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	NPS Medicinewise
Company/organisation name and address	Level 7/418A Elizabeth Sr Surry Hills NSW 2010
Contact phone number	

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*: Not for profit organisation

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.
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.

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>.

TGA EVIDENCE REQUIRED TO SUPPORT INDICATIONS FOR LISTED MEDICNES

CONSULTATION PAPER

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Independent, not-for-profit and evidence based, NPS enables better decisions about medicines and medical tests. We are funded by the Australian Government Department of Health and Ageing.

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Submission

NPS appreciates the opportunity to review the TGA Evidence required to support indications for listed medicines paper. We strongly support the firm assessment of evidence supporting indications and the guidance regarding the use of sources of established evidence. We commend the TGA on the work done so far in updating the requirements in an effort to instil transparency and rigour for listed medicines. This will improve the level of confidence and trust in the firmness and transparency with which the processes of listed medicines are marketed.

The evidence required from sponsors is robust and will strengthen the therapeutic claims which are able to be presented to consumers. How the levels of evidence are going to be effectively communicated to consumers to enable them to make informed choices needs further consideration.

We are happy to expand on any of the issues raised in this paper. Thank you again for the opportunity to contribute.

In reviewing the consultation paper we would like to highlight the following:

Issue	**Implication**
The 'expert' clause has been removed from this version.	This may potentially lead to an unbalanced representation of the evidence with all evidence not being taken into account with a submission. For example there may be scientific evidence which disputes the efficacy of a compound which is not provided by the sponsor. Therefore the claim must be supported by a balance of evidence which perhaps only an expert in the field would be aware of.
Communicating the implication of the different evidence bases to consumers.	Consumers need to be able to make an informed choice. The difference in meaning of the two evidence bases is made very clear in the document. However when this is expressed to consumers the word 'traditional' is solely used to convey the health benefit. This assumes the consumer understands 'traditional' means the evidence for this medicine is based on long term use or experience. For consumers to be well informed more information is needed to be given to them.
Naming and labelling of listed medicines.	Although not discussed as part of the paper the naming of listed medicines needs consideration in order to take into account marketing strategies which may negatively impact the safety of consumers. Another consideration would be the inflation of therapeutic claims, for example consumers may equate the word 'natural' with harmless. The labelling of listed medicines also needs deliberation in order to assess where on the label the information is going to be given to provide consumers with easy access to information.

Post marketing regulatory activities.	There needs to be greater clarity on the implementation plan, however we acknowledge this may come later when it is embedded in the legislative framework for regulation of therapeutic goods. None-the-less we would like to see more detail on the nature of of post-marketing surveillance and the sanctions for non-compliance. The paper makes reference to targeted and random desk-based audits compliance reviews amongst other measures. More information on these activities is needed. For example how frequently will desk-based compliance reviews be performed and what information will be looked at. Easily applied but appropriately punitive civil actions for non compliance should be considered to enhance accountability. This is a visible process for consumers as well as industry.