely no sense to develop a new pathway that will not be utilised to any great extent (as is the case with the current AUST R pathway).

As an overarching principle, there should be consistency of evidence and quality requirements across the medicinal products framework, between AUST R OTC products, AUST R complementary medicine products and new pathway complementary medicine products.

Implementing a list of permitted indications
It is our view that “Option 2: Core permitted indications which can be modified with pre-approved qualifiers” is the most suitable approach to developing a list of permitted indications.

Claiming evidence of efficacy
We are opposed to the introduction of claimers only for complementary medicines that have been assessed for efficacy. This has the potential to confuse consumers and cast doubt on other medicinal products and medical devices that have been assessed by the TGA.

The use of a TGA endorsement on product and in marketing materials for a sub set of evaluated products has the potential to create market distortions that could be considered anti-competitive.

We suggest that further research should be undertaken by the TGA to obtain consumer insights into this proposal prior to implementation.

Incentives for innovation
The current registration process in and of itself confers a level of protection for sponsors of these products.

Whilst supported in principle the proposed criteria for innovation incentives requires further development and consultation to provide meaningful deliverables.

The proposed timeframe of two years for exclusivity for new ingredients is insufficient to deliver a suitable return on the significant investment in the generation of safety and efficacy data for an ingredient. We propose that the following approach be given consideration.

For new ingredients that are the subject of a TGA recognised pharmacopoeial monograph (Ph. Eur. or USP) where the quality standard of the ingredient is established under a legislated standard, it is proposed that a period of three years market exclusivity from the date of approval be granted to the ingredient applicant.

For new ingredients that are NOT the subject of a TGA recognised pharmacopoeial monograph (Ph. Eur. or USP), it is proposed that a period of three years market exclusivity from the date of approval be granted to the ingredient applicant AND that the compositional guideline (quality standard) NOT be published by the TGA.

An alternative approach for new ingredients that are NOT the subject of a TGA recognised pharmacopoeial monograph (Ph. Eur. or USP) is for TGA to NOT publish the compositional guideline. This approach requires no legislative change and can implemented immediately.

Consideration should also be given to linking the approval for new ingredients that are NOT the subject of a TGA recognised pharmacopoeial monograph (Ph. Eur. or USP), to a specific manufacturer/manufacturing site. This would help to ensure that the manufacturing process is consistent with the manufacturing, quality and safety data submitted in the application. This approach would NOT need to be limited by an exclusivity period but would provide a level of exclusivity for the applicant.

With respect to protection for efficacy data from clinical studies we support the proposal for a three year period of data protection for applications supported by direct (product specific) clinical data.