Submission to the Senate Community Affairs Legislation Committee inquiry into the Therapeutic Goods Amendment (2016 Measures No. 1) Bill 2016

Submitted by:	Complementary Medicines Australia (CMA)
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About CMA:

Complementary Medicines Australia (CMA) is the peak industry body for the complementary medicines (CM) sector, representing members across the supply chain, including manufacturers, importers, exporters, raw material suppliers, wholesalers, distributors, retailers and practitioners. CMA promotes appropriate industry regulation and advancement to ensure consumers have access to complementary medicines of the highest quality.

CMA is the principal reference point for members, the government, the Health portfolio (including the Therapeutic Goods Administration), the media and consumers to communicate issues relating to the complementary healthcare sector.

Introduction:

On 8 April 2015, CMA made a comprehensive submission to the Expert Panel Review of Medicines and Medical Devices Regulation (MMDR), announced by the then Minister for Health, the Hon Peter Dutton MP and the Assistant Minister for Health, Senator the Hon Fiona Nash and chaired by Emeritus Professor Lloyd Sansom AO.

The main themes of the Review were to identify ways to improve access to therapeutic goods for consumers and ensure that regulatory settings are appropriately aligned to risk, to remove unnecessary regulatory and administrative burden for industry, whilst maintaining the safety of therapeutic goods in Australia.

There are a number of areas described within the Explanatory Statement accompanying the Bill that have been explored and agreed to in principle by the complementary medicines sector, as part of the MMDR reform consultation process.

However, there are also a number of proposed amendments outlined in the Bill that may impact on the complementary medicines sector, which CMA considers have not been fully explored and require further consultation with industry.

CMA's response to the proposed amendments to the *Therapeutic Goods Act 1989* is outlined below:

CMA supports the following proposed legislative amendments:

Propose legislative amendment:	CMA response/ comment:
New pathways for approval of medicines and medical devices • Review recommendations 3 and 15	Recommendation 3 relates to pathways for registration of a new chemical entity onto the ARTG and does not directly relate to lower risk complementary medicines. CMA **supports** the proposed legislative amendment to provide for a new assessment pathway for complementary medicines (recommendation 39 refers). This pathway will allow sponsors to opt-in for pre-market efficacy assessment to support higher level indications and claims on an otherwise listed medicinal product. Recommendation 15 relates to the medical devices regulatory framework. CMA provides no further comment here.
Variations to medicines through notifications • Review recommendations 13 and 42	CMA **supports** the proposed legislative amendments to adopt a risk-based approach to variations of complementary medicines in circumstances where the variation does not impact the quality, safety or efficacy of the product. Implementing a risk-based approach and abridged assessments of variations to listed CMs will reduce regulatory burden for sponsors. That is, any assessment that is required by the TGA should be abridged in scope, so that only those aspects that require evaluation in order to establish the continued safety, quality and efficacy of the complementary medicine following implementation of the proposed variation are examined (abridged

	assessment).
Amendments to TGA statutory advisory committees • Review recommendation 51	CMA **strongly supports** the retention and revitalisation of the Advisory Committee on Complementary Medicines (ACCM). ACCM provides an important avenue for TGA to receive expert advice in relation to the safety, efficacy and manufacturing quality of complementary medicines.

CMA supports the following proposed legislative amendments, subject to certain caveats:

Propose legislative amendment:	CMA response/comment:
Legislative timeframes for decisions in relation to listed complementary medicines • Review recommendation 41	CMA's position on this proposed reform is as follows: **a) New ingredients:** The CM industry **generally supports** the evaluation of new ingredients based on target/predictable timeframes as opposed to legislated timeframes. This is due to each individual complementary medicine ingredient often being complex and unique in its data requirements, necessitating some flexibility in the assessment process. CMA recommends the national regulatory authority (NRA) establish target timeframes for the assessment of complementary medicine ingredients that reflect international benchmarks and the inherent lower risk profile of complementary medicines. The development of target timeframes will provide greater certainty and clarity for sponsors of complementary medicines. Target timeframes should be considerably shorter than the timeframe currently prescribed for registered prescription and OTC medicines. **b) Publication of finalised compositional guidelines** CMA **supports** the development of Compositional Guidelines for newly approved ingredients for use in

	listed medicinal products, which should be finalised and published within a legislated timeframe. **c) Assessment of medicinal products listed under Option Two.** Implementation considerations will need to include timeframes for the evaluation of evidence of efficacy. See previous comments above. **d) Registration of Complementary medicinal products under Option Three.** The TGA Business Process Review (BPR) in 2015-16 proposed establishing target timeframes for the evaluation of Registered Complementary medicines. See previous comments above.
Review and appeal rights for persons applying to include new ingredients as permissible ingredients in listed complementary medicines • Review recommendation 47	CMA **supports** the proposed legislative amendment. CMA is supportive of broadening appeal rights for applicants of new ingredients *and* where the TGA refuses to list a product based on public health policy (Recommendation 34 refers). **Issue**: the existing section 60 appeals mechanisms under the *Therapeutic Goods Act 1989* is not considered appropriate to new ingredients, as the range of 'interested parties' that could appeal may extend to a large number of people and could create uncertainty in the predictability of the application progress. The design of potential review and appeal rights requires careful consideration of the application of administrative law principles in this context. **CMA Position**: To overcome issues concerning section 60 appeals, review and appeal rights could be <u>restricted to parties that made the application</u>. There is a general level of acceptance within the CM industry to proceed this way and as such, appeal mechanisms would be made available via section 60 of the Act and later, to the Administrative Appeals Tribunal

	in relation to a review of the Minister's decision for the applicant in respect of any refusal by the Secretary to make the requested variation. Implementation may be achieved by remodelling section 60 in conjunction with achieved by remodelling section 60 in conjunction with the Panels' proposed review of the Act and subordinate legislation (Recommendation 28 refers).

Propose legislative amendment:	**CMA response/ comment:**
Strengthening Post-Marketing Activity • Review recommendation 27 Introduces a provision to enable new record-keeping obligations for medicines sponsors to be prescribed in the Regulations to assist with post-marketing monitoring. The proposed amendment also ensures that 'authorised persons' (who are charged with monitoring compliance with the Act and Regulations) are able to enter premises where sponsors of therapeutic goods included in the Register keep documents that relate to those goods. This will enable authorised persons, who for example may be TGA medical officers, to establish whether sponsors are complying with all of their pharmacovigilance obligations.	CMA **supports** that lower risk complementary medicines are exempt from the provisions of recommendation 27. The expert Panel outlined in its stage two report recommendations in direct relation to the regulatory frameworks for complementary medicines and advertising of therapeutic goods. This report was consulted on with industry and commenced from recommendation 33 to 58. In reference to post market monitoring of complementary medicines, recommendation 49 recommended the NRA develop a more comprehensive post-market monitoring scheme for listed medicinal products, including complementary medicines. This includes an: a) increase to the number of products subject to random and targeted post-market review; b) provision to allow the NRA to complete a post-market review in the event that the sponsor withdraws the product from the ARTG during the course of the review; c) timely availability of information for consumers for each listed product in relation to whether the product has been subject to post-market review the timing and outcome of that review; d) integration and timely analysis of any available datasets, including eHealth and hospital records, to provide a more streamlined and cost effective approach to post market monitoring (Rx 27 refers), particularly for products including newly approved ingredients; e) provision of electronic reporting of adverse

	events; and f) enhanced collaboration with overseas NRAs to share information relating to safety or efficacy of comparable products. CMA submits that the above recommendations related specially to post-market monitoring of lower risk complementary medicines will enhance consumer protections and complement existing post market monitoring process.
The Bill also ensures that 'authorised persons' (who are charged with monitoring compliance with the Act and Regulations) are able to enter premises where sponsors of therapeutic goods included in the Register keep documents that relate to those goods, or premises where sponsors have an obligation to keep records about their goods under the Act or Regulations. This will clearly enable authorised persons, who for example may be TGA medical officers, to establish whether sponsors are complying with all of their pharmacovigilance obligations.	CMA's position is aligned to the TGA's risk management approach to therapeutic goods. That is, lower risk complementary medicines should continue to meet the requirements for pharmacovigilance as determined in the *Australian Pharmacovigilance requirements and recommendations for medicine sponsors*. This document recognises the lower risk profile of listed medicines and determines specific requirements as required. No further enhancements to the current requirements for this sector of goods has been presented or consulted on. Any additional powers permitted to authorised persons in relation to listed complementary medicine sponsors should be fully consulted on with industry.

Other amendments

The Bill contains a number of other amendments to the Act, that are principally aimed at achieving greater consistency between different types of therapeutic goods, reducing health risks to the public, reducing regulation or making other, more minor amendments to the Act.

These measures include the following:

- Enabling the cancellation of registered or listed therapeutic goods from the Register if the sponsor of the goods has supplied false or misleading information in relation to their application to include their goods in the Register. **CMA agrees in principle** with this amendment providing the opportunity for natural justice applies.

- Allowing the Secretary to require manufacturing licence holders to provide information or documents upon request. **CMA supports** that the manufacturing and quality control procedures used in the manufacture of complementary medicines are acceptable.

- Allowing the Secretary to reinstate therapeutic goods to the Register that were cancelled if the goods were cancelled for non-payment of annual charges and if, principally, the sponsor has paid the charge. **CMA agrees** with this amendment.

- Allow conditions on the inclusion of kinds of medical devices in the Register to be either prescribed by regulation, or set out in a legislative instrument made by the Minister, to bring the situation in relation to conditions for medical devices in line with registered or listed therapeutic goods under the Act. CMA make no specific comment.

Thank you for the opportunity to submit feedback to the Senate Community Affairs Legislation Committee on its inquiry into the *Therapeutic Goods Amendment Bill 2016*.
We would be pleased to discuss any points of this submission further as required.

ENDS