
COMMENTS ON:

DRAFT THERAPEUTIC
GOODS ORDER NO. 79

GUIDELINE FOR THE
LABELLING OF MEDICINES

DRAFT - VERSION 1.0, AUGUST 2014

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IGNORING CRI RESEARCH

In August 2012, CRI made a detailed submission to the TGA Medicine Labelling and packaging review.

The TGA has successfully ignored all of our detailed comments and recommendations.

Even though they had given an undertaking, following the review, to provide:

Evidence - the need, in subsequent analysis, to provide evidence that particular changes will improve medicine safety and the quality use of medicines;

and

A commitment to undertake independent consumer testing of proposed options.

There is no mention of either of these in the draft regulations or guidelines. The only mention of evidence is in:

*Labelling and packaging practices: A summary of some of the evidence
Version 1.0, January 2013*

Sadly, this is a summary of *some* of the evidence; and none of it has a direct bearing on the question of whether or not TG79 will improve medicine safety and the quality use of medicines.

Most notably absent is the body of work funded by the Commonwealth Government between 1992 and 2007 undertaken by the Communication Research Institute.

Apart from my own interest and participation in this work, I would like it noted on the public record that TGA has chosen to ignore work on medicine labelling funded by the government to which it is accountable. I will be referring this matter to the Australian National Audit Office.

It is not my intention in this set of comments to repeat those made in my earlier submission. However, I draw your attention to a number of recent public statements and publications which spell out my concerns with TGA's proposed regulations and provide a background to the work CRI has undertaken in this area.

<http://communication.org.au/guidelines-for-medicine-labelling/>
<http://communication.org.au/bad-design-by-tga/>
<http://communication.org.au/tga-ignores-consumer-research/>
<http://communication.org.au/product/regulating-information-for-people/>

OUTCOMES: A PROFESSIONAL OPINION

I am not going to comment on the detail of the proposed regulations. To do so would be akin to offer to rearrange the deck chairs on the Titanic. My single comment on the proposed TGA79 itself is that it should be held over until the expert committee recently appointed by government to review the TGA has completed its work.

<http://www.tga.gov.au/media-release/expert-review-medicines-and-medical-devices-regulation>

I am going to focus on the likely outcomes of TGA's current approach to labelling regulation in terms of the government's policy of Quality Use of Medicines (QUM).

It is important to note that Australia's QUM policy currently leads the world. Many countries, including the USA, do not have such a policy. Indeed the USA is probably 30 years behind Australia in the development of such a policy. This is clearly reflected in its labelling regulations, which are full of inconsistencies and do not draw on the world's best practices in information design. If Australia should now take its lead from the USA, as proposed by TGA, the QUM objectives relating to medicine labelling will be sent back 30 years.

By 2004 Australia was leading the world in medicine labelling developed to support QUM outcomes. At that point CRI had demonstrated that it was possible to regulate labelling in such a way that over 80% of literate consumers would be able to use medicine labelling at an acceptable level. The study demonstrating the evidence for this (one of many conducted by CRI at the time) was published by CRI in 2002. <http://communication.org.au/product/panadol-labelling-redesign/>

The principles and methods embodied in that work were adopted by the ASMI as a code of practice in 2004. <http://communication.org.au/product/labelling-code-of-practice/> This has led to a number of major pharmaceutical companies improving the quality of their OTC labels and having them approved by TGA.

TGA has either rejected or simply ignored this work.

Outcomes for consumers

The following is based on over twenty years of testing labels and closely observing consumers actually using the information on packs. The outcomes listed are those that obtained from pre-QUM labelling designs.

If TGA adopts TGO79 without major modification I anticipate the following outcomes for consumers:

1. The front-of-pack design will lead to confusion at the point of sale between products and within brands.
2. The back-of-pack design, with its black and white colouring and obvious 'bureaucratic' style, will be understood as meeting a legal requirement, not as serving consumers. There will be a strong tendency for consumers to ignore it at the point of sale and beyond.
3. If consumers do try to consult the back of pack, overcoming their dislike of its style and their suspicion of who it is really written for, the first thing they will notice is the list of ingredients. All the available research and experience in medicine information and labelling design shows that the ingredients are one of least salient of items of interest to consumers. Add to this that many ingredients with their chemical and pseudo-scientific names are both difficult to read and meaningless to most consumers, and you have a recipe for not reading any further and confirming consumers' suspicions that this has been produced as a legal requirement, not as information for consumers.
4. Those consumers who get past the above hurdles will find themselves struggling in a mire of unaligned dot points, items out of any sensible temporal order, and a grouped set of warnings that relate to different moments in the medicine-taking process. There is no 'before', 'during' or 'after'. Again, this goes against the major findings from consumer research in this area. As a model example based on the research, see *Writing about Medicine For People*, <http://communication.org.au/product/writing-about-medicines-for-people-hardcopy/>.

The overall outcome of these faults will lead to fewer consumers carefully reading the front or back of pack, which will increase the risk of medication errors—hardly a QUM desirable outcome. There will be a public loss of confidence in the value of medicine labelling information. In numerical terms I would expect fewer than 50% of literate consumers to be able to use the 'new' labels at an acceptable level.

At the very least, and in the interests of public health policy in Australia, the TGA has a duty of care obligation to provide convincing evidence that this will not be the outcome. To date it has not done so. Moreover, because it has not set any performance requirements for the labels, it is not even in a position to undertake such research. If it has misguidedly undertaken such research, the results will not provide a meaningful comparison with labels developed using the ASMI code of practice.

Outcomes for industry

1. Industry will benefit from the TGA's formulaic approach to labelling. With many products sold in Australia having the USA as their main market, the costs of adapting USA labelling to the Australian regulations will be easier: all the way to the bottom with FDA!
2. There are an extremely large number of design inconsistencies and vagueness of typographical specifications in both the TGA regulations and guidelines. There are some areas which are so poorly specified that multiple revisions of the typographical specifications in the regulations and guidelines will have to be produced in order for industry to comply technically with them. Industry will incur considerable costs in trying to comply with impossible specifications.

In my view, TGA does not have the technical competence to regulate in this area. To do so it would minimally need members who (a) are familiar in detail with the use and application of the Style Manual, and (b) have had considerable experience in Information Design, particularly label design and testing. However, if TGA followed a performance-based approach to regulation, it would not have to concern itself with any of these technical matters of appearance and wording.
3. Some of the requirements will lead to larger packaging to accommodate the information specified by TGA. I am not against larger packaging. Indeed there are grounds for suggesting that QUM outcomes should come before package size. But there is an additional cost to industry in complying with this requirement.

Missed opportunities

1. As I have already suggested, innovation in labelling and customer communication are totally inhibited by these proposed regulations. This will mean that many of the experiments that CRI and others have been undertaking to improve customer communication in a number of difficult areas will simply stop.
2. One of the great weaknesses of current labelling that will be reinforced by these regulations is the lack of integration between front and back of pack information. In a few experiments conducted by CRI, of which TGA has seen the results, it has been possible to greatly enhance the quality of consumer choice at the point of sale by integrating some of the front of pack and back of pack information. Once again, the current regulations will discourage such enhancements in QUM.
3. Once introduced, these regulations will totally inhibit any improvement in labelling to enhance consumer choice or use of medicines. The level of labelling usability established by these regulations will remain fixed for a number of years. It will be 10 years or more before we in Australia get another opportunity to improve medicine labelling as an aspect of QUM.

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