***Complementary Medicines Australia submission to the Therapeutic Goods Administration Consultation:***

# Consultation: Discontinuing pre-market evaluation of Herbal Component Names (HCNs)

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## Introduction

Complementary Medicines Australia (CMA) welcomes the opportunity to provide comment on the TGA's consultation on the proposal to discontinue the receipt and pre-market evaluation of HCN applications.

CMA is committed to a vital and sustainable complementary medicines sector, and represents stakeholders across the supply chain, including manufacturers, raw material suppliers, distributors, consultants, retailers and allied health professionals. CMA members represent greater than 80% of all product sales within Australia.

The increasing consumer demand for complementary medicines has resulted in the industry becoming a significant pillar in preventative healthcare, both economically and as an employer. Over the last few decades the Australian complementary medicines sector has evolved into a major world class industry supporting domestic jobs, research, manufacturing and exports.

As noted in the consultation document, many listed complementary medicines utilise Herbal Component Names (HCNs) as a method to communicate content and quality information about herbal extracts both within industry entities, as well as to consumers, including health professionals. The naming of herbal components has been a methodical and rigorous process producing determinations regarding the identity of chemical entities derived from herbal ingredients, including components that relate to the safe use of the goods, as well as quality and efficacy markers.

CMA notes the considerations and reasons which form the context for this consultation document, as well as the proposal to discontinue the requirement to evaluate herbal component names. In particular, that the evaluation of herbal component names has caused some challenges and difficulties for both industry and the regulator. This consultation represents an opportunity to consider de-regulation or improve the management of HCNs in parallel with co-occurring regulatory reforms. CMA wishes to provide feedback in response to this proposal and work with the TGA to create a well-considered, sustainable framework for retaining herbal component names, which will continue to provide high quality regulatory decisions that promote consumer confidence.

## Consultation comments

Before considering the regulatory options proposed, CMA wishes to make comment in relation to the issues raised in the context for initiating the consultation. In the following table please find a summary of the matters raised in the consultation with additional comment.

| Issues Raised & CMA Comments |
|---|
| *Issue raised*<br>Listed medicines themselves are not required to undergo any pre-market evaluation and comprise the lowest risk class of regulated medicines (i.e. the evaluation of HCNs is not consistent with the risk framework in-place) |
| *CMA Comment*<br>Whether pre- or post- market, it appears to us that the regulator will still need to play a role in the oversight of herbal component names, which are represented as components of active ingredients on product labels. Pre- or post- market considerations are expanded upon later in this submission. |
| *Issue raised*<br>The creation of an approved HCN is not a legal requirement for listed therapeutic goods. |
| *CMA Comment*<br>Further discussion and confirmation around this topic is needed. The definition of 'active ingredient' in Regulation 1 of the Therapeutic Goods Regulations defines that '*active ingredient', for a medicine, means a therapeutically active component in the medicine's final formulation that is responsible for its physiological or pharmacological action*", and there are legal requirements attached to actives in regards to the ARTG and the label via the Regulations and the TGO92.<br>We note there has not been any legislative change in regard to herbal components, previously the un-legislated evaluation and creation of HCNs has been the usual and accepted practice. |
| *Issue raised*<br>The HCN approval process is resource intensive and costs are not recovered from applicants at present. |
| *CMA Comment*<br>Although there is no fee charged per application, it is our understanding that the costs were calculated into and recovered by the existing annual listing fees. This has been considered appropriate, because a cost charged per application will be borne by the applicant but subsequently used by numerous sponsors (there is no market exclusivity or significant advantage in defending market exclusivity). However if the nature of most applications suggest this would be appropriate, an application fee system could be discussed further if HCN evaluations were to continue. |
| *Issue raised*<br>The regulated industry has raised concerns about the length of the evaluation process and the lack of predictability for business planning and the timing of product launches. |
| *CMA Comment*<br>Evaluation time-frames are lengthy and launches important for industry, therefore this could be an important de-regulatory advantage, if other potential disadvantages of de-regulation could be appropriately managed in a workable model developed between industry and TGA. |

## Regulatory Options

**Option 1**

**Maintain the status quo.**

**Consistent with the cost recovery arrangements in place, the TGA suggests a fee for such applications may be considered in the future.**

The benefits of this option are:

1. Minimal business process change for manufacturers and sponsors (save for an application fee).
2. Retention of existing HCNs on ARTG and Code Tables preserves the extensive naming work that has been conducted to date.
3. No new post-market work or possibilities for measured compliance issues around component naming.
4. Continued consistency in naming and decision-making across multiple medicines on the ARTG, limiting any potential for confusion if different names were used and maintaining consumer confidence.

**Option 2**

**Industry and the TGA to work together to produce a workable mechanism that allows for discontinuing pre-market evaluation of HCN applications.**

The benefits of this option are:

1. Freeing up of regulator resources to process other industry pre-market applications.
2. Fast to market approach with new herbs and herbal components and no time impediments to product launches.
3. May be possible for a sponsor to choose from several HCNs where variable names are available, to suit product purpose and consumers best.
4. Reduction in ARTG groupings/variations/Section 9Ds, and associated fees.

## Discussion - Discontinuation of evaluation of Herbal Component Names.

The proposal states that within this option:

- Applications for new herbal component names will no longer be accepted or required;
- Any reference to standardized components on medicine labels, will remain acceptable providing legislative labelling requirements are met.
- Any claims for non-mandatory standardised components will be assessed as part of the post-market compliance review.

**Labelling & Advertising**

Herbal component names are used throughout the supply chain. HCNs are employed across industry to demonstrate a standard or level of quality assurance and may be used to measure or predict an effect for those that are therapeutically active. In some cases, the therapeutic action of standardised components or a mixture of components is thought to apply but the mechanism of action or the interaction between components therapeutically is not yet fully studied. The ability to include herbal component names on product labels is an important consideration for sponsors, particularly those who primary focus is herbal ingredients. There is some concern that if HCNs are removed from the ARTG and are not included in therapeutic goods legislation, that there would be no legal or administrative protection for the ongoing use of HCNs on labels or in advertising materials in the event that the oversight and management of an alternate HCN process became overly difficult or became a negative focal point for media attention. Certainty of the continued use of HCNs on medicine labels and the ability to create an acceptable level of consistency of naming are considerations would need to be built into and protected within an alternate model.

Different or inconsistent naming, or the possibility of misleading naming by a small minority may be targeted to create negative media attention about the sector. Maintaining consumer confidence in Australian products by Australians helps prevent personal importation of goods that may be manufactured by lower standards overseas, similarly crucial to the sector is maintaining Australia's international reputation for high quality manufacturing and regulation. Any alternate model arrived at must take the prevention of such factors into consideration and be robust enough to prevent any issues.

**Manufacturing**

Standardised herbal components entered onto the ARTG are used as a reference point for manufacturers for validation when manufacturing and releasing for supply, and are tested at regular intervals to monitor stability over the shelf life of the product. In these cases, the ARTG record is used as the reference, which has PIC/S compliance ramifications for manufacturers and auditors that must be considered and a suitable course of action agreed upon before a change in the HCN process or removal of HCNs from the ARTG. For example, if stability testing of herbal components is expected to continue, set processes may need to be adjusted for sponsors, laboratories, manufacturers and TGA auditors. The TGA GMP area and manufacturers would need to be consulted regarding release for supply and other protocols in the absence of HCNs on ARTG records.

**Post-market Reviews**

The commentary in the consultation document regarding current regulatory requirements for standardised constituents, suggests that the following criteria is the evidence required to be held by sponsors:

- *identity of herbal components is no longer rigorously assessed, the name and chemical structure of the constituent or, where a component consists of a group of constituents, the name and chemical structure of each constituent in the group;*
- *evidence that the constituent(s) of the component occurs in the herbal species;*
- *details of the method of analysis used to quantify the constituent(s) of the component;*
- *where a component consists of a group of constituents, details of the approximate relative proportion of each constituent; and*
- *information about whether the component is a therapeutic marker (the component has known therapeutic activity) or a quality marker.*

We understand that in the current regulatory environment for HCNs, the quantity of a component may often by confirmed against manufacturing documents in desk-top post-market reviews. Whereas, the validation of the identity of a herbal component as a unique chemical entity, using the above criteria, is primarily a pre-market process. If the above information were required during post-market reviews on a product-by-product basis, it is possible this could introduce a significant multiplication of regulatory work for sponsors as well as the TGA's Listing Compliance Section. A plan to discontinue HCNs must ensure

there are de-regulatory benefits for all stakeholders and not represent a shift of or an increase in regulation for other divisions or stakeholders.

Evaluation by the Listing Compliance Section could place stresses upon the timelines for post-market reviews, due to the relatively complex subject matter being assessed. As noted in the consultation document, a resource of scientific skills are currently used to assess HCNs on the Herbal Ingredient Naming Committee. There would need to be a process to ensure the consistency of decision-making when accepting herbal component names for the ingredients that does not introduce labelling or media difficulties described previously.

Industry will also be seeking ways to work with the TGA to find ways to continue to reduce reported compliance rates. If a component name were used and it was deemed not acceptable, it would be a new source of measured non-compliance, against legislation such as the TGO 92 or 'separate and distinct' or 'unacceptable presentation'. A model to discontinue HCN evaluation would need to have particular agreement between industry and the regulator on what information was expected and required, what would be considered acceptable and compliant, and how any issues could be dealt with in a timely manner as to not overly affect review timelines.

## Summary

CMA note and acknowledge the current difficulties associated with receipt and evaluation of herbal component names and is willing to consider either available option proposed by the TGA, or an alternate improved mechanism developed by a working group, for managing HCNs. Any change must be de-regulatory and the mechanism of oversight considered in-depth to ensure there is a reduction of red tape on all levels (or suitable alternate regulation put in place if needed). An alternate process should offer benefits for industry and the regulator, whilst having the ability to maintain consumer confidence in complementary medicines.

CMA wishes to continue to work with the TGA to create the optimal and most streamlined solution, and would suggest that a technical working group could be formed with affected parties to discuss the best possible models and find solutions for any arising issues. CMA is willing to support the TGA in the formation, selection and facilitation of such a group, which could include representation from the TGA regulatory and manufacturing areas as well as sponsors, raw material suppliers and manufacturers.