~~R1/275872~~

R1/530905

Australian Government

Department of Health and Ageing
Therapeutic Goods Administration

Minute

To: TGA Executive

Comment [Burnej1]: We will need to confirm where we should be sending this ....

Purpose

To inform the Executive of a proposal from the Office of Complementary Medicines (OCM) / Industry Consultation Group (OICG) for a change in ~~policy direction~~process for the TGA generation of compositional guidelines.

Background

Compositional guidelines are intended to provide clarity to stakeholders on the specific form or type of a substances that the Therapeutic Goods Administration (TGA) has approveds for use in listed medicines, as either an active substance or an excipient ingredient.

Comment [Burnej2]: I think we need an extra para that outlines the current process for applications, evaluations of new CM subs noting creation of CGs and then providing the full details as set out in the next para

A compositional guideline is a summary of descriptions, tests and limits that define the composition and characteristics of a substance approved for use in listed medicines. Compositional guidelines are ~~required~~ provided by the TGA where there is no ~~standard~~ monograph for the substance in any of the default standards identified in the *Therapeutic Goods Act 1989* (i.e. the British Pharmacopoeia, United States Pharmacopoeia or the European Pharmacopoeia).

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Perhaps need a history of previous TGA consideration of CGs (ECCMHS recommendation, amendment to s26A in the Act)??

Comment [Burnej3]: See if you can find any of the history particularly when it was proposed to make CGs mandatory under the legislation. I don't think that it is something currently under consideration by MD et al.

Issue

New para – summary of industry's concerns ..... 'market exclusivity', anything else??

Comment [Burnej4]: Another new para here ..... industry dissatisfaction with current process, hence request for changes

At the 35th meeting of OICG (June 2010), members representing the Australian Self Medication Industry Association (ASMI) and Complementary Healthcare Council of Australia (CHC) proposed two changes to the current TGA process related to compositional guidelines:~~,~~ (i) relating to stakeholder consultation requirements for new and existing medicine substances, and (ii) relating to ~~the~~ application fees for amendments of compositional guidelines. The proposals are as set out below:

1. A compositional guideline for a new complementary medicine substance.

When a sponsor applies to the TGA for evaluation of a proposed new complementary medicine substance, a compositional guideline is generated as part of the process. This guideline defines the substance which has been evaluated and approved for use in Australia. Therefore, the reviewed version of the guideline should be published on the TGA website as a final compositional guideline. Public consultation, as current practice, would not occur.

The Industry Associations both agree that all compositional guidelines should be published to enable industry to refer to them as necessary.

If another company in industry wishes to amend the final compositional guideline, they can still do so by applying to the TGA. The amendment would need to include justification and would be evaluated by the TGA; this would include an ~~still to be determined~~ evaluation fee, at a level still to be determined.

2. A compositional guideline for a pre-existing complementary medicine substance.
Where a substance is already used in medicines in Australia, but there exists neither a default standard nor a compositional guideline to define the substance, issues of identity and quality can become problematic. To remedy the situation, the TGA may generate a compositional guideline for the substance in question.

In this case it is appropriate for the regulator to issue a draft compositional guideline and call for public consultation as this enables the TGA to ascertain the precise substance and test methods in current use. The consultation period should be 6 weeks to allow time for industry to source and obtain relevant documents. There should also be consideration for extension of this time when requested, for example to allow for documents to be translated into English. Once the consultation period has closed, the draft should be amended and the final version published by the TGA within 90 days.

3. Amendments to compositional guidelines.
Compositional guidelines should be living documents, which can be amended when necessary. The industry associations, sponsors, or TGA officers, may request an amendment to a compositional guideline, for example to allow or include the use of newer or better test methods. In each case, justification must be provided to support the amendment.

The TGA may request an application fee to recover the cost of assessment of a proposed amendment to a compositional guideline.

~~Action/Recommendation~~Summary

The Executive is requested to consider whether OCM should take up these proposals especially the issue of whether appropriate fees should be considered when a request to amend a compositional guideline is requested.

Comment [Burnej5]: Why don't we tweak this to highlight which parts of t proposal can be implemented easily, wh are more complex and would require RIS, etc ...If we are asking for a recommendation/action, then I think this should be an RPC paper!

Attached for information:

1) Attachment 1 of Item 8.2 from OICG 35 (24th June 2011)