



# SANDOZ

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Date 15 August 2012

TGA Labelling and Packaging Review  
PO Box 100  
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Dear TGA Labelling and Packaging Advisory Committee,

**Re: Feedback from Sandoz Pty Ltd to the TGA Medicine Labelling and Packaging Review Consultation Paper, Version 1.0, May 2012**

Sandoz Pty Ltd appreciates the opportunity to provide feedback to the above consultation paper.

It is understood that the new TGA packaging requirements are expected to be legislated in mid-2013 with an implementation period of 3 years. Although Medsafe has been included in the external reference group, it is unclear what packaging changes may arise through the packaging requirements that would need to be implemented as a result of the introduction of ANZTPA. To elaborate further, if industry is expected to comply with the new TGA labelling and packaging requirements and then is required to make additional changes as a result of ANZTPA requirements, then this is an unnecessarily resource-intensive and costly exercise.

With regard to specific feedback on the proposed recommendations:

1.2.4: Sandoz does not agree with the recommendation. It is unclear why having the first letter of the active ingredient in upper case adds any benefit to the consumer. ARTG entries always list the active ingredient in lower case lettering and this is widely accepted. Additionally, within PI and CMI documents, the complete active ingredient name is written in lower case.

6.1: Sandoz wishes to raise a concern regarding the proposal that on blister strip labelling the brand name, active ingredient and amount, batch number and expiry date be repeated at least once every two units be applied also to products with a calendar pack. If this was implemented, it will make the text very cluttered and difficult to read by the consumer.

Lastly, it is difficult for Sandoz to quantify the costs associated with the proposed changes however should these changes be implemented (in particular 1.2.4), it would require us to amend every piece of packaging resulting in significant internal and

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external resource. It is unclear as to what TGA fees would apply for packaging and labelling updates by companies although it is clear that with Sandoz having such a large product portfolio, should the usual TGA fee structure for packaging and labelling changes be payable, this will be a significant financial impost on the company.

Yours sincerely,

A handwritten signature in black ink, appearing to read 'D G Harle', written in a cursive style.

David G. Harle, PhD  
Scientific Affairs Manager