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For Discussion

Item 5.1
OICG 12
30 October 2006

COMPOSITIONAL MONOGRAPHS FOR COMPLEMENTARY MEDICINE INGREDIENTS

Background

At the September 2006 OICG meeting, the TGA tabled a paper outlining strategies for the implementation of Compositional Monographs (CM) in the ANZTAP. The committee asked that further information be provided on the template used to advise stakeholders / applicants on the creation of compositional monographs. This paper provides an example of that template, and discusses associated details underpinning its use.

Template for Compositional Monographs

Drawing directly from the current template for Compositional Guidelines (CG) in Appendix 1 of the Part III of the ARGCM (provided for reference in Attachment 1), a similar generic template for CMs has been derived and is presented in Attachment 2. The CM template has a key structural difference (to CGs) with the inclusion of a Part 2 of a CM is dedicated to the presentation of (non-compendial) testing methodology that underpin relevant requirements prescribed in Part 1. To assist the inquirer, reference is made in Part 2 of the template to advice offered elsewhere in ARGCM regarding method validation. If possible, the working electronic document available on the website will be hyperlinked to the advice. The guidance provided in Appendix 2 of part III (ARGCM) remains relevant and will receive minor edition to update references from "Guideline" to 'Monograph". Also, some minor editorial modifications will be necessary to bring portions of the Part III text into line with the introduction of CMs.

Given the varied and complex nature of complementary medicinal actives, it is not possible to present a single universal template covering all possible CMs. The template attached will be presented as a guide to all stakeholders; giving generic examples of the types and kinds of information that could be expected in the development of a CM (in conjunctions with an application for a new listable ingredient(s)). In practice, the full extent of requirements prescribed in any CM must be determined on a case-by-case basis; considering the relationship between the origin and / or composition of an ingredient and the physicochemical and /or microbiological factors that are likely to influence the safety of that ingredient when used for it intended purpose in listed medicines.

Following the current practices applied with compositional guidelines, the Office of Complementary Medicines will continue to work closely with all applicants (for new listable ingredients) on the information necessary to develop a specific CM that realistically and adequately defines and controls a listable ingredient.

Documentation underpinning Compositional Monographs

It must be recognised than any CM, read in isolation, is open for multiple interpretations and therefore its intended purpose and usefulness would be limited. For this reason, the OCM will develop a preamble that outlines interpretational and operational principles that will underpin all monographs.

It is also envisaged that over time the number of CMs will increase and will need to be managed in such a way that they are accessible to all stakeholders. A central repository of CMs will therefore be maintained and made available to all stakeholders. It is anticipated, at this stage, that a web-based form would be most convenient for reference and use.

Structure of the Compositional Monograph

To assist interpretation, CMs will be presented in two parts. Partl will cite the Australian Approved Name against which the definition and prescribed requirements apply. Part 2, will provide the operational details of any non-compendial methods that are used in requirements prescribed in Partl. In this way it is envisaged that all parties wishing to confirm the compliance of a specific ingredient can readily reference valid methodology on which to base such testing.

Recommendation

That the OICG note the draft template for the compositional monographs for ingredients proposed for use in complementary medicines under ANZTAP.

Attachments:

1. Current template (Part III, Appendix 1) for Compositional Guidelines
2. Template for a Compositional Monograph