# APPENDIX 1: REVIEW OF MEDICINES AND MEDICAL DEVICES REGULATION SUBMISSION COVER SHEET

Please complete all parts of this document, sign it, and attach it to your submission.

## 1. Contact information

| | |
|---|---|
| **Name and work title** | Dr Sasha Bennett<br>Executive Officer |
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## 2. Consent to publish on the internet

It is the intention of the Panel to publish submissions that it receives, along with the name of the individual or organisation that made the submission, on the Review's webpage, located on the Department of Health website. Please indicate your willingness for your details to be published on the website by checking the appropriate box below.

☒ I CONSENT to the attached submission being published in its entirety on the Department of Health website.

☐ I CONSENT to a redacted version of my submission being published on the Department of Health website. If you check this box please provide a copy of your submission with the information you do not want to be published redacted and clearly mark the submission *Redacted for Publication*.

☐ I DO NOT CONSENT to any information about my submission, including my name or the name of my organisation, being published on the Department of Health website. *

Signature__ A.A. Bennett. Date___8th April 2015_____

***NOTE:** The Panel will consider submissions in formulating its report to Government and may cite particular submissions. If your submission contains confidential information that cannot be cited, please clearly mark these parts of your submission as 'in-confidence'.

## 3. Abstract

NSW Therapeutic Advisory Group (TAG) believes poor consumer and health professional understanding is a major issue with the use of CM. A number of reasons for this exist but do include the current regulatory framework.

NSW TAG supports the use of a trusted regulator if they can meet the recommended criteria. We acknowledge that there may be other worthwhile criteria identified by other submissions. If the complementary medicine (CM) ingredient/product meets the required standards after assessments of quality, safety and efficacy by the trusted regulator, the ingredient may have tentative approval. Further assessments by the Australian regulator are likely to be required as determined by a gap analysis of differences between the Australian and trusted regulators e.g. quality control for stability under a wide range of temperatures. The requirements for advertising pre-approval should be the same as the requirements for listing i.e. the evidence requirements for the indications associated with listing must be met for pre-advertising approval rather than simply satisfying the claim that it is not false or misleading.

NSW TAG recommends a strengthening of the legislative framework for CM regulation to improve the rigour of the evaluation process (which may be augmented by the use of a trusted regulator and enable the TGA to address current gaps). The framework should enable CM evaluation to be more comprehensible to sponsors, consumers and health professionals. Improved evaluation of efficacy, communication to consumers and health professionals and post market monitoring are required. Further CM stratification according to risk profile, efficacy and indications would be useful.

If a therapeutic claim for any health conditions that are chronic, serious or could become serious is made (no matter what the dose) and/or a CM product can interact with any drug that has a narrow therapeutic index, the product must be treated as a therapeutic good. Such a therapeutic good should have accompanying product information and Consumer CM Information leaflet. There should be a high level evidence base, quality and safety for such therapeutic goods. Rating of evidence and safety (with explanation) for each product/ingredient should be available to consumers and health professionals. With some caveats, some current CM may be relegated to the food category e.g. dietary supplements such as water soluble vitamins or minerals when they are used in doses that are commensurate with dietary supplementation. Any product that solely relies on homeopathic principles should not be given the status of a therapeutic good.

Consumers would be assisted with an online Therapeutic Panel Calculator/Quality, Safety and Evidence Star Rating Calculator similar to that provided for food products. Links to examples of food rating schemes that could be used as a template for CM products are provided. Such a system could rate quality, evidence and safety for every listed and registered CM obtained as a result of the scrutiny (whether by the TGA or the trusted regulator) that the CM has undergone. It could also act as a portal for other important consumer information including alerts regarding harmful CM products that are sourced from overseas.

NSW TAG also refers to the Expert Review Panel to the Council of Australian Therapeutic Advisory Groups (CATAG) *Position Statement for the Use of Complementary and Alternative Medicines* [i] due to be published on the CATAG website in April 2015.

[i] www.catag.org.au