# CHC Submission on the International Harmonisation of Ingredient Names

To:
Project Manager

International Harmonisation of Ingredient Names

Management & Coordination

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**Introduction**

The Complementary Healthcare Council of Australia (the CHC) is pleased to provide comment, on behalf of the Complementary Medicines (CM) industry, on the International harmonisation of ingredient names consultation paper (May 2013). The CHC, in preparation for this submission, participated in the TGA Focus Group in relation to this project to communicate industry's concerns, as described below. We also note that harmonisation of herbal ingredient names is outside the scope of this consultation.

The CHC considers the objective of this consultation, to update ingredient names used in Australia to reflect International Nonproprietary Names (INN) policy, as commendable, provided it meets industry and consumer needs. We understand that changes to ingredient names in prescription and over-the-counter (OTC) products will cause relatively few problems if implemented as proposed in the consultation paper. However, many of the proposed changes to ingredients used in complementary medicines, in particular Listed complementary medicines (CM), will only cause confusion and difficulties for consumers and hence an additional challenge for the CM industry.

**Specific comment**

1. The CHC is concerned that while the objective is stated as harmonising ingredient names the consequence may in fact be to create more unique Australian ingredient names. For example, Table 1 summarises the types of proposed name changes. Although nine of these are noted as being consistent with INN policy, two types of changes are not and are included as being TGA naming policy. This has been justified in the consultation document by stating that INN policy is silent about these two matters. Has the TGA attempted to acquire INN policies for these matters, or considered moving to other commonly recognised names, for example the International Nomenclature of Cosmetic Ingredients (INCI), rather than the current proposal by which the TGA is proposing to set an Australian specific approach?

    a) The first type of TGA naming policy is reputedly based on using common names more easily understood by consumers. If this Australian specific policy is to be implemented, concerns raised later in this submission (under Transition) would be negated by extending this TGA naming policy to names of all other Listable complementary medicine ingredients with 'well established names in consumers' minds'. The possible incongruity of some of these other Listable ingredients with well established names falling within the scope of an INN policy needs to be countered by the needs of consumers, which are paramount.

    b) The second type of TGA naming policy seems to flow on from the one above in that if common names for metals are used, to avoid confusion, the oxidation state has to be specifically stated rather than be included in the Latin name of the metal. Within

this second type of TGA naming policy, if the metal exists in more than one oxidation state in the ingredient it appears, from Appendix 6, to be named, for example, as manganese (II/III) oxide. Presumably, any relative proportion of the two oxidative states would be compliant with that proposed name.

2. Changes to the names of any medicine ingredients will require widespread consumer and industry education. Such educative programs that attempt to resolve confusion resulting from the proposed name changes are unlikely to be fully successful. The CHC see the disbenefits of the proposed changes to include:

   a) Provision of no meaningful benefits to consumers;
   b) The resultant confusion could potentially lead to a loss of respect for the Australian regulatory system by consumers; and
   c) Offer very few benefits and many additional costs and activities for manufacturers and sponsors of complementary medicines.

**Dual labelling**

3. There are 34 substances proposed for temporary dual labelling. Such dual labelling will obviously require a new label during the temporary dual labelling period. No Complementary Medicine substances are proposed for inclusion in this group, hence Questions 2 and 3 are not relevant for ingredients included in complementary medicines, and the CHC will not specifically respond to these questions in this submission.

**Harmonisation**

4. Whilst ensuring Australian naming policy is consistent with other regulators worldwide is admirable, harmonisation of ingredients names will only be beneficial if all countries or regions adopt such harmonised names. The CHC believes that consumer confidence in the regulatory system outweighs the need for harmonisation of CM ingredient names at this time. A sample risk-benefit analysis would likely show that there is not a significant economic or public health benefit in harmonising complementary medicine ingredient names.

**Implications for consumers and healthcare professionals**

5. The consultation document asks if International naming consistency will assist in clinical practice. Given that very few complementary medicines are regulated as medicines in other countries, the use of names consistent with International Non-proprietary Names (INNs) policy on products sourced overseas is unlikely to be beneficial, as such imported products have to be especially labelled for Australian supply.

**Implications for Sponsors**

6. Entries on the Australian Register of Therapeutic Goods (ARTG) for products that contain 'harmonised ingredients' will need to be updated to reflect any new names. The TGA proposes to modify ARTG records if only the ARTG entry requires updating. Sponsors will,

however, need to, after notification that the TGA has modified ARTG records, check the newly modified ARTG record to confirm that it has been done correctly. Such checking and updating of internal records adds costs and time for industry, in addition to those associated with packaging artwork and marketing material changes.

**Trade Names**

7. While trade names are technically considered outside the scope of this consultation, the document provides the option for trade names to be changed to reflect the new harmonised ingredient name, at a cost. The CHC would like to highlight that this non-mandated proposal would, for example, lead to a product being called Poliglusam capsules consistent with the ingredient list, which would record that the capsule contained 400mg of poliglusam. If the trade name was not changed, it would remain as Chitosan capsules, which would be confusing to the consumer since the ingredient list still would be required to state the product as containing 400mg of poliglusam.

**Transition**

8. The section, dealing with proposed transitional arrangements, does not address the CM sector's transition to the Australia New Zealand Therapeutic Products Agency (ANZTPA). This is dealt with in a separate section, where it is acknowledged that the regulation of complementary medicines is to be further discussed as 'the implementation for ANZTPA gains momentum'. As it appears the TGA has not yet developed any proposals suitable for use relating to the naming of ingredients to be used in complementary medicines under ANZTPA, the implications for the naming of ingredients in such medicines remain unclear. Any consideration of transition periods is therefore considered premature.

9. The fine detail of how NZ Natural Health Products may either opt in or out of the ANZTPA arrangement is also not entirely clear at this stage. The CHC therefore feels that the current consultation paper can have little meaningful impact on ingredients used in complementary medicines. With regard to ANZTPA, it will be essential that complementary medicines sold in either or both countries are labelled in a consistent and consumer acceptable manner.

10. For any transition period that may come from this consultation, the CHC proposes the TGA offers a grace period, where updates to ARTG entries, including more complicated changes, can be combined to minimise costs and motivate industry to update the ingredient names, where identified.

11. The section relating to transitional arrangements proposes a maximum two year period to update packaging artwork (and presumably other documentation such as marketing material). The consultation paper does not provide any comment about how the TGA and sponsors will handle the resultant consumer confusion during this period. As an example, the potentially different ways that the very commonly sold and used fish oil capsules and the components within the oil – Eicosapentaenoic acid (EPA) and Docosahexaenoic acid (DHA) could be named are likely to lead to enormous consumer confusion.

**Appendix 5 and Appendix 6**

12. Appendix 5 and Appendix 6 of the consultation paper contain a number of issues that will impact on the way in which ingredients are proposed to be named when used in Complementary Medicines. The CHC provides specific comment on these in table 2, attached to this submission.

**TGA Approved Terminology for Medicines**

13. The CHC provides specific comment on the Approved Terminology for Medicines consultation document (May 2013). Please see table 1, attached to this submission.

**Concurrent CM reforms**

14. It is important to call attention to the fact that the CHC is concurrently in discussion with the TGA on many CM specific reforms and items yet to be resolved regarding free text and permitted (coded) indications, including any applicable transitions. It should therefore be acknowledged that any naming transitions would need to be aligned with other CM reforms and with the labelling and packaging reforms currently underway.

The CHC considers that a comprehensive communication strategy, explaining any new naming conventions to industry, health professionals and consumers must be made in a clear and accessible way for the success of the implementation process.

**Table 1: Specific comment on the Approved Terminology for Medicines consultation document (May 2013)**

| Reference | Comment |
|---|---|
| Page 10 | *'Sponsors and other users of a the ingredients database should note that'* - this section is missing a note to specify that inclusion of a name in the database does not imply that the substance has been approved for use or that it can be used in any or all medicines. For example, it may not be eligible for Listing or for OTC use, may be prescription only, or may be a name that was used in a product historically that is no longer enabled. |
| Page 10 s 1.5 | This section mentions disinfectants and sterilants, but omits mention of Class III devices containing medicines. |
| Page 13 s 1.7.3 | *'Inversion' of names* section makes no mention of any transitional arrangements in relation to the reversal of policy on the hyphens and inversions and the statement that ingredient names "must not be inverted on labels". Applies also to s 1.7.4, 1.7.5 and 1.12.<br><br>There is the potential for consumer confusion both during transition and also long-term if names such as insulin – bovine were changed to bovine insulin on the finished product label. Using the insulin – bovine example, the BP monograph for a finished product (injectable insulin) states as follows (dot points below).<br>• the potency in International Units per millilitre;<br>• the concentration in terms of the number of milligrams of insulin per millilitre (for preparations containing both bovine insulin and porcine insulin the concentration is stated as the combined amount of both insulins);<br>• where applicable, that the substance is produced by enzymatic modification of porcine insulin;<br>• where applicable, that the substance is produced by recombinant DNA technology;<br>• where applicable, the animal species of origin;<br>• that the preparation must not be frozen; and<br>• where applicable, that the preparation must be resuspended before use. |

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| | There has been no explanation provided with respect to the change in policy regarding inversion of names included in the document. The document makes no mention of a requirement to put the animal source before the actual ingredient name, even if that is how the ingredient as a raw material is named in its own monograph. |
| S 1.7.3 | The policy stated in s 1.7.3 is not consistent with other sections such as s 2.5.3. Whilst it is recognised that s 2.5.3 refers to starches, which are excipient ingredients, they may still be listed on labels by some sponsors and allowing inversion in one section and disallowing it in another (without justification) appears inconsistent. |
| S 4.10.2, 4.10.3 | There appears to be no mention in the document regarding the naming of homoeopathic ingredients, the use of the HPUS for naming, or applications for new homoeopathic names. |

**Table 2: Specific comment in relation to Appendix 5 and Appendix 6**

| Reference | Comment |
|---|---|
| | The same name has been used in the proposed name and the current name but refer to different ingredients. For example, Calcium hydrogen phosphate, Glucose, Magnesium aspartate, Sodium sulphate |
| | Many of the proposed names are considered to be very poorly recognised be experts in industry. For example, poliglusam, doconexent, icosapent, rutoside.<br><br>If there is to be a type of TGA naming policy based on using common names more easily understood by consumers, this TGA naming policy should be extended to names of all other complementary medicine ingredients with well established names in consumers' minds. It is proposed that there be candidates for names under the TGA naming policy (based on ease for consumer understanding) using the current name. |
| | It is not clear why the USP is preferred over the BP which results in a name change.<br>For example, Alpha tocopherol to dl-alpha-tocopherol. |
| | It is uncertain what the difference is between the USP and USP *. |
| | Certain proposed ingredients with a name consistent with INN policy have no reference whereas the current name of the ingredient does have a reference. For example, colecalciferol, heavy magnesium carbonate, light magnesium carbonate, magnesium phosphate – tribasic, magnesium sulphate heptahydrate, green lipped mussel, estrone, sodium phosphate – dibasic. It is therefore, unclear what reference is to be applied to those ingredients with these proposed names. |
| | It is observed that all the proposed names start with a lower case letter whereas the current names all start with an upper case letter. |