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TGA Labelling and Packaging Review
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Via email: labellingreview@tga.gov.au

TGA medicine labelling and packaging review[1]

This submission was authored by Dr Ken Harvey who has represented CHOICE on a number of recent therapeutic goods reviews, is one of our Life Members and a trusted advisor.

First, we draw the TGA's attention to three relevant documents produced by the Communication Research Institute of Australia (CRIA) in association with many stakeholders; "Writing about Medicines for people, 3rd Edition 2007"[2], "ASMI Labelling Code of Practice 2004"[3] and, "Designing medicines labelling".[4] All these publications stress the importance of testing proposed designs with consumers to determine if they assist consumers to:

- quickly and easily make a choice about the appropriateness of this medicine for their needs, at the point of sale;
- find and appropriately use instructions for using the medicine safely and effectively, at the point of use;
- access further information, if they want to know more about the medicine, at any point.

We agree with the CRIA that the label (and package) of a medicine should assist consumers to perform the following tasks (modified by us from the 2004 edition).

At the point of sale	**At the point of use**		
Identify and select	***Use***	***Store***	***Dispose of***
can locate and read product ingredients (generic names), their formulation (e.g. tablets, liquid) and their strength	can locate, read and understand product description	can locate, read and understand storage instructions	can locate and read expiry date
can locate and read product brand name	can locate, read and understand dosage and usage instructions		
can locate and read pack quantity	can locate, read and understand any warnings and/or precautions /what do if overdose / etc.		
can identify what the product is used for (indications)	Can find and read a batch number in case of a product recall		
can identify circumstances under which the product should not be used (warnings)	can locate and read sponsor contact information		

[1] http://www.tga.gov.au/newsroom/consult-labelling-packaging-review-120524-02-about.htm
[2] http://communication.org.au/modules/oledrion/product.php?product_id=10
[3] http://www.asmi.com.au/documents/Industry/labelling_code_of_practice.pdf
[4] http://communication.org.au/modules/oledrion/product.php?product_id=3/

We stress the need for the TGA to test the understanding of the proposed label and packaging changes with consumers and we also suggest that the above references be included in the final document.

We now address the specific recommendations proposed.

1. **Prominence of active ingredients on medicine labels**

   We support the current campaign of the NPS, "Know the active ingredient".[5] We are concerned about the potential for confusion of the current proliferation of different brand names for medicines containing the same active ingredients.

   We believe that the NPS message "Know the active ingredient" would be reinforced by listing the name of the active ingredients on the pack BEFORE the brand name and making it MORE prominent than the brand name (not below and of equal prominence as suggested). This principle should also apply to all other material related to a product, Public summary documents, approved product information (PI), Consumer Medicines Information (CMI) and promotional material)

2. **Look-alike sound-alike names and look-alike packaging**

   The Nurofen range of products targeting caplets for migraine, back, tension headache and period pain received a 2010 CHOICE "shonky" award.[6] We said, "filling up your medicine cabinet with different painkillers that contained the same active ingredient for every type of pain is unnecessary, not to mention wasteful, should they expire before you've used them all". It also makes an overdose more likely if a consumer takes several of these products because they have a headache as well as a back ache. Finally, these products were rip-offs as they cost almost twice as much as other comparable formulations of ibuprofen.

   We strongly support the proposals to reduce consumer confusion caused by look-alike medicine branding.

3. **Standardised Information Format: the Medicine Information Box**

   Strongly supported.

4. **Dispensing label space**

   Supported.

5. **Blister strip labelling**

   Supported.

6. **Small containers**

7. Supported.

8. **Pack inserts**

   Supported.

9. **Labels and packaging advisory committee**

   Supported.

Finally, while the following matters fall outside the scope of this review we emphasise that it is crucial that the TGA deals with them in the near future:

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[5] http://www.nps.org.au/bemedicinewise/brand_choices/know_the_active_ingredient

[6] http://www.choice.com.au/reviews-and-tests/awards/shonky-awards/shonkys/the-2010-shonky-awards.aspx

1. The inclusion of a mandatory warning on all listed medicines along the lines of, “The claims made for this product have not been assessed by Australian Health Authorities”.
2. The prohibition of brand names for listed medicines that make implicate claims that lack substantiation from well conducted clinical trials, e.g. Fat Blaster, Fat Magnet, SensaSlim, Undoit.
3. Homeopathic medicines (currently exempt from regulation) should have the name and the dilution of their starting ingredient spelled out in simple English, e.g. duck liver and heart extract diluted 1:100, 200 times NOT Oscillococcinum (or *Anas Barbariae)* 200 C.

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