Submission for:
Consultation: Reforms to the regulatory framework for complementary medicines (Assessment pathways)

I welcome the opportunity to address the submission in relation to the regulatory reforms for complementary medicines. My business involves a clinic, offering Acupuncture and Chinese herbal medicine consultations as well as a TGA licensed compounding dispensary. Please note, we are not directly manufacturers but apply GMP principles to our operation.

I wholeheartedly support the guiding principles bringing about the reform, as in recent years shocking discoveries especially relating to Chinese herbal patents have come to light and have upset not only the general public but also industry professionals.

My first observation is that the reform has been initiated by a panel consisting of three academic experts in western sciences, particularly pharmacy. While I appreciate they are undoubtedly highly acclaimed individuals, I am disappointed to see that there is no panel representative with any experience or background in complementary medicine. As such, their recommendations are hence based solely on their primary knowledge and expertise in pharmaceutics.

Our profession (Chinese herbalists, manufacturers and dispensers) believes it is important to have a key representative championing our interests as well for your expert advisory panel, to offer balance and perspective. A candidate such as [redacted] could offer great insight, having been involved in research for complementary medicines and particularly in Chinese medicine for almost three decades.

<u>The below outlines my view on the various recommendations included in the report.</u>

<u>3. Assessment pathways</u>

Proposal one and two:

3.1 - I welcome the introduction of a risk-based approach for therapeutic indications and hence the addition of a new pathway.

3.2 - I reject your proposal that complementary medicines lacking high quality scientific evidence are excluded from the new pathway. In general, all our formula products are supported by extensive empirical data. We do not use single ingredients but highly complex formulas that are based on 2,500 years of traditional use. Our medicine is not easily translated into Western scientific applications. I doubt, that our industry will be able to provide high-quality scientific evidence for those hundreds of formulas that were developed over thousands of years.

3.3 - I understand that chemical compounds and their action in the body is one way to assess efficacy but it's not the only way.

Proposal three

3.4 and 3.5 - As the TGA is excluding any evidence of traditional use to access the new pathway, we will be unable to provide clinical data (as research on formula is complex and difficult to design). Hence, I will reject this proposal, as empirical evidence of our formulas somehow needs to be included. I understand additional factors and criteria might have to be developed in order to facilitate this.

Proposal four

3.6 – Evidence-based requirements for complementary medicine accessing the new pathway is unacceptable and unachievable. See comments for proposal three.

3.7 – Broadly, I observe that the proposed assessment levels themselves align with the risk base, however I do not support the evidence-base required to satisfy those various assessment levels.

3.8 – See comments 3.3 for proposal three.

4. Implementing a list of permitted indications

Proposal five I do not possess sufficient experience to comment on this proposal.

Proposal six I do not possess sufficient experience in this area. However, the outline of the implementation and permitted indications as suggested makes sense. I understand that the TGA would go ahead and develop a comprehensive list of traditional and scientific core indications with the aid of an expert in the Chinese medicine field.

5. Claiming evidence of efficacy

Proposal seven I do not have sufficient experience or exposure to comment on this proposal.

6. Incentives for innovation

Proposal eight

6.1 – No comment.

6.2 - I agree with the proposal of a limited period of market exclusivity of two years.

6.3 – 6.4 – No comment.

Proposal nine

6.5 – 6.8 - I do not have sufficient experience or exposure to comment, however I suspect that clinical data for a formulation of Chinese herbal medicine will prove challenging.

7. Implementation

7.1 - I feel that a three year period for transitional arrangements sufficient.

7.2 – Nil.