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	XXX
Company/organisation name and address	XXX
Contact phone number	XXX
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.
A trial of the Appendix 4 Evidence report (traditional) that was carried out by the manufacturer of a multi-ingredient homoeopathic product found that the format was difficult to handle and very time-consuming to complete, taking up to 20 hours for each ingredient where it was necessary to search for primary sources. Several critical points were identified: (1) The tracing of primary sources in homoeopathy is difficult, requires enormous research and may sometimes not be possible at all. Secondary sources such as repertories and materia medica are the commonly used working documents in homoeopathy. (2) For each substance in combination products, a separate subsection 3 (3a, 3b, 3c etc.) would need to be introduced. (3) The assessment criterion "Relevance to medicine" does not work for homoeopathic medicines. Literature references will hardly ever be found for evidence of the effectiveness of a particular combination product, resulting in a score of only 1 or 0. "Dose" is not relevant for homoeopathics. (4) The assessment criterion "Relevance to target population" is difficult to assess as it is not usually specified in the homoeopathic literature. The likely evaluation would again be 0 since homoeopathic studies relevant to the Australian population will hardly ever be found, so strictly "not applicable". (5) It is unclear how the part 4 quality of evidence should be addressed for multi-ingredient homoeopathic products, whether an assessment should be made for the combination or for each ingredient and an average calculated [Ingredient described]. (6) It is unclear how the assessment expected under part 5 should be carried out. (7) It is unclear what is expected to be entered in the "Subtotal" section of part 3. It is of concern that a traditional evidence report may be required for most combination homoeopathic products since the majority of such products are not likely to have been on the market for at least 75 years. Homoeopathy has been in existence as a traditional system of medicine for over 200 years. It should be permissible that homoeopathic ingredients may be combined in a way that permits each ingredient to contribute to the therapeutic purpose of the product in accordance with the same traditional paradigm through sources of established evidence. The proposed change requiring completion of the evidence report seems likely to prove particularly and unnecessarily difficult, unsuitable and costly for multi-ingredient homoeopathic products. The justification for a combination product would need to be more flexible to do justice to homoeopathy. The extensive literature of the experimental and clinical foundations of homoeopathy should warrant the status of established evidence for a more reasonable and relevant evidence assessment of listed homoeopathic medicines.
Whether or not you support the revised Evidence Requirements. If not supported, please provide reasons why.

In consequence of the above discussion of compliance difficulties and in anticipation of greatly increased costs, we are unable to support the revised Evidence Requirements for listed products that are sponsored by this stakeholder. The new draft document proposes sources of established evidence, but completely fails to acknowledge any such sources for homoeopathy. This is certainly a retrogressive step for us compared with the current Guidelines dating from 2001. We would like to see multi-ingredient homoeopathic products eligible for evidence assessment under the Appendix 2 SEE template with suitable modifications to allow the use of SEE references to support the inclusion of each ingredient within the homoeopathic paradigm.
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.
Appendix 1: No SOURCE references for homoeopathic preparations (compare: V1.0 March 2012 Appendix 1 and the current Guidelines, Version 1.1, April 2011, Attachment 2). Appendix 2: SEE assessment template. SEE references for multi-component homoeopathic products only support individual ingredients, not the combination rationale. The homoeopathic rationale applies individually to the ingredients in relation to the one or more of the indications for a product. Appendix 4: traditional evidence report: it is not entirely clear what may be accepted as a national formulary or pharmacopoeia. The absence of any references to therapeutic indications in homoeopathic pharmacopoeias and perhaps any nominated formularies may result in an unacceptable evidence score, so they would appear to be unsuitable as sources of evidence for homoeopathic medicines.

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