# The Sansom Review of Medicines and Medical Devices Regulation: Streamlining the approval and advertising of therapeutic goods in Australia

## About the Sansom Review

**Two reports on the review to medicines and medical devices were prepared by the expert panel, together known as the Sansom Review. In September 2016, the Australian Government provided its written response to the Review, committing to the implementation 56 of the 58 recommendations.**

**The changes to the regulations will create a more streamlined and efficient system for the regulation of therapeutic goods in Australia. The recommendations will be implemented in a staged approach over the next 18-24 months to limit disruption to industry.**

*The Government has begun the implementation process by opening a series of consultations, which invite complementary medicine (CM) stakeholders to provide input on how some of the more complex recommendations should be implemented (see MMDR consultation forecast)*

## Top CM Reforms

**Incentives for innovation in complementary medicines**

**New approval pathway for listing complementary medicines with higher therapeutic indications where the efficacy of a product has been independently assessed.**

**A comprehensive list of permitted indications will be developed, in consultation with industry.**

**Efficacy monographs for commonly used active ingredients.**

**Risk based approach to variations to complementary medicines to a notification based system where the variation does not impact quality, safety or efficacy.**

## Complementary Medicine Highlights

### *Incentives for innovation in complementary medicines*

**The Review acknowledged that the current regulatory framework does not adequately incentivise innovation in CMs. As it stands, sponsors have little incentive to invest in research and development of complementary medicines, as they are not granted any form of market exclusivity period to recoup R&D**

**investment. The Government accepts-in-principle the recommendation to improve the competitiveness of the CM industry. The Department of Health will collaborate with the Department of Industry, Innovation and Science, and with relevant stakeholders to consider further options such as market protection for newly listed complementary medicine ingredients and data protection for product formulations seeking higher level indications supported by new clinical investigations.**

## New approval pathway for listing comp meds

### *The efficacy of a product has been independently assessed*

**The Review proposed that a new, third pathway be available for sponsors of complementary medicine products to seek entry onto the ARTG. The intent of the recommendation was to allow a sponsor to elect for their product, which contains ingredients already permitted in listed medicines, to undergo pre-market assessment of efficacy indications and claims (details to be released in consultation paper, January 2017).**

**Once pre-assessed, the product may be listed on to the Register and carry a 'claimer' indicating that the evidence for the product has been assessed.**

**The new pathway has been established for sponsors who wish to make higher level indications than currently permitted. This will encourage and reward greater investment in research and development by industry, and be an incentive to further expand the clinical research base on complementary medicine products.**

## Permitted Indications for listed medicinal products

### *A list of permitted indications which sponsors must exclusively draw from*

**The Review recommended that the TGA establish a list of permitted indications, from which sponsors must exclusively draw from when listing medicinal products on the ARTG, or sponsors may choose to utilise the new approval pathway (as detailed above). Variations to the wording of permitted indications on the product label and promotional material will be allowed, provided the meaning or intent of the indication is not changed.**

**To give effect to a full suite of permitted indications, the 'free text' field in ELF will be removed after the required legislative changes have been made. The overall intent is to improve transparency for both industry and consumers by**

**The reforms aim to increase certainty of processes and increase flexibility for Industry by:**

Making greater use of assessments for ingredients by comparable overseas regulators;

Implementing an additional listing pathway for new complementary medicines;

Introducing statutory timeframes for the approval of new ingredients;

Adopting a risk-based approach to the variations of complementary medicines; and

Introducing a support service to assist SMEs to navigate regulatory processes, along with improved regulatory guidance information.

**establishing a catalogue of approved ingredients and a list of permitted indications for use in complementary medicines.**

## *Efficacy Monographs*

### *Efficacy monographs for commonly used active ingredients*

**The Review recommended the development or adoption from comparable regulators of monographs, which has the potential to improve the availability and accuracy of information for consumers and to reduce time and costs for industry.**

**Currently, multiple sponsors are effectively conducting systematic reviews and literature searches of the same evidence, creating unnecessary industry-wide regulatory burden. Such monographs would document the evidence supporting the efficacy of common ingredients and potentially for specific indications and other relevant information. The efficacy monographs could be used by sponsors of low risk medicines as a primary source of evidence to support permitted indications selected for a medicine.**

*The MMDR Reforms will reduce regulatory burden and encourage innovation in industry*

## *Risk based approach to variations to complementary medicines*

### *Notifications where the variation does not impact quality, safety or efficacy*

**The review recommended a risk based approach to the management of variations to complementary medicines be adopted. Implementing a risk based approach to assessments of variation to complementary medicines will reduce regulatory burden for sponsors.**

## *When will the changes be implemented?*

**The reforms will be progressively rolled out by the TGA over the next 18 to 24 months, with new regulatory pathways for some medicines in place within 12 months.**

**To date, CMA has represented industry in several targeted stakeholder meetings and provided a submission to the TGA's recent call-for-comments regarding the regulatory framework for advertising of therapeutic goods. The TGA is expecting to conduct a number of both targeted and public consultations during the next 12 months.**

## *Have your say on the implementation of Complementary Medicine Reforms*

### Public Consultation Forecast:

**A consultation forecast has been developed to assist you in planning and providing input to the TGA on implementing the Australian Government response to the Review.**
**Full details can be found here:** https://www.tga.gov.au/implementation-reforms-public-consultation-forecast

**Please keep an eye out for CMA member alerts on each of the planned consultations.**

### Regulatory updates and training workshops 2017

**There will be a number of webinars, roadshows and seminars in 2017 to explain the detail and to answer questions in relation to the CM reforms. Please keep an eye on our events website here**

*Industry supports the goals of the MMDR reforms of better aligning regulatory protections with the lower risk imposed by the complementary medicines sector and to ease regulatory requirements where they do little to improve consumer protection but are a barrier to business.*

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