Consultation submission cover sheet

This form accompanies a submission on:

The document 'Evidence required to support indications for listed medicines (excluding sunscreens and disinfectants)'	
Name and designation	**Ian Hammond, Regulatory Affairs Technologist.**
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I would like the comments I have provided to be kept confidential: *(Please give reasons and identify specific sections of response if applicable)*	☐ Yes ☒ No
I would like my name to be removed from all documents prior to publication and not be included within the list of submissions on the TGA website.	☐ Yes ☒ No

It would help in the analysis of stakeholder comments if you provide the information requested below.

I am, or I represent, a: *(tick all that apply)*

Business in the therapeutics industry *(please tick sector):*

☐ Prescription medicines ☒ Complementary medicines ☒ OTC medicines

☐ Medical devices ☐ Blood, tissues, biological ☐ Other

☐ Sole trader ☒ Business with employees

☐ Importer ☒ Manufacturer ☐ Supplier ☐ Industry organisation

☐ Government ☐ Researcher ☐ Professional body

☐ Consumer organisation ☐ Institution (e.g. university, hospital)

☐ Regulatory affairs consultant ☐ Laboratory professional

☐ Health professional – *please indicate type of practice*:

☐ Other - *please specify*:

Evidence required to support indications for listed medicines (excluding sunscreens and disinfectants)

Consultation Paper

Response – 22nd October 2012

Nestlé appreciate the opportunity to respond to the consultation paper on Evidence required to support indications for listed medicines (excluding sunscreens and disinfectants).

Nestlé supports the aims of the document to help sponsors meet their obligations under therapeutic goods legislations and ensure that applications to TGA relating to listed medicine are supported by appropriate evidence.

Nestlé wish to make the following comments on the document.

It would help in the analysis of stakeholder comments if you provide the information requested below.

Comments

An assessment of how the proposed change will impact on you. That is, what do you see as the likely benefits or costs to you (these may be financial or non-financial). If possible, please attempt to quantify these costs and benefits.
Where ingredients and indications are not covered by a SEE, the requirement to conduct a full systematic review and prepare an evidence report for every ingredient and every indication is complex, costly and onerous for low risk indications and medicines. Compliant sponsors of products that are not covered by a SEE are faced with huge cost to provide a high level of data to support low level indications. The end result of increases in the cost and complexity of compliance will be, less variety of products available to the Australian consumer, increased prices for these types of medicines to the Australian consumer and more competitive advantage given to Sponsors who do not comply with the guideline. Without the addition of increased monitoring and effective enforcement, the proposal will have little or no effect on sponsors who do not comply with the guideline. **<u>P14 – 15 Identification of evidence</u>** The evidence report requirements for traditional use refer to searching databases and search interfaces and documenting the search to international standards. This may be suitable for looking up clinical trials and studies but is unsuitable for looking for evidence of traditional use and documenting the search. In most cases for evidence of traditional use databases will be of little or no help at all. The cost and effort to fully research an ingredient that is not covered in a TGA recognised SEE will mean that such an ingredient will not be likely to be continued to be available in traditional complementary medicines in Australia even if it is widely used elsewhere in the world. The list of Sources of established evidence should be as comprehensive as possible to allow Australian consumers to continue to enjoy access to a wide range of complementary medicines.
Whether or not you support the revised Evidence Requirements. If not supported, please provide reasons why.

Any additional information on issues not asked in the above questions.

If your comments relate to specific parts of the document please provide the page number and reference.

P9, 23 Information required from sources of established evidence & P62 SEE assessment template

The requirements for methods of preparation of active ingredients allow the method of preparation to be identical or **Comparable** to that described in the SEE. For extracts it appears that comparable is not acceptable as the method of preparation must be identical to that described in the SEE.

For extracts, if the SEE describes a method of preparation, then an equivalent method of preparation should be permitted. For example a different method of preparation for an extract to that described in the SEE should be permitted as long as the preparation method is still within the extraction method described in the definition of a what is a complementary medicine and that it provides a comparable quantity of a main ingredient or chemical marker compound as the extraction method described in the SEE.

An extract of a herbal substance may be also be used to obtain an ingredient that can be incorporated into modern dosage forms such as tablets. Extracts should be permitted to be used where they are not described in the SEE as long as the ingredient or main chemical components in the extract are present in the finished product at dosage levels comparable to that described in the SEE.

P56 Multi-Ingredient Traditional Medicines

For multi-active ingredient products where there are two or more ingredients, this section requires that traditional use ingredients must either be captured in a single product monograph or each ingredient must be within the same identified traditional paradigm (e.g. traditional Chinese Medicine). This is inconsistent with the information on Page 54 which allows products that combine non-traditional ingredients with traditional ingredients or that combine active ingredients from different traditional paradigms.

Listed medicines should be able to continue to combine non-traditional active ingredients with traditional active ingredients or combine active ingredients from different traditional paradigms.

P21 Nutrients and nutrient supplementation

The existing evidence guidelines allow reference to the presence of vitamins or minerals where they are present in the recommended daily dose of the product to at least the level of 10% of the RDI. This seems to be missing from this new guideline.

The requirements about vitamin and mineral supplementation are confusing.

"Statements relating to supplementation with vitamins, minerals or other essential nutrients (e.g. 'a source of calcium') imply a health benefit (i.e. the maintenance of good health). Such statements are permitted on products if the recommended daily dose of the product provides at least 25 percent of the Australian recommended dietary intake (RDI), adequate intake (AI) or nutrient reference value for that vitamin, mineral or nutrient."

However If the listed medicine states that it is intended to supplement a named nutrient, it must provide at least 50% of the RDI, AI or nutrient reference value for that nutrient.

The example "source of calcium" names the nutrient 'calcium' but only requires it to be present to at least 25% of the RDI or AI, in contradiction of the named nutrient requirement.

P56 -61 Appendix 1: Sources of Established Scientific Evidence

There should be a mechanism in place for proposal and recognition and acceptance of new Sources of established evidence to allow them be added to the list. As new high quality reputable references become available they should be recognised and added to the list to allow sponsors to use them without the need to perform a costly and complex full review of evidence and production of an evidence report.

Components of Volatile oils used as active ingredients in medicated throat lozenges.

Medicated Throat lozenges are permitted to use components of volatile oils as active ingredients. For example menthol and cineole. The Sources of established evidence does not look like it has any reference that could be used to substantiate the use of these ingredients as an active ingredient in a medicated throat lozenge so a full evidence review would be required.

The Sources of established evidence should be as comprehensive as possible.

Health Canada natural health product monographs are included but health Canada non-prescription drug product monographs do not appear in the list of acceptable reference. Why not?
e.g. HEALTH CANADA CATEGORY IV MONOGRAPH "Throat Lozenges" which does cover menthol lozenges.

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