Incentives for Research into Complementary Medicines – Joint Position Paper

The Australian Self Medication Industry (ASMI), Complementary Medicines Australia (CMA), and the National Institute of Complementary Medicine (NICM) have independently provided submissions to the TGA to support the reforms recommended under the MMDR to enhance incentives for research and innovation for Complementary Medicines. The following paper sets out the agreed principles and elements considered necessary for a model for incentivisation by industry and academia.

Agreed Principles

- **Data Protection**. Sponsors of Pre-Market Assessed (PMA) complementary medicines should be protected against unauthorised use of their novel clinical data in other PMA complementary medicines.
- **Formulation Protection**. Sponsors of PMA complementary medicines with novel clinical data should be protected from unauthorised listed (AUST L) medicines replicating key formulation details.
- **Five year protection.** A minimum of 5 years of protection from the approval of the PMA medicine is considered necessary to adequately support an incentive for research.

Essential Elements

- A dual approach is required incorporating data protection and formulation protection mechanisms, underpinned by a central database of clinical trials and product composition details that are subject to protection. Each approach operates independently of the other, although for ease of reference they may be both referred to within a single line of the database for a protected product.
- **The Database:** A central instrument for providing data and formulation protection containing:
    - registered clinical trials and persons/entities with authority to use these;
    - product details that are subject to formulation protection;
    - dates/duration of data and formulation protection.
    - Further consultation will be needed on the exact details included in the database, however the current proposal considers the clinical trial registration number, and the details of the active ingredients and quantities to likely be necessary.
    - The point of publication on the database will also require further consultation to determine how best to align the protection mechanisms with publication deadlines of research institutes and the application assessment times for Assessed Listed and Registered complementary medicines.
- **Data Protection:** A valid product supported by novel clinical data should be able to register the clinical trial on the database, enabling the TGA to ascertain during screening of any other PMA medicines application if the primary clinical data is subject to data protection. An unauthorised product using protected data as primary evidence should not proceed to evaluation.
- **Formulation Protection:** A valid product supported by novel clinical data should be able to register the critical formulation details (active ingredients and quantities) on the database.
    - Mechanisms should protect against listed products attempting to capitalise on a PMA CM's formulation (ingredients at the same dose or proportion), in a way that is sufficiently protective without being overly restrictive of expected listed medicine innovation.
    - Applicants of new listed medicines should be required to certify that their product does not replicate a protected formulation (unless it is the grouping of an existing ARTG product).
    - The Sponsor of a PMA protected formulation should be able to refer the TGA to a new listing that breaches the parameters included on the database.