

Complementary Medicines Reform Section  
Complementary and OTC Medicines Branch  
Therapeutic Goods Administration  
PO Box 100  
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**Re: TGA Consultation: Options for the implementation of a claimer for efficacy assessed non-prescription medicines**

Medicines Australia (MA) welcomes the opportunity to respond to the TGA Consultation: Options for the implementation of a claimer for efficacy assessed non-prescription medicines.

MA supports initiatives which assist consumers to make informed and better decisions with respect to all medicines, and in this matter, with respect to self-selected medicines. Therefore, MA supports the introduction of a claimer to be applied to medicines, including prescription medicines, which have successfully passed TGA pre-market assessment of efficacy, so long as a consumer education campaign is provided at the time of introduction. MA also supports initiatives which encourage sponsors to collect high quality evidence regarding the safety, quality and efficacy of their product.

***Education of consumers and other stakeholders is a priority***

It is estimated that 60% of adult Australians have low individual health literacy<sup>1</sup>. Consequently, the use of a claimer may not be easily understood by consumers, and this is compounded by the low level of consumer understanding of the medicines regulatory framework in Australia<sup>2</sup>.

Consumer confusion regarding the efficacy of those products not carrying a claimer, including prescription medicines, is exacerbated by limiting the use of the claimer to certain products. There is an assumption that consumers will know that prescription medicines have been fully assessed for efficacy and safety. Therefore, consumers need to be educated about the role of the TGA, the different levels of TGA assessment, and how this applies to different classes of medicines, otherwise there is a risk that consumers will not choose the most appropriate medicine for their circumstances.

1. Australian Bureau of Statistics. Health Literacy, Australia. Canberra: Australian Bureau of Statistics, 2008.  
2. <https://www.tga.gov.au/book/awareness-and-understanding-tga-and-its-role>

***MA supports the use of the claimer ONLY if it's used for all pre-market efficacy assessed medicines including prescription medicines***

The claimer should be used on all medicines that successfully pass TGA pre-market assessment of efficacy, including prescription medicines. This will improve the transparency about the efficacy of all medicines and allow consumers to make more informed health decisions regardless of whether the medicines they use are self-selected or prescription only.

In this regard consumers will be reassured that their prescription medicines have also had appropriate scrutiny for safety, quality and efficacy, preventing consumer misunderstanding which may result in decreased adherence to their prescribed medicines.

***The evidence required across the spectrum of TGA assessment is varied and to introduce labels which accurately reflect this may be challenging***

There needs to be a clear distinction between the different levels of TGA assessment. If labels are to be applied to different classifications of medicines, then that labelling must reflect the different levels of evidence required across the spectrum, (e.g. different labels corresponding to different levels of TGA assessment). However, this would need to be accompanied by appropriate consumer education in order for it to support consumers in making informed choices as it has the potential to cause further consumer confusion.

***Other Issues***

- Any application of the claimer would need to be mandatory for it to fully achieve the desired effect of allowing consumers to make better health decisions.
- Ongoing consultation with (and education of) the relevant stakeholders is required in order to provide a solution that leads to improving the quality use of medicines and better health outcomes for consumers.

Yours sincerely



Kim Bessell  
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