# Call for Comment: International Harmonisation of Ingredient Names (IHINs)

Dear member,

The CHC invites you to comment on the TGA consultation for the [International Harmonisation of Ingredient Names (IHINs) Project](http://www.tga.gov.au/newsroom/consult-ihin-130515.htm). Submissions are welcome to the CHC  **by COB Wednesday, 3 July** for submission to the TGA by the 10 July 2013. A CHC representative will also be attending a TGA focus group on this project in June 2013.

As we have previously highlighted, the TGA are in the process of aligning ingredient names to international standards as part of the IHIN project.

**Why?**

* Use of approved terminology ensures accuracy and consistency of information in the Australian Register of Therapeutic Goods (ARTG).
* Consistency in naming assists in the retrieval of information from the ARTG and limits confusion between goods.
* Ensures that Australian naming policy is consistent with other regulators worldwide and promotes international trade (interchangeable labelling).
* Consistent naming will also facilitate interoperability with other health related tools such as eHealth.

**When?**

The TGA intend to update the Ingredients Database in late 2013/ mid 2014. After the TGA Ingredients database is updated, no new products entered onto the ARTG will contain the pre-harmonised ingredient names. This means ARTG entries, including labelling and, where applicable, PI and CMI information will need to be updated to reflect the harmonised names. As you would be aware, the TGA are concurrently conducting a review on the Labelling Order (TGO 69) and the packaging and labelling requirements for medicines and is aware of the impact on industry. Currently the transition period is proposed to be for 2 years however, the TGA is considering coordinating the implementation of ingredient name changes as part of the IHIN with changes required for the packaging and labelling review.

Approved terminology must be used:

* when sponsors submit applications for registration, listing and export of medicines and notification of proprietary ingredients
* in records in medicine formulations included in the ARTG
* on labels of medicines
* other literature such as Product Information (PI) Consumer Medicine Information (CMI)

[**International Harmonisation of Ingredient Names (IHINs)**](http://www.tga.gov.au/newsroom/consult-ihin-130515.htm)This consultation includes proposed changes to approximately 472 ingredient names, of which approximately 100 will relate to complementary medicines, excluding herbal ingredient names. Updates are also proposed to the guidance document *TGA Approved Terminology for Medicines*, which incorporates feedback from industry and other stakeholders received during the 2006 consultation.

As part of the Blueprint reforms the TGA are undertaking consultation on the harmonisation of ingredient names, that is names  that currently do not align with international standards, based on International Nonproprietary Names (INNs) and other naming references (e.g. pharmacopoeias). This project will also increase preparedness for the transition to the joint agency with New Zealand and by removing ambiguity the proposed changes are said to aid international trade through interchangeable labelling.

The proposed ingredient name changes will affect sponsors of the following products:

•    Registered and listed Complementary medicines (both active and excipient ingredients)
•    Over the counter medicines (including sunscreens)
•    Prescription medicines
•    Export Only medicines

For further guidance on the TGA policies and processes around naming, please see the new update to [*TGA Approved Terminology for Medicines*](http://www.tga.gov.au/pdf/consult/consult-ihin-130515-atm.pdf) *,* which has been published for comment as part of this consultation.

**Action**
Please consider the changes outlined for:

* Implications for sponsors (page 17)
* Appendix 5: Registered complementary medicine active ingredients proposed for harmonisation (19)
* Appendix 6: Listed medicine active ingredients proposed for harmonisation (80 ingredients)
* Appendix 7: Australian Biological Names (eg green lipped mussel & honey bee)
* Appendix 9: All excipients proposed for harmonisation (262 ingredients)
* Appendix 1: A comprehensive list of all ingredient name changes is provided (472 ingredients)
*Note that several ingredients may appear in more than one list.*

Please comment on the following:

* What are the issues faced by the complementary medicines industry as a result of the harmonisation? For example, appropriate transition periods to align with other labelling reform changes.
* An assessment of how the proposed changes will impact on your business
* Specific feedback on the update to the *TGA Approved Terminology for Medicines* document (see questions below)
* Are there any names that may have been missed for harmonisation?
* General questions are outlined below to assist you in responding to this consultation

**Medicine ingredient names and the transition to ANZTPA**

The ingredient naming policy for prescription and over-the-counter medicines outlined in *TGA Approved Terminology for Medicines* is likely to be adopted in a similar form for the purposes of the joint agency.

It should be noted that even though the draft guidance *TGA Approved Terminology for Medicines* captures complementary medicines, at this stage these only apply to Australian stakeholders.

The regulation of complementary medicines under the joint agency will be further discussed as the implementation for ANZTPA continues to gain momentum. We encourage NZ stakeholders to provide comment on this consultation paper and the update to the guidance as part of this consultation.

**General questions on the proposed name changes**

1. Looking at the list of proposed ingredient name changes, do you foresee any specific concerns or benefits as a result of any of the proposed name changes?

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**Implications for healthcare professionals and consumers**

1. Do you agree that harmonising the names of ingredients with international practice will be beneficial?
2. Will having international naming consistency assist in clinical practice?

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**Implications for Sponsors**

1. Do you agree that harmonising the names of ingredients with international practice will be beneficial?
2. Specifically, will the name changes make preparing labels and other documents for the Australian market easier, in terms of international consistency?

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1. Do you agree that the proposed transitional period is sufficient to ensure associated costs, such as printing new labels, could be met through business-as-usual activities? If not please give an estimate of the financial impact of the changes.

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**TGA Approved Terminology for Medicines**

[*The TGA Approved Terminology for Medicines*](http://www.tga.gov.au/pdf/consult/consult-ihin-130515-atm.pdf) provides guidance on TGA policies relating to how approved names for new medicine ingredients are determined, and describes the TGA process for entering new approved names onto the TGA Ingredient database. Although the scope of the document has not changed since the 2006 consultation, the update includes significant enhancements to the previous version:

* Increased guidance about the TGA naming policy and related business process
* Improved usability through simplified layout and use of practical examples
* Removal of the printed ingredients list – the current ingredients list is printed on the TGA website

General questions on the update to TGA Approved Terminology for Medicines

1. Do you believe anything is missing from this document? If so, please specify.
2. Do you agree that the updated document is user-friendly?
3. Will this update to the guidance assist you in proposing new ingredient names?
4. Are there any general concerns with the update to the structure of the document?

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Any additional comments:

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**For further information contact:**

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