

# Consultation submission cover sheet

This form accompanies a submission on:

<b>The document ‘Evidence required to support indications for listed medicines (excluding sunscreens and disinfectants)’</b>	
<b>Name and designation</b>	XXXXXXXXXX
<b>Company/organisation name and address</b>	XXXXXXXXXX
<b>Contact phone number</b>	XXXXXX
I would like the comments I have provided to be kept confidential: <i>(Please give reasons and identify specific sections of response if applicable)</i>	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> 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.	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No

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

<b>I am, or I represent, a: <i>(tick all that apply)</i></b>	
Business in the therapeutics industry <i>(please tick sector)</i> :	
<input type="checkbox"/> Prescription medicines	<input type="checkbox"/> Complementary medicines <input type="checkbox"/> OTC medicines
<input type="checkbox"/> Medical devices	<input type="checkbox"/> Blood, tissues, biological <input type="checkbox"/> Other
<input checked="" type="checkbox"/> Sole trader	<input type="checkbox"/> Business with employees
<input type="checkbox"/> Importer	<input type="checkbox"/> Manufacturer <input type="checkbox"/> Supplier <input type="checkbox"/> Industry organisation
<input type="checkbox"/> Government	<input type="checkbox"/> Researcher <input type="checkbox"/> Professional body
<input type="checkbox"/> Consumer organisation	<input type="checkbox"/> Institution (e.g. university, hospital)
<input type="checkbox"/> Regulatory affairs consultant	<input type="checkbox"/> Laboratory professional
<input checked="" type="checkbox"/> Health professional – <i>please indicate type of practice:</i> Homeopathy	
<input checked="" type="checkbox"/> Other - <i>please specify:</i> Considering importing and manufacturing Homeopathic medicines	

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## 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 impact upon my desired business pathway financially in 2 ways

a/ the costs of meeting your proposed 'listings' requirements is prohibitive for a small trader

b/ the stealthy way that all the approved Homeopathic references, which were included in the first draft, have been removed from the second draft -means that the TGA have removed any likely chance of being able to utilise 'Traditional use' as the means of listing a Homeopathic product. It will therefore make it almost impossible to grow my business as per my plans

Whether or not you support the revised Evidence Requirements. If not supported, please provide reasons why.

I do not support the revised Evidence requirements - again because of the unwarranted and unexplained removal of all the approved Homeopathic references which were to have been available for citing 'traditional use' - I have searched all the submissions to draft 1 and have found no reference to anyone wanting these removed so can only assume that this is yet another attempt to marginalise or remove Homeopathy by stealth with no basis other than the medical profession/NHMRC want it removed.

As where is the basis for this decision? - I can find no statistics to support an argument that Homeopathic remedies are unsafe or dangerous (yes there have been 2 cases in recent years where Homeopaths have been under scrutiny - but this has been about poor judgement/ or education of practitioners and NOT about the remedies being unsafe.)

Placed against the huge evidence of fraud in drug company research and reporting (as evidenced by the millions of dollars in fines imposed on drug companies) citing the supposed 'gold standard' double blinded randomised trials do not equate to safety nor efficacy and we as a population can no longer trust in this research especially when it is run and paid for by the drug company. With around 200 years of Homeopathy one would think that there would be a body of evidence to prove that this traditional use has been erroneous for you to try and remove it - but Homeopathy has according to WHO, 550 million users worldwide and growing fast, as is the body of research to back it.

I hereby request some formal and logical explanation for this removal of references.

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.

FIRST DRAFT 120423

Appendix 1 Page 43

TGA accepted Monographs and authoritative texts

All Homeopathic references have been removed in

SECOND DRAFT 120827

Sources of Established Scientific evidence

Page 65-71

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