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Over-the-Counter Medicine Labelling Strategies in Comparison with

the Standardised U.S. Drug Facts Label

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Conflict of interest

David K Raynor is the co-founder and academic advisor for Luto Research, a company that provides performance-based testing services for health information.

Kim Hamrosi is currently employed as a Health Economics and Outcomes Consultant at Optum which provides medical market access, health economics and outcomes research, real-world evidence generation and pharmacoepidemiology services.

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Main text (excluding abstract, tables, figures, references)	3489
References	803

Consumer Opinions on Existing and Proposed Australian Over-the-Counter Medicine Labelling Strategies in Comparison with the Standardised U.S. Drug

Facts Label

Abstract

Background

With common over-the-counter (OTC) medication use, OTC labels as medicine information sources must be of high quality and usability. Standardised OTC labelling has been proposed in Australia using the Medicine Information Box (MIB), modelled on the U.S. Drug Facts label. However, limited research has explored consumer opinions on existing nonstandardised Australian OTC, Drug Facts, and proposed MIB labels. Therefore, this study aimed to explore consumer opinions on all three groups of OTC labels.

Methods

Three focus groups (n=21 participants) were conducted in Sydney, Australia. Participants were shown existing Australian OTC labels, U.S. Drug Facts labels, and mock MIB formats based on the Australian Therapeutic Goods Administration proposal. Discussions were audio recorded, transcribed verbatim, and thematically analysed.

Results

Participants expressed varying opinions regarding existing non-standardised Australian OTC labels' content and design, from acknowledgement of positive aspects (clear headings, relevant content), to decreased perceived readability (suboptimal colour use, font size) and content discrepancies. Participants identified key Drug Facts and MIB label characteristics which contributed to perceived usability and format clarity (good headings, black and white format). Many preferred the Drug Facts label due to greater perceived clarity and usability. Missing content (inactive ingredients, further contact details) were identified and consequently, were opportunities for MIB improvement.

Conclusions

Most participants seemed to prefer the Drug Facts label partly due to its perceived completeness. These findings suggest further improvements for the proposed MIB as a step towards Australian OTC label standardisation.

Key words

Drug labeling; consumers; non-prescription medicines; focus groups; consumer perspectives

Introduction

Consumer use of over-the-counter (OTC) medicines is common,¹ and the availability and provision of relevant, high quality OTC medicine information is therefore necessary to assist consumers with safe medication use. Consumers want information on the effectiveness of the medicine, dosing, potential side effects, and possible drug interactions prior to taking an OTC medicine,² and will read OTC labels to obtain such information.³ As consumers recall only a proportion of spoken information provided by pharmacists,⁴ written medicine information sources are critical.

Design and comprehensibility of written OTC medicine information contribute to their quality.⁵ Consequently, efforts to improve the usability of OTC labels and leaflets are imperative in supporting medication safety. For example, standardisation of OTC labelling in the United States (U.S.) using the Drug Facts label format⁶ was implemented to ensure format consistency and increase usability. Consumers who utilised the Drug Facts label gave statistically significantly more correct responses on the whole, in relation to the appropriate action required to be taken in four different scenarios relevant to warnings information, than when using the older label format.⁷ Furthermore, consumer preference ratings for the Drug Facts label for a pain reliever were statistically significantly higher than for the corresponding older label format.⁷ Other studies have also noted an improved time taken to find information when using the Drug Facts label compared to older label formats.^{8,9} In contrast to the U.S., OTC labels are not standardised in Australia.¹⁰ Despite this, standardisation of written medicine information in Australia is not unknown, as leaflets known as Consumer Medicine Information are available in a standardised format and are mandatory for both prescription and pharmacist only OTC medicines.¹¹

In Australia, existing legislation¹² provides a comprehensive outline of the label content required.¹³ However, with labelling, consumers face a number of potential problems such as impaired label readability (due to factors such as small font size and amount of content), difficulty in understanding and acting upon relevant medicine information, in addition to relating the information back to their own personal needs.¹⁴ A 2012 consultation paper published by the Australian Therapeutic Goods Administration (TGA) implied the need to improve OTC labelling, proposing the introduction of a standardised OTC label format entitled the Medicine Information Box (MIB), modelled on the U.S. Drug Facts label format.¹⁵

Limited research has explored consumer opinions on the MIB in Australia. Furthermore, opinions on existing labelling standardisation, namely the U.S. Drug Facts label, have not been explored in a consumer population such as Australia, where regulatory activities indicate that OTC label standardisation may be implemented in the near future. As the MIB is based on the Drug Facts label format,¹⁵ it is prudent to explore consumer opinions on both formats for comparison prior to the implementation of standardisation. Therefore, the study aim was to explore consumers' opinions on: existing Australian non-standardised OTC labels; the Drug Facts label; and the MIB.

Methods

This study formed part of a larger international research project exploring consumer OTC medicine information needs and use, and perspectives on OTC medicine information. This study received ethics approval from the University of Sydney Human Research Ethics Committee (Project number 2013/1013). Participants provided written informed consent to participate in this study.

Participants and setting

Three focus groups lasting approximately 1-1.5 hours were conducted in Sydney, Australia, in February 2014 with a total of 21 participants (Table 1). Focus groups were utilised to address the study aim, and complement a series of earlier semi-structured interviews which explored consumer perspectives on the MIB specifically.¹⁶ The group dynamic inherent in focus groups was intended to encourage discussion about, and comparison between, all three label types.

[insert Table 1]

Each focus group was conducted by two experienced female focus group facilitators (PA, KH), with field notes taken by two researchers (NP, BA). People were eligible to participate if they were: aged 18 years and above, conversant in English (did not require a translator to participate in the study), and had purchased an OTC medicine in the 6 months prior to the study for personal use or for an individual under their care. All participants were identified from a market research company consumer database, using the inclusion criteria specified. Potential participants were contacted and provided with an information sheet and consent form, and if willing to participate, were assigned to attend one of the scheduled focus groups held at various venues in Sydney. Participants were reimbursed \$80 AUD for their time.

Focus group protocol

The focus group protocol was developed to address the broader research project aims, and included specific questions regarding consumers' OTC medicine information needs, utilisation of OTC medicine information, and perspectives on existing and proposed OTC labelling strategies (Australia and U.S.). Only findings pertaining to the study aim described here will be presented.

During the focus groups, participants were shown three broad groups of stimulus materials in the following order:

- one product per participant from a random selection of existing Australian OTC product labels (Table 2);
- one product per participant from a random selection of U.S. OTC product labels which displayed the Drug Facts label format (Table 2);
- two mock MIB labels for exemplar study medicines diclofenac and pholcodine (developed and published previously,¹⁶ based on the TGA consultation paper¹⁵) (Figure 1).

Participants were asked to review the stimulus materials provided and participant opinions on the different labels were sought. Table 3 provides the broad, core questions included in the semi-structured focus group protocol, utilised by the facilitators to help stimulate discussions.

[insert Table 2]

[insert Figure 1]

[insert Table 3]

Labels on existing products were presented as they would be available at the point of purchase, with no changes in packaging or removal of leaflets (where available). They were randomly chosen and purchased from a pharmacy in Australia and the U.S. to represent a range of dosage forms, potential user demographics and labelling characteristics/conditions (for instance, total packaging size). The U.S. products allowed participants to visualise actual OTC label standardisation and its impact on overall OTC packaging.

Both MIB labels were given to the participants as paper copies, not contextualised as part of complete OTC product packaging.

Data analysis

Thematic saturation¹⁷ was achieved with the three focus groups conducted. All focus groups were audio recorded with permission from the participants and transcribed verbatim. Transcript accuracy was verified by checking transcripts against the relevant original audio recording prior to analysis. Checked transcripts were analysed via thematic content analysis.¹⁸ Three researchers independently analysed the data (BA, NP and VT), and themes verified in consultation with another researcher (PA). Preliminary data analysis was conducted by hand on the checked transcripts. Subthemes were determined from the data, refined and conceptually grouped under identified broad themes. One researcher (VT) presented the data using a matrix display,¹⁹ which was compared with the themes and subthemes identified by the other two researchers.

Results

1) Consumer perspectives on existing Australian OTC labels

Positive label characteristics

Some participants appreciated the clear headings and large font size of the writing on a proportion of existing Australian OTC labels examined. Simple wording and colour used on the Nurofen[®] label was perceived positively, and believed to increase readability (see quote 1, Table 4).

[insert Table 4]

Barriers contributing to perceived information retrieval difficulty

Participants noted numerous label characteristics that contributed to information retrieval difficulties. A mixed portrait and landscape headings arrangement adopted by the Codral[®] 4 Flu label was perceived to contribute to increased time needed to read the information, in comparison to the simpler Gastro-Stop[®] label (2 column landscape format) (see quote 2). Small font size was an issue mentioned in every focus group. Decreased font size increased perceived consumer difficulty in reading information, but this appeared to be less if the participant thought they had good eyesight. Specifically, small font size proved problematic with the Panadol[®] suppositories label (most label text printed in font 1mm high), potentially contributing to self-selection errors as the dosage form was not immediately apparent (see quote 3).

Colour had varying impact on readability, where the red and orange Nurofen[®] label was seen as more difficult to read than a label that utilised higher contrasting colours (see quote 4). This was in contrast to an earlier comment made by Participant FG2F3. Label content- perceptions and identified discrepancies

Overall, many thought existing Australian OTC labels included relevant key information relating to product use (such as directions and warnings), raised in every focus group. Despite this, the notion of content discrepancies was also discussed in every focus group, where some identified content discrepancies between different OTC products, and/or between the label and corresponding leaflet for a single product such as the Daktarin[®] cream. For instance, contact details such as a website and/or telephone number were identified as missing from some labels. In particular, the potential safety implication for inconsistent inclusion of emergency contact information between the label and corresponding leaflet was implied by one participant (see quote 5). Another participant echoed this sentiment regarding the lack of pregnancy precaution included on the Daktarin[®] label (see quote 6).

Suggestions for label design improvement

A few participants recommended increasing the font size to improve label design; placing small bottles in a larger box was one suggestion: "maybe you could put it [the bottle of Panadol[®] suppositories] in a box with big writing on it" (FG2F2). One participant preferred to have the active ingredient in larger font. Another recognised a potential to more effectively utilise the total packaging space to include more relevant content (such as contraindications) (see quote 7). 2) Consumer perspectives on existing and proposed OTC labelling standardisation strategies Participants from every focus group were positive towards OTC label standardisation. Standardisation of OTC labels (both Drug Facts label and MIB) was positively supported by most participants, with many having a more positive disposition towards the Drug Facts label in comparison to existing Australian OTC labels. Many appeared to prefer the Drug Facts label compared to the MIB, explicitly identifying that, firstly, it was more helpful due to reference to additional information sources such as websites and telephone numbers, allowing people to seek information beyond the label; and secondly, the use of additional, descriptive subheadings (corresponding to the action required to be taken) in the Drug Facts label, which helped divide the large 'Warnings' section.

Conversely, some MIB aspects were appreciated and seen as favourable over the Drug Facts label, such as tabulated dosage and slightly clearer headings. A few did not indicate a preference, where both formats were seen as comparable regarding perceived ease of use.

a) Consumer perspectives on the Drug Facts label

Drug Facts label- Positives

Participants reported that the Drug Facts label had a good or clear layout, which was indicated in every focus group. It was seen as easy to navigate, and could promote increased ease of OTC product selection. Effective subheadings helped break up larger sections such as 'Warnings'. A few thought that the Drug Facts label was 'perfect'. The black and white format exhibited by most labels contributed to their clarity.

Participants found the inclusion of a phone number or help-line helpful. The inclusion of both active and inactive ingredients was liked (see quote 8).

Inclusion of inactive ingredient information provided reassurance that manufacturers were not withholding information. The communication of active ingredient together with its purpose was seen to give meaning to the active ingredient.

Drug Facts label- Negatives

There were very few negatives raised by participants regarding the Drug Facts label. One participant implied that there was insufficient information regarding drug interactions, where "you would still have to jump on the Internet or ask the pharmacist to get that information" (FG2M2).

b) Consumer perspectives on the MIB

The MIB was appreciated for its bullet points, clear headings, ample white space and plain English use.

Some liked the black and white format. A few participants noted that the headings stood out more clearly, compared to the Drug Facts label. Specifically, pholcodine dosage tabulation was liked (raised in each of the focus groups), seen to help support accurate retrieval of pholcodine dosage information (see quote 9). However, a small number of consumers did not like the tabulated directions in the diclofenac MIB.

Participants identified areas for improvement, broadly regarding MIB content and title. Although content coverage was considered good, participants identified discrepancies between the Drug Facts label and MIB content. One participant felt that the MIB was not sufficiently informative. Absence of inactive ingredient information, manufacturer information (website and/or emergency contact information), and lack of active ingredient conveyed side by side with the 'purpose' were identified as MIB shortcomings, which could then be inherently and/or directly linked in many cases to perceived necessary improvements.

One participant raised that despite the warning to avoid use if allergic to any of the ingredients, the lack of inactive ingredient information in the MIB meant they could not satisfactorily discern if allergies were applicable.

Participants compared the two titles used for the standardised label formats and proposed possible variations to the title 'Medicine Information Box'. They preferred the term 'medicine' over 'drug'. However, the Drug Facts title was favoured by one participant as "Drug Facts is better because it sort of conveys the gravity of it a little bit more than medicine" (FG2F3).

Others suggested Medicine Facts as a potential title, regarded as "a good blend of seriousness but not using the word drugs" (FG2M2). In addition, one participant assumed that in Australia, "we preferentially used 'information' rather than 'facts' because it's less prescriptive and... there isn't as much weight behind information. Like not saying that it's a fact; you're just giving us information in you know good umm good... faith." (FG3M4). Omission of the word 'box' in 'Medicine Information Box' was also proposed.

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Discussion

This is the first study that has evaluated Australian consumer opinions on current Australian OTC labels, the proposed standardised OTC label format for Australia, and U.S. standardised Drug Facts labels. The evaluation was qualitative and exploratory in nature, and has identified consumer preferences as well as recommendations to inform the standardisation of OTC labelling in Australia. Participants on the whole preferred the Drug Facts label over the existing Australian OTC labels and MIB.

Despite the MIB being modelled on the Drug Facts label,¹⁵ all aspects of the Drug Facts label appear not to have been fully adopted. Many MIB shortcomings identified by participants were in fact the preferred characteristics seen on the Drug Facts label. This therefore brings to the forefront the notion of whether the MIB would constitute an overall improvement over the existing Drug Facts standardised OTC label format that participants preferred. The observed preference for the Drug Facts label, also supported by previous work,⁷ indicates that the MIB should incorporate more Drug Facts label aspects to better cater for consumers' reported needs. Interestingly, the Australian TGA released a follow-up consultation in August 2014 (post study completion), proposing a revised version of the MIB.²⁰ This revised format shares more similarities to the Drug Facts label⁶ in comparison to the original proposed MIB,¹⁵ such as the structure of the 'Warnings' section and the inclusion of the heading 'Other information'. However, the present study highlights some potential improvements which still remain unaddressed.

Inclusion of additional information sources, inactive ingredients, contact details and the colocation of the active ingredient(s) and its purpose were key reported differences between the Drug Facts label and MIB. Participants preferred the Drug Fact label over the MIB as it included content on additional information sources. Consumers do not solely rely on the label for all their OTC medicine information needs,² and both receive¹ and utilise²¹ a variety of information sources in the context of self-management. Consumers have also previously noted that labels alone are unable to completely support safe OTC medicine use as a standalone information source.²² Further contact information should therefore be included in the MIB in future.

More comprehensive inactive ingredient information inclusion in the MIB should also be considered and taken forward, similar to the conclusion of an older U.S. study published prior to the implementation of the Drug Facts label.²³ However, a potential barrier, from a regulatory perspective within the Australian context, is that complete inactive ingredient information on Australian OTC labels is currently not legislated; only specific inactive ingredients are mandated for inclusion, such as ethanol and lactose.¹³

Participants liked the active ingredient(s) presented alongside its purpose. Consumer focus on OTC medicine benefits²⁴ and the opportunity for information contextualisation may explain why linking the two through effective information design is of particular importance. Consequently, adoption of this strategy in the MIB should be considered as a step to promoting safe and quality use of OTC medicines.

Existing diversity amongst Australian OTC packaging contributed to variations in perceived quality in the present study, where OTC label content diversity has also been previously identified.^{25,26} Despite many participants indicating an overall preference for the Drug Facts label, aspects of existing Australian OTC labels and the MIB were still considered as positive. This reflected good information design principles advocated for use in written medicine information,²⁷ and were comparable to the findings of semi-structured interviews previously

conducted with Australian and UK participants.¹⁶ When comparing these study findings to the semi-structured interviews,¹⁶ participants in the group discussions focussed more on identifying content discrepancies demonstrated by the MIB, and suggesting alternative titles for the MIB. This may be due to differences in stimulus material provided to participants between the two studies (one existing OTC label and a corresponding mock MIB label provided in the semi-structured interviews¹⁶; various OTC label formats provided in the present study), impacting the scope of discussion. Additionally, negative emotional responses to the MIB, mentioned in the semi-structured interviews,¹⁶ were not raised in this study. This may be due in part to the black and white Drug Facts labels available as comparators, which may have been less daunting when presented as part of complete packaging, with colour used on other panels on those packs. Consequently, future work should explore consumer opinions of alternative MIB versions, with the MIB revised in light of these study findings, as part of complete packaging to provide context for consumers. The aim should be to develop better performing labels which take into consideration characteristics relevant to both preferences and results from evaluations by consumers.²⁸ In addition, efforts should ensure that packaging size does not become a rate limiting factor influencing OTC label content and design, and their ability to support safe medication use. As OTC label standardisation is currently implemented in the U.S., regulatory bodies such as the Australian TGA should learn from the impact of the Drug Facts label; however, proposals put forward must remain within the Australian context. Presently, there is insufficient evidence to support the implementation of either the Drug Facts label or the MIB in an Australian context or that this strategy would be advantageous from a label usability standpoint. As this study did not aim to investigate the usability of the MIB or the Drug Facts label formats using diagnostic performance testing with consumers,²⁹ future research

should apply the recommendations and user test standardised OTC labels to ensure that implemented labels are fit for purpose.

When examining research conducted in relation to the Drug Facts label, whilst evidence suggests that it was an improvement on label formats available around the time of its proposal, some evaluations^{8,9} were conducted post introduction. Unsurprisingly, issues pertinent to potentially reduced OTC label quality still exist post-implementation of the Drug Facts label,^{30,31} highlighting the critical role of post-implementation evaluation, in conjunction with thorough pre-implementation needs analysis and performance testing. OTC label standardisation in Australia must be implemented alongside an audit process to ensure ongoing monitoring, thereby enabling opportunities for timely optimisation where necessary. Similarly, the positive impact of a U.S. campaign which yielded an increased use of medicine information included on OTC labels, with more than half being knowledgeable of the Drug Facts label one year post widespread implementation,³² indicates the potential importance of a similar, timely campaign in Australia if standardisation is implemented. Certain limitations of the present study should be acknowledged. The MIBs were presented to participants as paper copies, rather than incorporated as part of complete OTC packaging. This was due to the exploratory nature of the study, and as the MIB has not been implemented. Accordingly, this distinction amongst stimulus materials may have impacted

participant opinions of the MIB.

Conclusions

Participants appreciated characteristics of existing Australian OTC labels, Drug Facts and MIB label formats that contributed to perceived usability and format clarity. However, many implied a broad preference for the Drug Facts label partly due to its increased perceived completeness. The absence of inactive ingredient information, contact details, and parallel communication of active ingredient and its purpose were identified as gaps in the MIB labels. Consideration should be given to incorporating these aspects into the MIB. Performance testing of the resultant improved label format with consumers is a key necessary next step to demonstrate the extent to which the format supports both perceived and actual OTC label quality and usability.

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Tables

Table 1- Summary	of focus grou	p participant	demographics
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Demographic	Three focus groups
	(n=21)
Gender	
Male	10
Female	11
Age	
18-29	7
30-49	7
50-69	6
70+	1
Highest level of education	
School certificate or below	1
Higher School Certificate/College qualification	15
Bachelor degree or above	5
Main language spoken at home	
English	17
Other	4

Country of birth	
Australia	11
Overseas	10

Table 2- Products shown to consumers as stimulus material during the focus groups

Proprietary product label	Products
type	
Existing Australian OTC	 Nurofen[®] for Children 1-5 years oral suspension
product labels	(ibuprofen)
	 Panadol[®] Children 5-12 years oral suspension
	(acetaminophen)
	 Bisolvon[®] Dry oral liquid (dextromethorphan)
	 Children's Panadol[®] 6 months- 5 years suppositories
	(acetaminophen)
	• Earclear [®] Earache Relief ear drops (phenazone,
	benzocaine)
	 Codral[®] 4 Flu tablets (acetaminophen, codeine,
	phenylephrine, chlorpheniramine)
	 Gastro-Stop[®] capsules (loperamide)
	 Panamax[®] tablets (acetaminophen)
	 Daktarin[®] Cream for Athlete's Foot (miconazole)
Existing U.S. Drug Facts	 Up&Up[®] naproxen sodium tablets, 220mg (naproxen)

labels	Advil [®] caplets (ibuprofen)
	 Up&Up[®] acetaminophen extra strength caplets, 500mg
	(acetaminophen)
	Natureplex [®] Maximum Strength Hydrocortisone Cream
	(hydrocortisone)
	 Up&Up[®] Acid Reducer Original Strength tablets
	(famotidine)
	Children's Quick-dissolving Wal-Tussin [®] Cough Relief
	tablets (dextromethorphan)
	 Benadryl[®] Extra Strength Itch Stopping Cream
	(diphenhydramine, zinc acetate)
	 Up&Up[®] Gas Relief Extra Strength chewable tablets
	(simethicone)
	 Well at Walgreens[®] Sterile Lubricant Eye Drops
	(carboxymethylcellulose)
	Children's Mucinex [®] Chest Congestion Mini-melts
	granules (guaifenesin)
	Well at Walgreens [®] Sterile Original Prescription Strength
	Eye Itch Relief eye drops (ketotifen)

Table 3- Broad questions included in the semi-structured focus group protocol

Opinions on existing OTC	If we specifically looked at the product labels and written
medicine information	medicine information (WMI) leaflets of non-prescription
	medicines, what are your thoughts about the quality and
	amount of information, as well as how easy it is to
	understand the information?
Suggestions for	If you think about the currently available product labels and
improvement of OTC	WMI leaflets for non-prescription medicines (examples
medicine information	provided as stimulus prompts), how do you think the format,
	layout and content can be improved?
Perspectives on	What are your thoughts about standardising the WMI
standardisation of OTC	leaflets and product labels, so that the same type and level
medicine information	of information is provided with all medicines?
Perspectives on existing	What do you think about this label?
and proposed OTC	(provide U.S. OTC product label displaying Drug Facts label
labelling standardisation	format, and then the two mock MIB labels, and state type of
strategies	label appropriately)
1	

Table 4- Identified themes/subthemes and relevant illustrative quotes

Theme/subtheme	Illustrative quote
1) Consumer perspo	ectives on existing Australian OTC labels
	1. "Yeah really easy Like none of it [Nurofen [®] label] is in like
Positive label	complicated language or anything, it's all really simple and easy

Theme/subtheme	Illustrative quote
characteristics	visually to read because of the colours. And it's good." (Focus group
	2 (FG2), Female 3 (F3))
Barriers	2. "They are both in a different order. Gastro-Stop [®] is a lot easier to
contributing to	read and it just has the headings and tells you what's underneath
perceived	them. As where Codral [®] , has, like, headings across the page and
information	headings down the page and then, they divide the page in half. It's
retrieval difficulty	two sections; I'd have to keep looking around. It would take me a
	while to read the Codral [®] 4 Flu [as] opposed to the Gastro-Stop [®] ."
	(FG1F1)
	3 "It's very small writing. I mean my eyes are good and it's yeah it's
	S. It's very shall writing. Thear my eyes are good and it's year it's
	[Panadol [®] suppositories label] tiny writing, not easy to read. I mean
	I really would have picked this up by accident so" (FG2F2)
	4. "You see for me that's different. That one [Nurofen [®] label] for me
	is harder to read just because I have eye problems, whereas this one
	where it's clearly darker blue and the yellow – that's easier for me
	to read. Umm everyone is different but that's just me." (FG2F4)
Label content-	5. "The thing I noticed is that this one on the box it doesn't have
perceptions and	anything about the poisons [centre] or what to call, but it has it in
identified	here [in the leaflet], so if someone goes and throws that out and it's
discrepancies	not on the box and they can't use the Internet" (FG2F2)

Theme/subtheme	Illustrative quote
	6. "There's not much information on the [Daktarin [®]] box as such so
	you really do need to take out the brochure and the brochure is
	really good because it has lots of clear sub-headingsone of the
	sub-headings is umm why not to use it and it's if you're pregnant.
	And I'm thinking why isn't it on the outside of the box? You
	wouldn't think athlete's foot cream would annoy a pregnancy but it
	obviously does and I think that's really important, that it's just not
	there." (FG3F2)
Suggestions for	7. "Umm yeah they, they could have done less of the blue and more
label design	you know "Don't use if" umm before I have to drag this [leaflet] out
improvement	in the supermarket. It's not that easy to start reading pamphlets in
	the supermarket because you're always in a hurry to get home."
	(FG3F2)
2) Consumer persp	ectives on existing and proposed OTC labelling standardisation
strategies	

Theme/subtheme	Illustrative quote
a) Consumer	8. "I like that it has the active ingredients as well as inactive
perspectives on	ingredients. It has all the colourings and stuff like that so you can
the Drug Facts	see if you're allergic to something." (FG2F2)
label	
Drug Facts label-	
Positives	
b) Consumer	9. "I like the line in the directions where you've got the, the
perspectives on	children's ages and the mL's there's definitely a line so it's quite
the MIB	easy to see and you're not going to mess up in the middle of the
	night when you're dealing with children's medication." (FG3F2)

Figures

Medicine Information Box		Medicine Information Box		
Active Ingredient		Active Ingredient		
Each tablet contains:	diclofenac potassium 25mg	c potassium 25mg Every 5mL of Benpholc contains: 5mg pholcod		5mg pholcodine
		Uses		
Uses		Helps relieve a d	dry cough in the sl	nort term in
Short term relief of p	pain and swelling related to	adults and child	ren more than 6 y	ears old
migraines, back, join	ts, period pain, or sprains/strains.	Warnings and	Allergy Informat	ion
Warnings and Aller	gy Information	Do not use Ben	pholc if you or the	person you are
Do not take Diclofen	if you have:	giving it to:		
A stomach ulcer	or other stomach problems	 Is a child less 	than 6 years old	
Heart failure		 Has breathin 	g problems	
Kidney problems		 Has an allerg 	y to any ingredien	ts in Benpholc
Allergies to any of the second s	of the ingredients in Dicloten, or	Has a wet co	ugh	
Do not take Diclofer	inatory medicines like aspirin	Speak to a doct	or, pharmacist or	nurse before
Do not give Diclofen	to children less than 14 years old	giving Benphoic	to a child betwee	in 6 and 12 years
Please read the Med	icine Information Leaflet inside the	Diu. Please read the	Medicine Informa	ation Leaflet
pack before using Di	clofen.	inside the pack	before using Benr	holc.
When using this pr	oduct	When using th	is product	
Do not take Diclofen:		 Benpholc ma 	phole may make you or your child drowsy	
Together with ot	her anti-inflammatory medicines.	Take care when driving or using machines if you		
including other r	nedicines that also contain	are an adult		
diclofenac		 Avoid drinking alcohol whilst taking Benpholc 		
• For more than a	few days at a time, unless advised by	Speak to your doctor or pharmacist:		
your doctor		 If the cough worsens, changes or does not get 		
You may experience	common side effects like: nausea,	better		
stomach upset and c	lizziness.	Before using	/giving any other	cough and cold
Be careful if driving of	or operating machines until you know	medicines to	gether with Benpl	noic
Talk to your doctor of	you.	Directions		
worse or do not get	hetter	Age	How much	How often
Worse of do not get		6-12 years	2.5-5mL	3 to 4 times a
Directions		Adult	10-15 mL	day
Adults and	Take 2 tablets at first	Do not give or t	ake more than 4 d	loses of Benphol
children older	Then take 1-2 tablets every 8	in 24 hours.		. Is a sea the set
than 14 years old	hours if needed.	Do not give Ben	r doctor bas advis	or longer than 5
		Storage inform	ation	eu you to.
Do not take more than 8 tablets in 24 hours.		Storage Inform	Store Bennhold in a cool, dry place at room	
Storage information				
Store tablets in a cool, dry place at room temperature		Keep out of reach of children.		
(below 30°C).				
_ \ F		1.3		
a) Diclofenac MIB		b) Phoicoaine MIB		

Figure 1- Mock MIB label formats shown to participants

(These label formats have also been previously published in: Tong V, Raynor DK, Aslani P.

'It's all there in black and white' - or is it? Consumer perspectives on the proposed Australian

Medicine Information Box over-the-counter label format [published online July 31, 2015].

Health Expect. doi: 10.1111/hex.12389.)