Australian Government
Department of Health and Ageing
Therapeutic Goods Administration

Questions & answers about compositional guidelines

Q. What is the purpose of the Compositional Guideline?

Compositional Guidelines are intended to provide clarity to the specific form or type of substances that the Therapeutic Goods Administration (TGA) approves for use in listed medicines, as either an active substance or an excipient, where there is no standard in the British Pharmacopoeia (BP) or other acceptable monographs.

Compositional Guidelines link formal descriptions and specifications of substances, approved for use in listed medicines, with regulatory (Australian Approved) names.

TGA intends compositional guidelines to assist sponsors and stakeholders in the following ways:

- To assist sponsors and stakeholders to understand the specific nature of the substance(s) which has been approved for use by the TGA, rather than requiring correct definitions to be determined, on an *ad hoc* basis, from the Australian Approved Name. Experience has shown that often the nomenclature of a substance may be insufficient information to define, unambiguously, what form of the substance has been approved by the TGA for use in listed medicines.
- To minimise the risk associated with the substance by establishing specifications for parameters identified as influencing the safety of the substance.
- To assist sponsors to assess whether material they intend for use in a listed medicine conforms to TGA's definition and requirements for that substance

Q. When do (draft) Compositional Guidelines apply?

As new complementary medicinal substances are approved for use, the TGA will advertise the associated draft Compositional Guideline(s).

TGA anticipates substances will conform to the draft Guideline(s) from the time of substance approval. Compositional Guidelines will be in draft form for six weeks after the gazettal date of the substance. During that time TGA will invite stakeholder comment.

After consideration of comments, a final form of the Compositional Guideline(s) will be prepared.

Q. What sources of information are there to help develop Compositional Guidelines?

There are often no current pharmacopoeial references covering complementary medicinal substances. To fill this gap, the TGA requires that draft Compositional Guidelines be proposed by the sponsor as part of the application process. The Guidelines allow the sponsor to define the substance(s) to which the data refers, rather than relying on an identity associated with a name only. The Compositional Guidelines form part of the application package that is evaluated by the Office of Complementary Medicines. It is then considered by the Complementary Medicines Evaluation Committee (CMEC) when that committee reviews the eligibility of substances for use in listed products.

All applications for evaluations of new complementary medicine substances must include a characterisation of the substance proposed for medicinal use. If the substance is already defined

in a raw material monograph of the British Pharmacopoeia (BP), the substance must meet those requirements. If the proposed new substance is included in a pharmacopoeial monograph other than the BP, for example the United States Pharmacopoeia (USP), Commission E Monographs, European Pharmacopoeia (EP) or Peoples Republic of China Pharmacopoeia (PRCP), the TGA will expect that monograph to apply to the proposed substance, unless otherwise justified in the application.

It is important to note that recommendations made by CMEC regarding the eligibility for use of a substance in listed medicines, relate to the substance described in the relevant compositional guideline.

Q. What happens if my substance does not meet the Compositional Guideline?

Where a sponsor wishes to include a substance in listed medicines that does not meet the Guidelines, a request may be made to justify the safety of that specific material and/or the safety of any listed medicines containing that material. Where a substance(s) may have been approved in those situations and later is found to be profoundly and unjustifiably different from the relevant Compositional Guideline(s), the sponsor may be requested to no longer use that material.

Q. Where do I find new (draft) Compositional Guidelines?

As new complementary medicinal substances are approved for use in listed products (through publication in the Commonwealth Gazette), Draft compositional guidelines for approved substances will be available on this Internet site and through industry organisations.

Compositional Guidelines that have been finalised will also be available on this site and through industry organisations.

What is the process for developing a Compositional Guideline?

STEP 1 - Application

As part of the Application, a sponsor proposes a compositional guideline. It must be supported by details of any references or analytical method used. It should also be consistent with the types and ranges of tests in pharmacopoeias and include any relevant general pharmacopoeial requirements.

STEP 2 - Evaluation

During the evaluation of the new substance, the TGA will consider the guideline to determine whether it is sufficiently detailed and appropriate for the substance being considered.

The Sponsor is requested to address any deficiencies in the draft compositional guideline.

Once TGA is satisfied, the draft compositional guideline is included in the Evaluation Report.

STEP 3 - Consultation

Once the Evaluation Report is considered by CMEC, TGA consults the sponsor about the draft compositional guideline if the CMEC consideration results in any changes to the compositional guideline. The sponsor is advised that the 'draft' compositional guideline is to be circulated for public consultation for six weeks. A 'draft for comment' of the compositional guideline is included on this website.

Comments received during consultation are considered and assessed and if any amendments are justified, then the sponsor is informed.

STEP 4 - Completion

After gazettal of approval to use the substance and after the consultation phase has been completed, the compositional guideline is included on the website and the word 'draft' is removed.

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