
Comments

TGA Medicine Labelling and Packaging Review

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Contents

Executive summary	1
CRI and Medicine Labelling	2
The TGA Review	3
Principles absent in TGA review	4
1. Performance requirements	4
2. Functional analysis	6
3. Evidence	9
4. Information design is a specialist craft	11
Contact details	15

Executive summary

The Communication Research Institute (CRI), founded in 1985, is a world leader in medicine information design. In 2004, CRI's research findings were incorporated into the TGA labelling regulations, TGO69A, together with ASMI's Labelling Code of Practice and CRI's guidelines for designing usable OTC medicine labels.

CRI has integrated the design and testing of medicine information into a rigorous evidence based process. It routinely tests all its designs with medicine users and provides tangible evidence of successful and unsuccessful labels. This is particularly important with medicines, whose inappropriate use can be dangerous or fatal.

It is against a background of experience, research, development, and real evidence that CRI offers these comments on TGA's Medicine Labelling and Packaging Review Consultation Paper (2012).

The issues raised by TGA are legitimate, and the labelling regulations need updating. However, the Consultation Paper ignores the established, evidence-based approach to medicine information design currently enshrined in regulations, and re-introduces an outdated, discredited approach.

Absent from the Review are four well-researched principles which demonstrably lead to labels that consumers can use appropriately. These are (1) performance requirements, (2) a comprehensive functional analysis of labelling parts, (3) the provision of testing to provide evidence of the success or failure of a label, and (4) the need for specialist information design skills.

These four principles are briefly explained, using illustrations to show the differences between CRI's approach and that of TGA.

Full details and references can be found on CRI's website: communication.org.au

If TGA is to enjoy the public's confidence in its decision making, it must demonstrably proceed as an evidence-based regulator drawing on the cumulative research and know-how in the field of medicine information design. The following comments by CRI are made in the hope that TGA incorporates this research and know-how into its future recommendations.

CRI and Medicine Labelling

The Communication Research Institute (CRI) is a not-for-profit membership organisation dedicated to improving the quality of communication between large organisations and the public for the public good.

Established in 1985, it has been at the forefront of international developments in best practice methods of designing information which is accessible and highly usable by the public.

In the 1980s, CRI made a substantial contribution to the design of forms, bills, and legal documents for public use. Many of its research findings and methods of that period continue to be used to set the standards for highly usable documents by most Commonwealth Government departments, including the ATO, ABS, Centrelink and Health. The work was also taken up and applied by major organisations in the financial and utilities sector, including the RBA, Commonwealth Bank, AIG, Capita, AMP, National Mutual, Telstra, Optus, AGL, and several others.

In the 1990s, CRI's Board of Governors suggested that the lessons learnt in these areas might be applicable to medicines information. In 1992 CRI was commissioned by PHARM (Pharmaceutical Health and Rational Use of Medicines) to undertake the research, development, and publication of usability guidelines for CMI (Consumer Medicines Information). The result was *Writing about medicines for people* (WAMFP)—now in its third edition (e-version 2006, print version 2007). This work is the most widely cited and applied work in the field, both in Australia and overseas, and it has been a major influence on medicine information regulations in the EU and Latin America. Both versions remain top of the CRI publications bestseller list. It is the de facto standard for writing CMI in Australia and has resulted in the highest overall national standard of CMI in the world.

Alongside the research and design for prescription medicines information, a substantial part of CRI research and development has focused on the labelling of consumer medicines, particularly OTC (over-the-counter) non-prescription medicines. This work, in collaboration with all key stakeholders, resulted in major changes to OTC labelling regulation in 2004—TGO69A. This was complemented by the Labelling Code of Practice, 2004—*Designing usable non-prescription medicine labels for consumers*, published by ASMI (Australian Self-Medication Industry)—and a suite of usability guidelines specifically for OTC medicine label design.

Since 2004, CRI has assisted many of the major OTC brands to develop and test highly usable medicines information labelling for consumers. Apart from its accumulated research findings, practical knowledge, and experience, CRI also now has the largest data base of consumer test results for OTC medicines in Australia. Though some of this data is subject to commercial confidentiality, some key studies and findings are available in the public domain, and with the agreement of the pharmaceutical industry, more of this data will be placed in the public domain in coming years.

It is against this background of experience, research, development, and real evidence that CRI offers some comments on the *TGA Medicine Labelling and Packaging Review Consultation Paper* (2012).

The TGA Review

The review states its objective as follows:

...to develop appropriate regulatory solutions that effectively address the consumer safety risks posed by the following issues:

- *information about the active ingredient(s) contained in the medicine is not always easy to find*
- *use of the same brand name for a range of products with different active ingredients resulting in look-alike medicine branding (this is known as brand extension or trade name extension)*
- *medicine names that look-alike and sound-alike that can lead to use of the incorrect medicine*
- *medicine containers and packaging that looks like that of another medicine*
- *lack of a standardised format for information included on medicines labels and packaging*
- *dispensing stickers that cover up important information*
- *information provided on blister strips*
- *information included on small containers*

TGA Medicine Labelling and Packaging Review V1.0 May 2012 Page 8

CRI is pleased to see these issues being considered by TGA.

CRI research confirms that some of these issues are indeed in need of regulatory solutions.

However, CRI is concerned and disappointed in the way these issues are being considered.

The current review completely ignores the evidence-based labelling design principles, methods and standards enshrined in TGO69A, the ASMI Labelling Code of Practice, and the supporting Labelling Guidelines (the *Medicine Labelling Guidelines* or *MLG*). Instead, it reverts to the use of outmoded and discredited principles and methods that pre-dated the introduction of TGO69A. Thus the review is not just tackling a series of issues; it is overturning methods and practices which have placed Australia at the forefront of OTC medicine labelling regulation in the world, and is reverting to an approach which will lead to an overall deterioration of the usability of OTC labelling in Australia.

In other words, far from addressing a number of specific (and important) issues within an established evidence-based approach, this review re-introduces a untrustworthy approach to the design of medicine labelling content and appearance and does so completely outside the accumulated evidence and experience.

If TGA is to enjoy the public's confidence in its decision making, it must demonstrably proceed as an evidence-based regulator drawing on the cumulative research and know-how in this field. The following CRI comments therefore turn to what is absent from the TGA review in the hope that this absence may be remedied.

Principles absent in TGA review

1. PERFORMANCE REQUIREMENTS

The most important aspect of labelling regulation deals with how the information on a medicine label should be presented. This can be approached in two very different ways. The first approach asks the question: What information about this medicine should be on this label? The second asks: What do we want consumers to be able to do with this label? The differences in these approaches are crucial to the success or failure of a label.

CRI has characterised the difference between these two approaches to labelling regulation as *content based* and *performance-based*:

- Content-based regulation seeks to control the information content of the label. It answers the question “What information about this medicine should be on this label?” by listing the information they believe that consumers should be given, and checking that the information is present on the label. The presence of the information is taken as evidence of efficacy.
- Performance-based regulation seeks to regulate the effectiveness with which consumers can perform a given range of tasks using the label. It answers the question “What do we want consumers to be able to do with this label?” by compiling a comprehensive list of all the tasks consumers should be able to perform with the label (*performance tasks*), and testing the labels to ensure that consumers can perform these tasks.

Thus the performance-based approach demands *evidence of appropriate usage* as a measure of the efficacy of the label. Just as in the medicine itself, efficacy is determined by evidence, so in performance-based labelling, evidence of appropriate usage determines the label’s efficacy.

Specifying the performance requirements is an essential first step in developing usable labels.

TGO69A opens with a summary of the performance requirements that consumers are expected to perform with OTC labels.

For non-prescription medicines, the aim is that the information on the label is presented in such a way that consumers can:

- (a) choose an appropriate medicine on their own;
- (b) use the medicine safely and effectively;
- (c) readily find the information they need, understand it and act on it appropriately; and
- (d) access further information, if they want to know more about the medicine.

The elaboration in the ASMI Code of Practice was as follows:

PERFORMANCE TASKS. ASMI CODE OF PRACTICE 2004

AT THE POINT OF SALE	AT THE POINT OF USE	
IDENTIFY & SELECT	USE	STORE
1. can locate and read product name	5. can locate, read and understand product description	10. can locate, read and understand storage instructions
2. can locate and read quantity	6. can locate and read product ingredients	
3. can identify what the product is used for	7. can locate, read and understand dosage and usage instructions	DISPOSE OF
4. can identify circumstances under which the product should not be used	8. can locate, read and understand any warnings	11. can locate and read expiry date
	9. can locate and read information/enquiry number	

These performance tasks are also specified at a particular target level:

Every consumer tested should be able to find at least 90% of what they look for and appropriately use 90% of the information they find.

Performance level: 90% x 90% =81%

The criteria against which the performance of any specific label should be tested are provided by combining the performance tasks with the performance level.

It is important to note that in the 2004 Code of Practice there are no performance tasks associated with differentiating between 'look alike' products or brand extension. At that time, none of the stakeholders raised that as a concern.

However, almost as soon as the Code and Labelling Guidelines began to be applied, CRI discovered that differentiating between products within a brand was indeed an issue. This has resulted in a further refinement of the performance requirements, shown on the next page, with the performance requirements related to differentiating between products highlighted in yellow.

ASMI was informed of these changes and developments. CRI has been applying them in its research and development work for pharmaceutical companies. It must be noted, however, that this revised list of performance requirements is an internal CRI document developed to deal with the changing needs of pharmaceutical companies. It does not reflect an agreed position among the stakeholders.

1. IDENTIFY	2. SELECT	3. USE
1. Locate, read and recognise brand	3. Locate and read brand	14. Locate and explain new product description
2. Locate and read product names	4. Locate and read new product name	15. Locate and read new product ingredients
	5. Locate, read and explain new product strength	16. Locate, read and explain dosage and usage instructions
	6. Identify what symptoms the new product is used for	17. Locate, read and explain any warnings
	7. Differentiate between the products in the range	18. Locate and read information/enquiry number
	8. Explain circumstances under which to choose the new product	4. STORE
	9. Identify under what circumstances the new product should not be used	19. Locate, read and explain storage instructions
	10. Locate and read active ingredients of new product	5. DISPOSE
	11. Locate, read and explain dosage and usage instructions of new product	20. Locate and read expiry date
	12. Locate and read quantity	
	13. Locate and read expiry date	

CRI takes the view that the revised list of performance requirements goes some way towards articulating the issues raised in the TGA review. CRI also takes the view that there is room for considerable further refinement of these performance requirements, particularly given the concerns expressed by consumer advocates.

In a collaborative spirit, CRI is prepared to share this document and assist in its refinement to ensure it meets stakeholder concerns. CRI is nonetheless disappointed that the collaborative work undertaken with all stakeholders to develop the original ASMI performance requirements was not used by TGA as a necessary starting point for its current review.

2. FUNCTIONAL ANALYSIS

Labels are built up out of multiple parts, each with a particular function. A prerequisite for good label design is to list all these parts and then describe their function. When designing a label that consumers will use to perform a variety of tasks, it is important to describe the function of each part in relation to consumer tasks.

The TGA Review provides a crude analysis of label parts. Clearly, this analysis is not based on a detailed analysis of actual labels, but has been compiled using content elements over which the regulator seeks to exercise control.

1. *TG is the company name*
2. *Brand name*
3. *Name of the active ingredient. The active ingredient is what makes the medicine work.*
4. *Warning label*
5. *The AUST R or L numbers shows that the medicines are accepted by the Therapeutic Goods Administration for supply in Australia.*
6. *Website address of the TGA*
7. *Batch number. In case of a recall the batch number will be quoted.*
8. *The medicine should not be used after the expiry date because it can lose its effectiveness or become unsafe.*
9. *Barcode*
10. *Address & contact details*
11. *Country of origin*
12. *Standardised Information Format: the Medicine Information Box. See recommendations*

Contrast the above with the functional analysis in the ASMI Code of Practice, given below. It was developed by CRI based on the extensive research into how consumers read labels and the analysis of a large number of labels in use at the time. It takes account of *all* elements, not only those over which the regulator seeks to exercise control.

It is always important in analysing a label's functional components to bear in mind that consumers generally do not know which elements are prescribed and which are at the discretion of the pharmaceutical company. They see the label as one object, and make their own decisions about which elements to pay attention to and which to ignore.

Parts of the label

Label parts are described from a consumer's perspective. The parts are:

- ▶ named to reflect what consumers do with them
- ▶ shown in the order in which research suggests they are likely to be used
- ▶ ordered independently of the regulatory requirements for what has to appear on front/back of labels
- ▶ important at the time of purchase and through the life of the product

	<i>Name of part</i>	<i>Function</i>
<i>Consumer choice</i>	Product/Brand name	Recognised when making a choice of product and provides brand identity
	Technical / Generic name/s	Helps choice of product
	Pack size	Number of individual items or total volume in pack (tablet, capsules, liquid, etc)
	Dosage form	Helps choice of product

	<i>Name of part</i>	<i>Function</i>
	Dosage information	Strength of product/amount per item
	Type of product*	Helps choice of product
	What it's used for (indication)	Helps choice of product
	Qualified claim for product*	Helps choice of product
	Do not use (contraindications)	Helps choice of product
	How it works*	Reinforces choice of product
<i>Consumer instructions</i>	How to use	Provides instructions on use
	How much and when (dosage)	Provides instructions on dosage
	How to store	Provides instructions on appropriate storage
	Expiry date	Gives the date after which the product should not be sold or used
	More information on product*	Used for the consumer to obtain further information about a product e.g. 1800 number or website
	In case of overdose*	Used to obtain advice in case of overdose, eg Poisons Information Centre number
<i>Ingredients</i>	Active ingredient/s	Provides active ingredient details
	Inactive ingredients (excipients)	Provides information on presence of specified inactive ingredients
	About ingredients*	History of usage
	Absent ingredients*	May provide information on absent inactive ingredients
<i>Administrative details</i>	Signal/Availability heading	Where and how a product can be sold and purchased
	Barcode*	Used by retail
	Product number*	Sometimes used for stacking products in code number order on the shelf
	Label number	Used by sponsor to identify label version
	Unique identifier	Identifies the specific product
	Batch number	Used for identification, e.g. in the event of a recall
	Device starburst*	Used to highlight information
<i>Brand</i>	Brand descriptor*	Non-promotional reinforcement of brand value
	Brand tag line*	Non-promotional reinforcement of brand value
<i>Sponsor</i>	Supplier	Identifies the product sponsor and their address. The sponsor has full responsibility in event of a product recall.
	Manufacturer*	Identifies the product's manufacturer, where there is no more than one manufacturer.

* non-mandatory information according to legislation

The contrast between the two descriptions is stark. TGA identified only 12 parts to the label

using content criteria. CRI, in collaboration with stakeholders, identified 30 functional elements that contribute to consumers' use of the label information. This analysis closely parallels the level of detail found in CRI's functional analyses of other consumer-focused documents such as bills, forms and legal documents. Note also that the TGA review shows no understanding that consumers perform very different tasks at different stages of using the information on a label. Lumping many diverse activities things under the heading *Standardised Information Format* is not particularly useful.

CRI takes the view that an analysis of the depth and type shown in the current ASMI Code of Practice is necessary before any substantial redesign work is undertaken on behalf of consumers, and once again expresses its disappointment that TGA has ignored past work and produced an inferior outcome based on inappropriate principles and no evidence from actual labels.

3. EVIDENCE

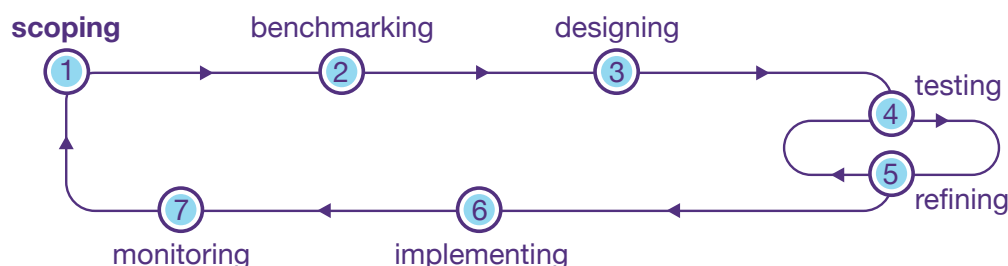
The single most egregious absence from the TGA review is evidence of the usability of any of the labels presented in the review. Had the timeline for submissions to this review been extended, we would have been able to undertake the necessary testing of the recommended labels and compared them with the available evidence from labels that have actually been tested for usability by consumers.

Unfortunately, the closing date for submissions has not provided enough time, so CRI presents a summary of the accumulated evidence from its testing of OTC labels over the last ten years.

CRI will not disclose the product names or any details of the results which would reveal the information on specific products. It is up to the individual companies to release that data, if they so wish. CRI's purpose here is to provide an overview of the current state of the art, as seen through CRI's experience, so that interested parties can discuss and comment on the TGA proposed changes to labelling regulation with some evidence-based practice to draw upon.

CRI collated data from the testing of 13 brands. They were a mixture of non-prescription pharmacy-only medications and pharmaceutical products available at grocery outlets. Twelve of them were part of umbrella brands. Ten had been already been approved by TGA for marketing with their existing packaging before we tested them.

Most of the products went through our normal seven-stage information design process as illustrated in the ASMI Labelling Code of Practice cited in TGO69A.



This is a validated design process which has been subject to multiple peer-reviewed tests and is now widely used in the design of information. The closest to this process in medicine is the clinical practice in which symptoms are presented and tests are performed, followed by

diagnosis, appropriate treatment, retest, and (hopefully) the elimination of the malfunction and the disappearance of symptoms.

The validity of the information design process is derived from the disappearance of symptoms. In the case of medicine labelling, the main symptom is the inability of people to use the labels at an acceptable level.

In label design, an existing label is normally tested at the benchmarking stage (CRI calls this the baseline measurement stage) to determine how it performs before it is subjected to any redesign work. If necessary, a prototype is developed and tested, and sometimes a second prototype has to be designed and tested, until the label performs at an acceptable level. In the research under discussion here, three products were not tested at the benchmarking stage because they were new products, so work started with the development of a new prototype. In two cases a second prototype had to be designed and tested. The decision to cease 'treatment' (i.e., not refine a prototype) was always made by the 'patient' (client). Eleven of the prototypes were developed in accordance with CRI's Labelling Guidelines cited in TGO69A. The two that were not developed following the Guidelines were products 7 and 8 (highlighted in yellow).

The test groups ranged from n=5 to n=21. The total number of participants across all tests was 249. In all there were 23 rounds of testing.

The results from each round of testing are expressed as a percentage of participants who could perform all tasks associated with using that label at an acceptable level. The acceptable level is that used in the Code of Practice. In addition to the tasks specified in the Code, tasks associated with differentiating between products within an umbrella brands were tested in 11 of the products. (In this analysis of the data we do not distinguish between usage and differentiation tasks.)

	BENCHMARK		PROTO 1		PROTO 2	
PRODUCT	%	N	%	N	%	N
1	81	21	-	-	-	-
2	42	19	81	21	100	9
3	-	-	80	10		
4	60	10	90	10	90	10
5	27	15	67	9		
6	-	-	100	5		
7	17	6	17	6		
8	50	6	0	6		
9	83	10	90	10		
10	17	10	83	10		
11	62	8	100	10		
12	-	-	100	10		
13	0	8	90	10		
average %	49		88		95	

When CRI tested labels already approved by the TGA but not conforming to the Guidelines, it found that fewer than 50% of the participants were able to use the labels at an acceptable level at the benchmarking stage. CRI's overall finding is that labels that follow the Guidelines show a higher performance level both in usage and differentiation tasks. Products that do not follow the process (7 and 8) show either no change or reduced performance (50% to 0%).

None of the proposed TGA changes to labelling follow either the Code of Practice or the Guidelines cited in TGO69A. Based on experience to date and on the attached data from the testing, CRI believes that the implementation of these changes would result in a deterioration of OTC labelling performance to less than 20%, meaning that only 2 out of 10 people would be able to use the labels at an acceptable level. This stands in stark contrast to the 9 out of 10 people who can use labels that have fully complied with the recommendations in TGO69A, and can successfully differentiate between products within an umbrella brand when the labels are well designed.

TGA provides no evidence that its proposed changes will improve people's capacity to choose appropriate products and use them safely.

4. INFORMATION DESIGN IS A SPECIALIST CRAFT

To achieve the level of performance shown in CRI results requires specialist skills. These are a combination of the traditional crafts of typography, graphic design, writing, and editing, as well as more recent skills of analysis, testing and stakeholder management. There are undergraduate and post-graduate degrees in information design, international professional bodies, awards, and refereed journals regularly publishing research in the field. These professional skills are not represented in TGA. This in itself would not constitute a problem, provided that TGA did not seek to undertake information design work; but it does, and further suggests that these designs be used as models which industry should follow. This would result in industry copying poor examples in order to meet regulatory requirements, the outcome of which being labels that were difficult for the public to use.

This has happened before in a number of jurisdictions, most notably in the USA and the EU. The EU case is instructive. In 1998 the EU Pharmaceutical Committee published its *Guidelines on the readability of the labels and package leaflets of medicinal products for human use*. Much of the content was copied almost *verbatim* from the second edition of WAMFP, including the guidance on testing. They also copied the testing performance levels set out in WAMFP. Unfortunately, the EU copied without any understanding of the principles or the design skills underlying WAMFP. Instead, they developed their own 'model' design of a Patient Information Leaflet, without any information design skills, and without any testing.

Unlike Australia, where testing of labels and CMI is not mandatory, the EU required mandatory testing—and every pharmaceutical company using the EU 'model' discovered that it was impossible to achieve the performance requirements laid down in the EU *Guidelines*.

CRI's concern is that TGA may be about to repeat the EU mistake. This will not only cost industry a great deal of money, it will also result in labels that consumers cannot use.

It is difficult in comments of this type to give a blow by blow account of what is wrong with the TGA's designs. Instead, as an illustration, these comments describes some of CRI's own model designs which have been tested with consumers and achieved an acceptable level of performance. These are juxtaposed next to the untested TGA designs.

TGA Model Design for the front of pack



CRI Model Design for front of pack



The TGA design shows no understanding of the range of graphic possibilities available to achieve particular effects. It simply assumes that size and area determine importance, equating label design with a grab for real estate: the more area occupied and the bigger the font, the better.

Testing has found that consumers can readily identify active ingredients without their being in such a large font as in the TGA design. Moreover, the typesize is so large and crowded, so ignorant of typographical principles, that it is difficult to read. It is also unattractive and could constitute a disincentive to the consumer. The additional information contained in the TGA design could easily be accommodated in the CRI label with very minor changes.

TGA Design Back of Pack

Medicine Information Box
Active ingredient
Glucosamine sulfate sodium chloride complex 1886 mg (equivalent to glucosamine sulfate 1500 mg) Chondroitin sulfate-bovine sodium 95% 842 mg (chondroitin sulfate sodium 800 mg)
Uses
<ul style="list-style-type: none"> • May help to relieve osteoarthritis joint pain • Helps reduce cartilage wear • Chondroitin provides nutrition to the joints
Warnings and allergy information
<ul style="list-style-type: none"> • Glucosamine is derived from seafood. Not recommended for people with seafood allergies • Contains approximately 228 mg sodium per daily dose • May occasionally cause mild gastrointestinal symptoms • Check with your doctor or pharmacist if you are taking any other medications
When using this product
If pregnant or breastfeeding, ask a health professional before use Keep out of reach of children. In case of overdose, seek medical attention or call the poisons information line on 13 11 26
Directions
Adults - Take 1 easy to swallow tablet twice daily with meals or as professionally prescribed Children under 12 years - Only as professionally prescribed. If symptoms persist, see your healthcare professional
Storage information
White, vanilla flavoured tablet with easy to swallow coating. Store below 30°C. Protect from moisture

CRI Design for back of Pack

KangaCold & Flu NEW FORMULA				24 CAPLETS
Who can use Kanga Cold & Flu	How many	How often	Maximum	When to stop
<ul style="list-style-type: none"> ✓ Adults ✓ Children 12 years and over 	2 caplets with food	3-4 times a day	8 tablets in 24 hours	Adults after a few days Children after 48 hrs except on medical advice
Use Kanga Cold & Flu for <ul style="list-style-type: none"> ✓ headaches and fever ✓ body aches and pains ✓ blocked/runny noses Do not use <ul style="list-style-type: none"> ✗ for children under 12 years without medical advice ✗ if you have taken paracetamol ✗ if carton seal is broken or missing or if caplet foil is broken Ask your doctor before use <ul style="list-style-type: none"> ? if you have high blood pressure ? if you are taking anti-depressants ? if you have heart problems ? if you are pregnant 	Caution: If symptoms persist, see your doctor. Warning: Phenylephrine may cause sleeplessness in some people. Keep to recommended dose. If an overdose is taken or suspected, ring the Poisons Information Centre (Australia 13 11 26, New Zealand 0800 764 766) or go to a hospital straight away even if you feel well because of the risk of delayed serious liver damage. Store below 25°C. Keep in a dry dark place. Each caplet contains Paracetamol 500mg, Codeine Phosphate 9.5mg and Phenylephrine Hydrochloride 5mg Also contains: Lactose and Gluten. New active ingredient Phenylephrine Hydrochloride has replaced Pseudoephedrine Hydrochloride			

Once again, the CRI design was tested with consumers and performs at an acceptable level. The TGA offers no evidence in support of its design, which ignores many typographic principles of readability.

There are three main point to be made about the differences.

1. The order in which the TGA headings appear is unlikely to make it easy for consumers to use. All the evidence points to placing the active ingredients last and the other headings following the temporal decision-making path used by consumers to choose and then use a medicine.

2. The idea of a standardised medicine information box is in CRI's view misguided. Products differ in too many ways to achieve maximum usability by a 'one size fits all' approach. This has been tried in the USA and it leads to many anomalies. Far better to specify strict performance requirements and leave it to the manufacturer to provide evidence that demonstrates that the label is usable in accordance with those performance requirements, as is specified in TGO69A. This closely parallels the approach taken to testing the efficacy of the medicine itself—the TGA does not prescribe the formulation of the medicine but requires the manufacturer to provide evidence that the formulation works.

3. In CRI's view both its own and the TGA designs are compromised by the available space on the packaging. This is unacceptable for dangerous products which are highly dependent on information for their safe use. The space available for information should not be compromised by the shape and size of the packaging, nor by the imposition of a standardised medicine information box.

Instead, packaging should be adapted to provide information without compromise. Given the innovations that packaging design and manufacture have undergone in recent years, there are no technical barriers to achieving far more effective designs, particularly if the design of the blister pack is integrated into the overall package design, which would greatly benefit consumers. The adoption of a standardised medicine information box would stifle this desirable innovation and lead to labels that are less usable than they should be.

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