

# TGA Medicine Labelling and Packaging Review

Submission:

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*TGA Medicine labelling and Packaging Review - Submission from Anne McKenzie The UWA School of Population Health.*

Thank you for the opportunity to provide a submission to this Review.

### **Background to the submission**

The content of this submission is derived from consumer and community participation activities in two large research projects funded by the NHMRC and conducted at The University of Western Australia's School of Population Health (2006 – 2011). The projects looked at chronic disease outcomes and enhanced primary care in seniors and improving medication safety in seniors (65+) using linked state and commonwealth health information to investigate and identify:

- evidence on how best to use the efforts of Australian GPs to obtain better outcomes in patients aged 65+ years who suffer from chronic
- priorities for tackling the current epidemic in Australians aged 65+ years due to side effects of their medications.

There was a planned budgeted strategy for consumer and community participation which included:

- Three community forums attended by over 105 consumers who took multiple medications and had one or more of the chronic conditions being studied in the projects.
- A Seniors Consumer Panel of 10 members who provided a consumer perspective on all aspects of the research for the duration of the project
- a series of 6 focus groups to further investigate in more depth a range of issues raised at the community forums

In order to represent as many health consumers as possible, the membership of the Seniors Consumer Panel aimed to reflect the diverse groups the research projects would cover.

It was considered to be important for consumer members of the Seniors Consumer Panel to:

- Speak strongly and independently on consumer issues relating to the research projects
- Have insight into consumer issues that affect a wide range of health conditions, that is, not limited to the condition the member has the most direct experience with
- Have links to community, seniors or chronic illness support groups

The Seniors Consumer Panel was established in 2007 and met regularly with one of the Chief Investigators, a researcher and the consumer advocate for the duration of the project. The Panel's tasks included:

- Input into the development of the 6 focus groups which were held to further explore key topics and issues raised by consumers at the three community forums
- Providing input into the questions and results from the focus groups
- Developing a good practice suggestions for packaging and labelling of prescription medicines
- Attendance at four workshops with researchers and health professionals to discuss research findings
- Meeting with researchers regarding specific unexplained findings from individual research projects
- Lobbying and supporting the project to the wider community through attendance at forums and meetings
- Supporting and/or advocating for changes to policy and practice relating to dosing instructions on prescription medicines
- Presenting about the consumer participation activities in the two research projects at the National Primary Health Care Research Conference in Darwin in 2010

We acknowledge the contribution from the members of the Seniors Consumer Panel, the people who attended the three community forums and the 6 focus groups and the Health Consumers' Council of WA.

## Responses to general questions in the Review

<b>Prominence of active ingredients on medicine labels</b>
<b>General questions on the proposed regulatory changes for the prominence of the active ingredients on medicine labels</b>
<b>What do you think will be the impact of increasing the prominence and standardising the location of the active ingredient on the medicine label?</b>
<p><i>Bulsara et al (2010)<sup>1</sup> reports widespread mistrust and confusion from consumers: 'There was also confusion about terminology and the distinction between brand names, generic names and the active pharmacological ingredient in a medicine'.</i></p> <p>There was a general consensus amongst consumers that attended the forums and focus groups that the active ingredient on prescription medicines should have the same prominence as the brand name: <i>'The active ingredient should always be used first on labels. The use of different names for the same medication; e.g. brand name and generic name is very confusing to patients and can cause double dosing of the same medicine'. Health Matters Report July (2010)<sup>2</sup></i></p> <p>The issue of mistrust and confusion could be greatly reduced if there were standardised requirements that were enforced by the regulator authority regarding the location and prominence of the active ingredients on medicines.</p>
<b>What do you think about the proposed warnings for paracetamol and ibuprofen containing products?</b>
<p>I agree with the proposal to provide warnings as this would enable consumers to make more informed decisions about long term use of medicines that are potentially harmful.</p> <p>It would also be necessary to couple this with a comprehensive health professional education program to build awareness and reinforce the need for consumers, particularly those with low literacy levels or English is a foreign language, to be made aware of the quality use of medicines issues surrounding long term use of these medicines. Consumers repeatedly stated that there was insufficient time given to discussing interactions and side effect of their medicines. Bulsara CE, Emery JE, McKenzie AE, Conference Poster (2010)<sup>3</sup> highlighted that consumers felt more comfortable speaking with Pharmacists about interactions and side effects.</p>
<b>Are there any other concerns you have with the size or position of brand names and active ingredient?</b>
<b>If the active ingredient name is clear, directly below the brand name and in a large font, what are the additional benefits that you see by making it the same size as the brand name?</b>
<p>Regulating this may address some of concerns that consumers raised about issues such as poor eyesight, confusion between the brand name and active ingredient and concerns about double dosing particularly when a carer or second party is involved.</p>
<b>What is the smallest size font that you consider readable?</b>
<p>Consumers reported that the minimum size should always be 12 point.<sup>4</sup></p>

<sup>1</sup> [Bulsara CE, McKenzie A, Sanfilippo F, Holman CDJ, Emery J. 'Not the full Monty': a qualitative study of seniors' perceptions of generic medicines in Western Australia. \*Australian Journal of Primary Health\*, 2010; 16: 240–245](#)

<sup>2</sup> [McKenzie A. Seniors have a say in research on medication safety. \*Health Matters\* 2010; 81:45-47](#)

<sup>3</sup> [Bulsara CE, Emery JE, McKenzie AE, Conference Poster, Primary Health Care Research Conference, Melbourne, 2010.](#)

<sup>4</sup> [McKenzie A. Seniors have a say in research on medication safety. \*Health Matters\* 2010; 81:45-47](#)

<b>Look-alike and sound-alike medicine brand names and look-alike packaging and branding</b>
<b>General question on the proposed regulatory changes for look-alike sound-alike names and look-alike packaging</b>
Do you think the proposed changes to address LASA names and LA packaging will improve medicine safety? Why/why not?
The proposed regulatory changes outlined in 3.1 regarding consumer testing, must be done in consultation with health consumers who use multiple medicines, have low literacy levels or English as a foreign language. This would ensure that the testing is appropriate and it would also limit opportunities for 'tick box' compliance.
<b>General questions on the proposed regulatory changes for look-alike medicine branding</b>
<b>What benefits, if any, do you think the proposed changes to address look-alike medicine branding will have for consumer safety?</b>
Any regulatory measures that reduce the potential for adverse medicine events will provide better quality of life for consumers and their carers' as well as positive flow-on benefits to the wider community by reducing unnecessary hospital admissions and better use of finite health funds and resources.
<b>Do you understand the proposed changes?</b>
I understand them but I would like to see how compliance with these regulatory changes will be: <ul style="list-style-type: none"> <li>• measured and reported on</li> <li>• how the community and health consumer organisations will have access to information around compliance and any improvements in reducing adverse medicine events.</li> </ul>
<b>If you can read the labels and warnings clearly, will these changes reduce the potential for harm?</b>
If consumers can read the labels and warnings clearly this must result in a reduction in adverse medicine events. Consumers and carers expressed concerns about: <ul style="list-style-type: none"> <li>• eyesight becoming poorer with age and increasing the potential for mixing up medicines</li> <li>• increased confusion and possibility for doubling up of dosages</li> <li>• keeping on track with multiple medicines was difficult and was compounded by poor / confusing packaging</li> </ul> <p>The Panel identified a number of points relating to good practice standards for packaging and labelling<sup>5</sup>. They advised that many older Australians think about their medicines in terms of target organs or diseases; 'my heart medicine'; 'my stomach medicine', 'my diabetes medicine', 'my blood pressure medicine'. They suggested that a series of stickers could be developed to pictorially show 'symbols' for the major body organs and some common generalised diseases. Pharmacists could attach the stickers at the time of dispensing and this would assist patients with multiple medications to avoid confusion with dose regimes as well as support adherence to treatment. It would also have a positive impact on medication safety for people with low literacy levels and English as a foreign language.</p> <p>The Panel we asked to develop their standards for packaging and labelling. These standards included:</p> <ul style="list-style-type: none"> <li>• The minimum font size should be 12 point;</li> <li>• The active ingredient should always be used first on labels. The use of different names for the same medication; e.g. brand name and generic name is very confusing to patients and can cause double dosing of the same medicine;</li> <li>• Space for subsidised price information on dispensing labels would be better used to improve</li> </ul>

<sup>5</sup> [McKenzie A. Seniors have a say in research on medication safety. \*Health Matters\* 2010; 81:45-47](#)

dosing information;

- Major side effects or interactions should always be shown;
- Include "last repeat" on the dispensing label when appropriate to alert patients that they need a new script;
- Pharmacists should avoid accidentally covering use-by dates with stickers; and
- Include stickers (or graphics) to show the part of the body the medicine is intended for.

The NHS's National Patient Safety Agency had patient, carers and patient organisations provide input into the development of the *Design for Patient Safety: a guide to the design of dispensed medicines*<sup>6</sup> (2007). The Panel referred to this document during their deliberation.

## Standardised Information Format: the Medicine Information Box

### General question on the proposed regulatory changes for Standardised Information Format: Medicine Information Box

To what extent do you think a standardised format for information on the labels of over-the-counter and complementary medicines will improve access to information for these medicines?

Are there other ways that the presentation of information could be improved?

Do you think the proposed requirements for products with more than three active ingredients (directions and warnings and allergy information), is sufficient for these products? Please propose an alternative if you don't agree with current recommendation.

## Dispensing label space

### General question on the proposed regulatory changes for dispensing label space

Do you support a designated space for the dispensing label on prescription medicines? Why/why not?

Having a designated space for the dispensing label will limit the practice of putting labels anywhere on the packaging i.e. over expiry dates of other important information.

Consumers repeatedly spoke of their concerns about this practice:

*"The use by date on medicines which you don't take all the time, nine times out of ten it's stuck under your name and address or whatever they put on the thing and then if you try to rip it off the expiry date comes off so you've got no idea if it's good or not. Usually it has a life of a couple of years, but by that time it's been in the cupboard and you haven't had to take it and then you get this spasm or something and you think I'll go and get one of those, but why shouldn't the expiry date be put on the front where everything else is."* Quote from consumer who attended focus group in 2008

A further issue raised by the Seniors Consumer Panel (Panel) was the non-specific dosing instructions on dispensing labels. Whilst this issue may not be considered under the terms of reference for this Review it is certainly pertinent to medicine packaging and labelling and to the quality use of medicines.

The Seniors Consumer Panel recommended that non-specific instructions as outlined below, should

<sup>6</sup> [Design for Patient Safety: a guide to the design of dispensed medicines. 2007.](#)

be strongly discouraged and eventually defined as unacceptable and unsafe practice:

- 'Take as directed by Dr' or 'Take as directed when required'; and
- Use of Latin abbreviations such as 'bd', 'qid'.

(See Appendix 1 for photo example)

The Panel considered instructions like this could in fact be a major contributor to adverse drug reactions in seniors. Often seniors may be taking multiple medications and may not always remember or understand the doctor's verbal instructions given during a brief consultation where numerous issues are discussed. In addition, seniors may be unable to recall and relay appropriate information to caregivers. This may also have financial implications if people are being hospitalised for adverse medicine events due to this practice.

Since the original issue was raised by the Panel the following points have also been put forward by other numerous health consumers and researchers:

- The use of non-specific dosing instructions for medicines would not be considered acceptable practice in hospitals, for example a Dr would not write in patient notes 'take as directed by the Dr ' and expect that a nurse or patient would just remember what instructions had been given.
- This practice also has serious safety issues for a patient presenting to a hospital emergency department (particularly after-hours) with medicines that have non-specific instructions on them. This could be especially difficult if the person is not able to give reliable information on dosages.

This issue has been raised by consumers and consumer organisations for the past two decades. Since it was raised by the Panel in 2008, we have lobbied a wide range of government and non-government agencies and published several articles on this issue<sup>7</sup>.

Still this remains as acceptable practice in Australia regardless of the potential negative implications for all Australian health consumers.

## Blister strip labelling

### General question on the proposed regulatory changes for blister strip labelling

Do you think the proposed information for blister strips is sufficient?

Consumers considered blister strip packaging was difficult for seniors or people with poor fine motor control to use. The limited information on the blister packaging often caused confusion. The proposed changes would address some of these concerns.

*"A lot of these medicines that you buy the come in these silver packety things, why can't they work them out like Monday, Tuesday, Wednesday, Thursday, Friday on the back of the packs of the pills themselves? You don't have to then take them out and you put them in these little boxes. If you put them in the wrong one or whatever, particularly if you're looking after someone who's elderly or older like your mother or something like that, who don't really know what they're taking. If the actually pill was marked and if she'd forgotten to take it on Monday then too bad and you would at least know."* Quote from a consumer who attended a focus group in 2008.

What other changes would you like to see for this type of packaging?

<sup>7</sup> [www.involvingpeopleinresearch.org.au](http://www.involvingpeopleinresearch.org.au)

<b>Small containers</b>
<b>General question on the proposed regulatory changes for small container labelling</b>
To what extent do you support the proposed changes for small container labels? Please provide details.
The proposed changes to small container labelling are supported.
Do you have any further suggestions for how labelling of small containers could be improved?

<b>Small containers</b>
<b>General question on the proposed regulatory changes for pack insert requirements</b>
Do you support the proposed changes for pack inserts? Why/why not
<p>The proposed changes are supported. Consumers frequently referred to the lack of information about their medicines. They reported a high level of trust and reliance on the Pharmacist in providing this information although they did say they would not bother the Pharmacist if they appeared to be too busy.</p> <p><i>“With all due respect to GP’s, medications are not part of their training, I find you get the best information going to the pharmacist and if you get the right who’s got a good knowledge of interactions most of them are very approachable.”</i> Quote from a consumer who attended a focus group in 2008.</p> <p>Many consumers also referred to the inserts that used to be in their medicines. It is considered putting the inserts into all medicines will assist with the provision of information to consumers.</p> <p>It will be important to develop a range of strategies to assist in the provision of information to consumers who have low literacy or English as a foreign language. Only providing an insert in a medicine package may not address the needs of these specific groups.</p>
Do you have any further suggestions regarding pack inserts?
There needs to be an intensive education campaign to promote the need for all health professionals to alert the consumer to the insert being in the package. This may prompt an opportunity for dialogue with the consumer about safe use of medicines.

<b>Labels and packaging advisory committee</b>
<b>General question on the proposed establishment of a labels and packaging advisory committee</b>
To what extent do you think that a Labels and Packaging Advisory Committee will assist the TGA to manage consumer health risks associated with medicine labels and packaging?
The advisory committee can play a vital role in providing timely and appropriate input to the TGA. It is imperative that the advisory committee has at least 2 consumer representatives as full members of the group. Ideally there will be a separate consumer group that would provide input and feedback to the advisory committee on an as needed basis. This will ensure that the consumer voice is integral to decision making processes relating to packaging and labelling.

<b>Other ideas:</b>