Consultation submission cover sheet

This form accompanies a submission on:

The document 'Evidence required to support indications for listed medicines (excluding sunscreens and disinfectants)'	
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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*:

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.
The proposed changes will have minor impact on most professional homeopathic practitioners who dispense medicines extemporaneously in the context of a professional consultation. There may be a larger impact and increased costs for practitioners who provide acute care kits to clients, and negatively impact ease of access to homeopathic medicines by the public in over-the-counter sales.
Whether or not you support the revised Evidence Requirements. If not supported, please provide reasons why.
We do not support the current draft, but would do so with the reinclusion of previously incorporated homeopathic texts with the list of SEEs.
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.

If you would like to be kept informed about TGA activities, please subscribe to one of the TGA's email lists <http://www.tga.gov.au/newsroom/subscribe.htm>.

AUSTRALIAN HOMOEOPATHIC ASSOCIATION INC.

Similia ◆ Similibus ◆ Curentur

ARBN 077 464 101

20 October 2010

To whom it may concern

Australian Regulatory Guidelines for Complementary Medicines, Part IV
Evidence required to support indications for listed medicines (excluding sunscreens and disinfectants)

Submission on behalf of Australian Homoeopathic Association

1. General Comments on the consultation document

After discussion with the Office of Complementary Medicine we would like to include some general comments on the overall clarity of the document.

i. Absent from the document are any references to requirements for medicines which are exempt from listing (ie homoeopathics) under Australian Regulatory Guidelines for Complementary Medicines, Part IV, 2.1.3.

ii. It would be useful to include a statement in the document as to the requirements for these medicines to enable sponsors/stakeholders to connect the various documents required for providing evidence for both listed and exempt medicines.

iii. Omission of homoeopathic texts which were previously present in the SEE list furthered the possibility for confusion in this regard.

2. Part A 1. Listable Indications

The document states that *"An indication, in relation to therapeutic goods, must describe the specific therapeutic use(s) of the goods".*

As submitted previously, single homoeopathic medicines are not traditionally dispensed with indications. This is because each of our medicines has a multitude of uses for both acute and chronic conditions.

It is restrictive, potentially misleading and inappropriate to select one or two indications for a particular medicine. Homoeopathic medicines are traditionally applied holistically within a homoeopathic diagnostic frameworks.

Users of homoeopathy are generally well informed and will either select or be prescribed a medicine appropriate to their particular situation. In the majority of cases they would purchase a medicine according to the individual medicine name and not the indications.

3. Part A Table 1. Criteria in a SEE required to link an active ingredient(s) or product to an indication(s) for listed medicines.

There are several references to *"active ingredients"* in the document.

There is no definition in the glossary for active ingredients.

The Australian Homoeopathic Association refers to the World Health Organisation definition in their document *"safety issues in the preparation of homoeopathic medicines"*.

In annex 4, page 54 in 'Australia', an active ingredient is defined as *"product name and name(s) of all active ingredients in the goods (i.e. name of active ingredient or the substance from which the dilution was prepared)".*

In order to avoid confusion around the term "homoeopathic medicine" in regard to active ingredients we would like this definition to be included in the glossary. This would clarify that a homoeopathic medicine is made from the substance from which the dilution was prepared.

4. COMMENTS ON APPENDIX 1

Appendix 1: Sources of established scientific evidence

- The title of this Appendix should be "Sources of established scientific **and traditional** evidence" as the source list at the end refers to the traditional texts.
- The sources of homoeopathic evidence (pharmacopoeia and materia medica) which were present in **Attachment 2: TGA–approved texts (v1.1 April 2011)** have been omitted from Appendix 1 of the updated consultation paper. We have listed our references below for inclusion in the final document.
- These pharmacopoeia and materia medica were selected by the Australian Homoeopathic Association as being those documents which best represented the traditional usage of homoeopathic preparations. .
- These texts list the traditions usage of homoeopathic preparations. Additionally we have included some suggestions not present in the previous draft.
- These texts describe the traditional uses of homoeopathic medicines, based of clinical evidence and homoeopathic trials. They also are foundation documents for most modern publications.
- The combined texts represent the accumulated experience of many doctors and homoeopathic practitioners' use of the medicines providing a wide body of evidence in their entirety.

- The included homoeopathic medicines can be traced back to the original supporting documentation. These are the texts in use today by both practitioners and pharmacies around the world.

- This list represents the latest edition/version of the texts, though the information contained fulfills the requirements for traditional usage.

- It is necessary that this list is included again in the list of established evidence for homoeopathy as representative of our ingredients and their uses.

Pharmacopoeia

1 *British Homoeopathic Pharmacopoeia*, British Homoeopathic Society, London.

2 *German Homoeopathic Pharmacopoeia*, MedPharm Scientific Publishers, Germany

3 *Homoeopathic Pharmacopoeia of the United States/Revision Service*, Homoeopathic Pharmacopoeia Convention of the United States, Southeastern

4 *Homoeopathic Pharmacopoeia of India*, Ministry of Health, India

Item 1 was included in the original Evidence list and is the accepted Homoeopathic Pharmacopoeia in the UK.

Item 2 – addition - German Homoeopathic Pharmacopoeia contains nearly 600 hundred monographs covering homoeopathic or medicinal products and their related analytical and manufacturing techniques. Each monograph is uniformly structured supplying origin, description, characteristics, identification, tests on purity, and assays, where applicable. All the analytical methods contained in this publication have been harmonized with the European and German Pharmacopoeias.

Item 3 – addition - The American Homoeopathic Pharmacopoeia originated in 1882 and is the basis of much of our homoeopathic information on our medicines. Homoeopathic Pharmacopoeia Convention of the United States (HPCUS) decided to republish previous texts into this one compilation

Item 4 – addition - Homoeopathic Pharmacopoeia of India is regularly updated for accuracy and currency.

Materia Medica and Repertory

1 Boericke W (1927*) Pocket Manual of Homoeopathic Materia Medica, comprising the characteristic and guiding symptoms of all remedies (clinical and pathogenetic)*, Boericke and Runyon Inc, New York, USA.

2 Boger CM (1983) *Boenninghausen's Characteristics and Repertory*, B Jain, New Dehli.

3 Boger CM (1992) *Boenninghausen's Characteristics Materia Medica and Repertory with Word Index,* Jain Publishing, New Dehli.

4 Julian OA (1979) *Materia Medica of New Homoeopathic Medicines*, Beaconsfield Publishers, Beaconsfield, Bucks, UK.

5 Kent JT (1935) *Repertory of the Homoeopathic Materia Medica*, Enrart & Karl, Chicago.

6 Kent JT (1978) *Repertory of the Homoeopathic Materia Medica*, 6th American edition, Jain Publishing, New Dehli.

7 Murphy R (2006) *Nature's Materia Medica* Third Edition, Lotus Health Institute, USA

8 Reckeweg HH (1991) *Materia Medica*, volume 1, Aurelia Verlag, Baden Baden, Germany, ISBN 3-922907-16-4.

9 Vermeulen F (2011) *Concordant Reference*, 1st edition, B Jain Archibel, Assesse, Belgium

10 Vermeulen F (1993) *Synoptic Materia Media I*, Emryss, The Netherlands.

11 Vermeulen F (1996) *Synoptic Materia Medica II*, Emryss, The Netherlands.

Item 7 is the most current version of the publication, previously titled *Lotus Materia Medica* 1997. The publication contains corrected and updated information from the source material.

Item 9 is the most current version of the publication, previously titled *Concordant Materia Medica*. This is the largest single volume compilation of the traditional indications for homoeopathic medicines, containing materia medica from 1790 to 1930. Included are accurate identification of source material for the homoeopathic preparation, utilising the APG III taxonomical system.

Greg Cope
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Australian Homoeopathic Association