ASMI Response

TGA Medicine Labelling and Packaging Review

Appendix 1

Issues with the consultation process and paper

Summary

In ASMI's view the principal deficiencies with the consultation process and paper are that:

- The COAG Principles of Best Practice Regulation have not been taken into account.
- Critical views of an External Reference Group specifically set up to advise the TGA on this consultation were not taken into account.
- Insufficient time has been allowed to prepare a comprehensive industry response with tested alternative proposals.
- The paper contains errors and inconsistencies which resulted in a lack of clarity and which made interpretation difficult.
- The figures include material which is not explained in the text, which do not comply with current labelling requirements, demonstrate a lack of internal consistency within the Consultation paper and imply additional proposals.
- No attempt was made to appropriately segregate the evidence of risk in relation to prescription and non-prescription medicines.
- No evidence was provided that the proposed reforms will achieve the stated objectives of the review.
- The Consultation paper anticipates that all the proposed changes can be incorporated into a single Therapeutic Goods Order.
- The poor quality of the Consultation paper has resulted in a significant waste of industry resources in having to understand and address the scope and nature of the proposed changes. A large proportion of this expenditure could have been saved if the Consultation had been better prepared and if a risk-based approach to reform had been adopted.
- The proposed changes involve both increased font sizes and increased levels of content. The inevitable consequence of this will be an increase in the physical dimensions of the product packaging. The ramifications of this will be far-reaching and extremely costly.

Each of these deficiencies is discussed in more detail on the following pages.

A more complete discussion of our concerns (together with our request for an extension) is presented in our letter to Dr John Skerritt (of 12 July) which has been included in Appendix 2.

COAG principles

COAG has agreed that all governments will ensure that regulatory processes in their jurisdiction are consistent with the following principles:

> *1. Establishing a case for action before addressing a problem;*
> *2. A range of feasible policy options must be considered, including self-regulatory, co-regulatory and non-regulatory approaches, and their benefits and costs assessed;*
> *3. Adopting the option that generates the greatest net benefit for the community;*
> *4. In accordance with the Competition Principles Agreement, legislation should not restrict competition unless it can be demonstrated that:-*
> > *(a) The benefits of the restrictions to the community as a whole outweigh the costs, and*
> > *(b) The objectives of the regulation can only be achieved by restricting competition;*
> *5. Providing effective guidance to relevant regulators and regulated parties in order to ensure that the policy intent and expected compliance requirements of the regulation are clear;*
> *6. Ensuring that regulation remains relevant and effective over time;*
> *7. Consulting effectively with affected key stakeholders at all stages of the regulatory cycle; and*
> *8. Government action should be effective and proportional to the issue being addressed.*

ASMI suggests that the TGA has not properly complied with these principles, because:

- A case for action has not been established in relation to the labelling of non-prescription medicines (principle 1).
- A range of feasible policy options have not been considered (importantly, there is no evidence that the TGA has considered self-regulatory, co-regulatory or non-regulatory approaches) (principle 2).
- There has been no attempt to demonstrate that the proposed changes generate the greatest net benefit for the community (principle 3).
- The impact on the brands of non-prescription medicines is likely to be profound (and competition thereby restricted). However, the TGA has not demonstrated that either; the benefits of the restrictions to the community as a whole outweigh the costs, or; that the objectives of the regulation can only be achieved by restricting competition (principle 4).
- The TGA has not consulted effectively with affected key stakeholders at all stages of the regulatory cycle. Notably the TGA has not provided sufficient time to prepare a comprehensive industry submission (see below). Further the TGA has ignored key recommendations of the External Reference Group established in advance of the Consultation Paper being published (see below) (principle 7).
- The proposed changes are not proportional to the issues being addressed. Firstly, the risks associated with non-prescription labels and packaging have not been properly articulated. Secondly, the proposed changes are to be applied across the entire spectrum of medicines (irrespective of risk)(principle 8).

The recommendations of the External Reference Group have been ignored

On 26 October 2011, representatives from industry, consumer and healthcare professional groups met to discuss possible solutions to the ten key labelling issues identified from previous consultations regarding labelling. These issues included:

- space for dispensing labels,
- look alike sound alike names and look alike packaging,
- active ingredient prominence,
- small container labelling requirements,
- pack inserts,
- umbrella branding / name extension,
- standardised label design,
- blister pack labelling,
- child resistant closures, and
- tamper evident packaging.

The following extracts are taken from the minutes of that meeting [emphasis added]:

> *"Throughout the discussion there were several recurring suggestions for reforming medicines labelling, including consideration of separate requirements for different classes of medicines; the use of a review panel for assessing names and labels prior to market authorisation; and the use of emerging technologies for providing access to information. It was also recognised that there was considerable overlap of the issues and the potential solutions, and it was proposed that a whole of label approach may provide a better consumer safety outcome than focussing on the individual issues in isolation. There was also strong support for harmonising with existing requirements in other jurisdictions where possible."*
>
> *"The need to provide evidence to support the need for reform was also discussed throughout the day. In order to develop this evidence base, the TGA will work with several members of the external reference group to support the need for change. This evidence will be included in the discussion paper which will be released for public consultation."*
>
> *"The importance of transparency and consistency in decision making was also recognised for all stakeholder groups. It is expected that this will be reflected in any new labelling requirements and associated guidelines."*

It is disappointing therefore that these pertinent assertions have been ignored by:

- Co-mingling prescription and non-prescription issues and solutions.
- Proposing the same changes to all the different classes of medicines.
- Proposing uniquely Australian requirements which fly in the face of harmonisation.

Insufficient time has been allowed

In our view, the TGA has not allowed sufficient time to prepare a comprehensive industry response to reforms on the scale and of the magnitude put forward in the consultation paper.

As indicated above, we requested an extension for the following reasons:

- The magnitude/scale of changes
- Insufficient time had been allowed to assess the changes, understand the implications of the proposed changes, develop and prepare alternatives, test those alternatives and synthesise all the issues into a comprehensive industry submission.
- The proposed changes were not clear and we suggested that until clarification was made that it was not possible to properly assess the proposed changes and respond to them. On this point, we believe that the consultation paper contains sufficient errors and inconsistencies so as to compromise the consultation process itself.
- In order to develop a full and considered response to the consultation, we needed to develop alternative proposals, test those proposals and assess the impacts of the proposed changes and the alternatives. We could only do that if the proposals were clear.
- In addition to the changes to the product packaging, we would also need to consider the flow-on effects to secondary packaging and the whole supply chain.
- We would need to estimate the cost implications for developing new packs that were unique to Australia.
- In order to achieve this, we needed an extension of time at least until the end of November to respond to the consultation in full.
- Within the current timeframe, we would only be able to provide a preliminary response to the proposed changes (as we understood them); we would not be able to put forward developed or tested alternatives.

Errors and inconsistencies with the information provided

ASMI is concerned that the proposed changes in the consultation paper are not sufficiently clear because the paper itself contains the following errors and inconsistencies with regard to the information provided:

- The consultation paper does not indicate that the labelling requirements for prescription and non-prescription products are currently different, nor does it explain the reasons for the different requirements.
- The consultation paper fails to clearly articulate how (or if) the proposed changes will apply differently to Prescription medicines, OTC medicines and Complementary medicines. This is inconsistent with the TGA's risk-based approach.
- Section 3 includes the erroneous amalgamation of four separate issues (look-alike sound-alike products, different strengths within a prescription medicine brand, umbrella branding and indication specific branding) into a single topic applicable to both prescription and non-prescription products. These four topics ought to be addressed separately because they each represent different sets of risks and they each have varying relevance for prescription and non-prescription products.
- Confusingly, the consultation paper introduces a new term "Look-alike medicine branding" in place of the internationally recognised term "umbrella branding".
- The consultation paper does not define the term "look-alike/sound-alike" which is generally linked to confusion between prescription medicine brand names.
- The term "complementary medicines" is defined differently on pages 6 and 12 and in any event the consultation paper does not properly indicate that complementary medicines can be prescription or non-prescription (as well as being listed or registered).
- As a member of the External Reference Group, ASMI saw the previous draft (dated October 2011) which more clearly differentiated the prescription and non-prescription issues and proposals. On this point, ASMI notes that the separation of prescription and non-prescription issues has been an integral, long-standing and consistent part of previous regulatory discussions; not just in relation to labelling and not just between the TGA and industry (but between all stakeholders).

<u>These errors make it difficult to assess the basis and/or the merits of the proposed changes.</u>

Errors and inconsistencies in the figures

The figures presented throughout the Consultation Paper contain numerous faults which impair the consultation process. These can be summarised as follows:

- Material is included in the figures which is not explained in the text. Because these inclusions are not discussed, respondents will be unable to assess and comment on the reasoning for their inclusion. Similarly, respondents will be unable to develop and propose suitable alternatives. Also, respondents are unable to determine whether or not the apparent changes are intentional or an oversight. This absence of commentary makes it difficult to assess the basis and/or the merits of the proposed changes as well as the actual scope of the consultation.
- Figures are included which do not comply with current labelling requirements. In reviewing the label examples provided, ASMI notes a number of examples where the current requirements have not been complied with. This lack of compliance means that the examples do not accurately reflect the impact of the proposed changes. Furthermore, respondents are unable to tell whether the examples reflect further changes not explained in the text.
- There is a lack of internal consistency within the consultation document. In reviewing the label examples provided, ASMI notes a number of examples where there are inconsistencies between the figures themselves and between the figures and the written content of the consultation paper. This lack of consistency makes it difficult to assess the basis and/or the merits of the proposed changes as well as the actual scope of the consultation.

A more complete discussion of our concerns with the figures (listing the errors and inconsistencies) is presented in our letter to Dr John Skerritt (of 12 July) which has been included in Appendix 2.

ASMI further notes that figure 10 (which purports to show compliance with the proposed changes) shows a perforation which will separate every piece of required information into two incomplete parts. This figure cannot represent the proposed changes.

ASMI notes that the launch of the consultation paper was delayed so as to incorporate these figures. It is therefore disappointing that instead of aiding the consultation the figures confuse it.

Insufficient Evidence has been provided

No attempt was made to appropriately segregate the evidence of risk in relation to prescription and non-prescription medicines.

In relation to the TGA's stated "risk-based approach to regulation", the TGA states that:

> *"One of the roles of the TGA is to regulate therapeutic products based on an assessment of the evidence of the risks compared to the benefits of the therapeutic products. The TGA does this by applying scientific and clinical expertise."*[1]

Despite this, the Consultation paper proposes uniform solutions across medicines categories. We do not support such a blanket approach.

Furthermore, no evidence was provided that the proposed reforms will achieve the stated objectives of the review.

ASMI is unaware of any evidence suggesting that the current labelling requirements for non-prescription products are inadequate or represent a risk to consumers.

Anticipation of a single Therapeutic Goods Order

ASMI notes that the Consultation Paper anticipates that the proposed changes will be encompassed in a Therapeutic Goods Order. ASMI suggests that the issues raised in the consultation paper and the proposed changes are too complex to be adequately addressed through a Therapeutic Goods Order alone. In fact, ASMI suggests that a number of guidelines will be necessary to complement any Therapeutic Goods Order.

Resource implications from a poor quality Consultation paper

The errors and inconsistencies in the Consultation paper, coupled with the complex and wide-ranging implications of the proposed changes has resulted in a significant amount of time and money being spent by ASMI and its members in preparing this response.

To date, ASMI and its members have spent more than 2100 person hours reviewing the Consultation paper, interpreting the proposals and preparing responses. On top of this ASMI members have spent more than $60,000 preparing artwork mock-ups of labelling in an effort to fully understand the impact of the proposed changes.

ASMI suggests that a lot of this time and money was spent as a direct result of the issues surrounding the quality of the consultation paper and the consultation process. Much of this cost could have been avoided if the Consultation had been better prepared and if a risk-based approach to reform had been adopted.

[1] http://www.tga.gov.au/about/tga-regulatory-framework.htm

Pack size implications

The proposed changes involve both increased font sizes and increased levels of content. The inevitable consequence of this will be an increase in the physical dimensions of the product packaging. The ramifications of this will be far-reaching and extremely costly.

In our response we have made no attempt to address this complication in detail or to quantify the significant costs associated with any such change. Indeed, any attempt to address this issue in the absence of finalised proposals would be premature.

Having said that, we wish to point out that there will be numerous and significant flow-on implications should the physical dimensions of the product packaging increase to accommodate the reforms, some of these implications include:

- Increased costs associated with capital equipment and facilities.
- Increased costs of packaging (both primary and secondary).
- For imported goods, increased costs of unique Australian packaging and overhead recovery for down time and line changeovers (which could impact on the viability of Australian specific production).
- Decreased freight efficiencies.
- Storage space implications at the manufacturer, wholesaler and retailer levels.
- Shelf-space implications at retail level (with impacts on planograms and line fees to stock product).
- The extra packaging materials will result in increased wastage and possible incompatibilities with the Australian Packaging Covenant.

<u>The financial impact of changes to the physical dimensions of the packaging should not be under-estimated.</u>

ASMI Response

TGA Medicine Labelling and Packaging Review

Appendix 2

ASMI Letter to Dr John Skerritt (12 July 2012)

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12 July 2012

Dr John Skerritt
National Manager
Therapeutic Goods Administration
PO Box 100
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Email: John.Skerritt@tga.gov.au

Re: TGA Medicine Labelling and Packaging Review

Dear Dr Skerritt,

ASMI (Australian Self Medication Industry) is the peak body representing companies involved in the manufacture and distribution of consumer health care products in Australia. ASMI also represents related businesses including advertising, public relations, legal, statistical and regulatory consultancy companies and individuals.

Thank you for agreeing to meet with ASMI representatives on Friday 13 July to discuss the TGA's Labelling and Packaging Review.

In advance of that meeting we would like to outline for you our concerns and our reasons for seeking an extension to the closing date for submissions.

Introduction

As you know the TGA's Labelling and Packaging Review will close on 24 August 2012.

ASMI is meeting with you to discuss an extension to this deadline for two reasons:

- Even if the proposed changes were clear, 3 months does not allow sufficient time to assess the changes, develop and prepare alternatives, test those alternatives and synthesise all the issues into a comprehensive industry submission.

- However, the proposed changes are not clear and we suggest that until clarification is made then it is not possible to properly assess the proposed changes and respond to them. On this point, we believe that the consultation paper contains sufficient errors and inconsistencies so as to compromise the consultation process itself.

These two reasons are expanded upon below.

We would also like to note that all eight topics in the consultation paper are relevant to non-prescription products and the proposed changes will have a significant impact on both OTC and Complementary Medicines (in terms of brands and products).

1. Insufficient time allowed

The consultation paper was released on 24 May 2012. At that time ASMI notified members of its release and commenced reviewing the paper. We have held preliminary meetings with our subcommittee and working group representatives and members have agreed on the main issues and a draft timeline for the response.

Members have also agreed to develop artwork incorporating the TGA proposals (as we understand them) across a range of OTC and complementary products and pack sizes.

We have scheduled a 2 day workshop for our members (on 25 and 26 July) to examine the issues in depth and to develop alternate proposals.

We have continued to examine the consultation paper in detail and are preparing an issues paper for workshop participants.

However, in order to develop a full and considered response to the consultation, we need to understand the implications of the proposed changes, develop alternative proposals, test those proposals and assess the impacts of the proposed changes and the alternatives. We can only do this if the proposals are clear.

In addition to the changes to the product packaging, we will also need to consider the flow-on effects to secondary packaging and the whole supply chain. We will also need to estimate the cost implications for developing new packs that are unique to Australia.

Having said that, we provide the following broad outline of the time required:

Action	**Est. Timing**	**Est. Date of completion**
Develop revised artwork to comply with the proposals contained in the consultation as we understand them.	6 weeks	To be available for the ASMI workshop on 25 and 26 July.
Review and identify alternate approaches to address the perceived intent of the labelling proposals.	2 weeks	9 August
Develop alternate artwork.	6 weeks	20 September
Test the current, proposed and alternate labels with consumers.	8 weeks	15 November
Concurrently prepare case studies. Assess the cost implications to capital equipment, packaging, secondary packaging, shipping, storage, shelf space and line fees. Assess the environmental impact.	8 Weeks	15 November
Prepare of a comprehensive response.	4 weeks	13 December

In order to achieve the above, we therefore request an extension of time at least until the end of November to respond to the consultation in full. Within the current timeframe, we would only be able to provide a preliminary response to the proposed changes (as we understand them); we would not be able to put forward developed or tested alternatives.

2. Issues with the consultation document itself

As mentioned above, we are concerned that the proposed changes in the consultation paper are not sufficiently clear because the paper itself contains errors and inconsistencies. We suggest that if the consultation paper is unclear to industry representatives then it must be even less clear to consumers.

This is of particular concern because the consultation paper states that: “care has been taken to develop a paper that can be easily understood by a consumer audience”.

The consultation paper indicates that responses should include: “whether or not you support the proposed changes” and “an assessment of how the proposed change will impact on you or your business”. We would argue that no such opinion can be formed and no such assessment made while the precise nature of the proposed changes remains unclear.

We would like to draw your attention to the following errors and inconsistencies in the consultation paper.

2.1 Co-mingling of prescription and non-prescription requirements, issues, proposals

The consultation paper does not indicate that the labelling requirements for prescription and non-prescription products are currently different, nor does it explain the reasons for the different requirements. This has proven confusing for industry.

Further, the consultation paper fails to clearly articulate how (or if) the proposed changes will apply differently to Prescription medicines, OTC medicines and Complementary medicines. This is inconsistent with the TGA’s risk-based approach and seems to suggest, for example that consumers will have the same difficulties with a sunscreen label as they would with the label of a prescription product.

Section 3 includes the erroneous amalgamation of four separate issues (look-alike sound-alike products, different strengths within a prescription medicine brand, umbrella branding and indication specific branding) into a single topic applicable to both prescription and non-prescription products.

These four topics need to be addressed separately because they each represent different sets of risks and they each have varying relevance for prescription and non-prescription products.

Confusingly, the consultation paper introduces a new term “Look-alike medicine branding” in place of the internationally recognised term “umbrella branding”.

The consultation paper does not define the term “look-alike/sound-alike” which is generally linked to confusion between prescription medicine brand names.

ASMI notes that the term “complementary medicines” is defined differently on pages 6 and 12 and in any event the consultation paper does not properly indicate that complementary medicines can be prescription or non-prescription (as well as being listed or registered).

As a member of the External Reference Group, ASMI saw the previous draft (dated October 2011) which more clearly differentiated the prescription and non-prescription issues and proposals. On this point, ASMI notes that the separation of prescription and non-prescription issues has been an integral, long-standing and consistent part of previous regulatory discussions; not just in relation to labelling and not just between the TGA and industry (but between all stakeholders).

This co-mingling makes it difficult to assess the basis and/or the merits of the proposed changes.

2.2 Material included in the figures which is not discussed in the text

In reviewing the text of the consultation paper against the label examples provided, ASMI notes the following items included in the figures but not discussed in the body of the paper:

- The inclusion of the Company Name immediately prior to the Brand Name on all panels in which the Brand Name appears.
- The inclusion of the TGA website URL www.tga.gov.au immediately under the AUST L/R number on the front panel.
- The mandatory inclusion of the Country of Origin immediately under the company address (in figure 2) as well as on the back of the pack under “Storage information”.
- The inclusion of CMI style statements on the back of the pack. For example the statement “your doctor may have prescribed TGGeneral for another reason” in figure 2, which is wholly inappropriate for a non-prescription medicine.
- The description of the dose form under “Storage Information”.

Because these inclusions are not discussed, respondents will be unable to assess and comment on the reasoning for their inclusion. Similarly, respondents will be unable to develop and propose suitable alternatives.

The absence of commentary makes it difficult to assess the basis and/or the merits of the proposed changes as well as the actual scope of the consultation.

2.3 Figures which do not comply with current labelling requirements

In reviewing the label examples provided, ASMI notes a number of examples where the current requirements have not been complied with:

- The SUSMP requirements in relation signal headings and their sizes do not appear to have been met, nor has the requirement that nothing else appear on the same line as the signal headings (see for example, figure 3).
- The statement "Do not use if package is broken or damaged" (see for example, figure 2) is not, in fact, an appropriate tamper-evidence statement. ASMI also notes that the label examples otherwise make no provision for statements about child-resistant-packaging or tamper-evident-packaging.
- Figure 7 contains a fictional schedule ("Pharmacy Only Medicine").

The requirements in relation to barcode sizes and locations also do not appear to have been complied with.

<u>This lack of compliance means that the examples do not accurately reflect the impact of the proposed changes.</u>

2.4 Lack of internal consistency within the consultation document

In reviewing the label examples provided, ASMI notes a number of examples where there are inconsistencies between the figures themselves and between the figures and the written content of the consultation paper:

- In relation to the back of the pack, which if any of the following must appear above the active ingredient information; the signal words, the cautionary statements, the product name, the term "Medicine Information Box" (see for example, figure 7 which includes all four)(see for example figure 2 which only includes one).
- In relation to the back of the pack, the heading "when using this product" appears in figures 6 and 8, but not in figures 2 and 7.
- In relation to the back of the pack, a physical description of the product appears under the heading "storage information" in all the figures except figure 7.
- In relation to country of origin, the mandatory inclusion of the Country of Origin immediately under the company address is shown in figures 2, 3 and 8, however this information also appears on the back of the pack under "Storage information" in figure 2 (but in no other figure) and appears above the company name in figures 11 and 12.
- The indications appear on the front of pack in figure 4, but on no other packs.
- Figure 3 is supposed to illustrate the proposal for including a paracetamol warning statement on the label of a non-prescription pack (but is in fact a prescription product/label).
- In accordance with proposal 1.1, the active ingredient must be listed immediately below the brand name. However, figures 4 and 8 do not show this. Also, figures 2, 4 and 11 present the amount of active ingredient differently.

This lack of consistency makes it difficult to assess the basis and/or the merits of the proposed changes as well as the actual scope of the consultation.

3. Other concerns

We have confined our comments above to our concerns about the consultation document itself. Although we do have significant concerns with the *merits* of some of the proposed changes, we intend to address those issues as part of our formal response to the consultation document.

Having said that, we are concerned that certain of the COAG Principles of Best Practice Regulation have not been applied to this consultation and we are also concerned that the consultation paper does not discuss international harmonisation (particularly since a number of the proposals appear to be uniquely Australian).

4. Summary

ASMI has sought a meeting with you in order to present the above concerns and to discuss an extension to the 24 August deadline. ASMI's concerns can be summarised thus:

- Even if the proposed changes were clear, 3 months does not allow sufficient time to prepare a comprehensive industry submission.

- However, the proposed changes are not clear and so it is not possible to properly assess the proposed changes and respond to them.

In ASMI's view, the errors and inconsistencies in the consultation paper have jeopardised the consultation process itself. We therefore also seek a discussion on how best to remedy the consultation paper and inform affected stakeholders.

Yours faithfully,

Steven Scarff
Regulatory and Scientific Affairs Director

ASMI Response

TGA Medicine Labelling and Packaging Review

Appendix 3

ASMI Letter to ACSQHC (29 September 2010)

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29 September 2010

Mrs Margaret Duguid
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Australian Commission on Safety and Quality in Health Care
GPO Box 5480
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Email: Margaret.duguid@safetyandquality.gov.au

Dear Mrs Duguid

Re: Confusing drug names, labelling and packaging of medicines

Thank you for your letter of 22 July 2010 and the opportunity to provide information on Australian Self-Medication Industry (ASMI) and its member company activities aimed at reducing the risk of harm to Australian consumers resulting from confusing names, labels and packaging.

ASMI is the peak body representing companies involved in the manufacture and distribution of non-prescription consumer healthcare products in Australia. ASMI's vision, *Better health through responsible Self Care*, is central to our work and objective of gaining recognition for Self Care as an integral element of a coordinated and comprehensive national health policy.

In 1998, a special working group of the World Health Organization (WHO) offered an inclusive definition of Self Care:

> *Self Care in health refers to the activities individuals, families and communities undertake with the intention of enhancing health, preventing disease, limiting illness, and restoring health. These activities are derived from knowledge and skills from the pool of both professional and lay experience. They are undertaken by lay people on their own behalf, either separately or in participative collaboration with professionals.*

One aspect of Self Care is the ability of consumers to access, choose and use non-prescription products in a responsible manner. However, to do this, consumers require good information.

There are already many legislative/regulatory requirements in place to control labelling and packaging of non-prescription products. In addition, industry and government have been involved in many initiatives over the last 20 years to ensure that non-prescription labels are clearly written and designed consistent with Quality Use of Medicines (QUM) principles: 1) select management options wisely, 2) choose a suitable medicine if one is considered necessary, and 3) using medicines safely and effectively.

For non-prescription products, the label is the single most important source of information available to consumers.

A well-designed label:

- is easy to **read**;
- enables the consumer to easily **find** what they need to know; and
- is written in such a manner that the information can be easily **understood** and **used**.

Background:

As far back as 1990, ASMI, then known as PMAA, understood the importance and role of labelling in ensuring responsible use of non-prescription products.

There were 2 main activities around that time:

1. The association commissioned research on labelling requirements in 2 categories – analgesics and cough/cold – testing for understanding and interpretation of label information and the implications for responsible use and compliance. This study also involved redesigning the labels using 'plain English'. The results of this research clearly showed that redesigning the label significantly improved consumer understanding of its information (*Making medicine labels work*, the Executive summary of the research is attached).

2. The association produced a brochure, under the banner of the Council on Family Health, 'Before you take the medicine, take in the label'. This brochure was launched in 1991 by Minister Peter Staples at a PMAA Conference at the ANU in Canberra. This event coincided with the first National Medicines Week, during which the brochure was distributed to every pharmacy in Australia as part of the package of materials for the week.

1994 onwards saw a renewal of efforts to improve labelling of non-prescription products:

1. Prof David Sless, Communication Research Institute (CRI) approached the association and suggested that he could offer a method of improving the outcomes even more significantly by applying the methodology used in the CMI work going on at the time, i.e. the performance-based model. Prof Sless was engaged to replicate the research, which demonstrated the benefits of the performance-based approach. The outcome was a report to the Pharmaceutical Health and Rational Use of Medicines (PHARM) committee in February 1995.

2. Publication of an Issues Paper on Consumer Product Labelling by the Federal Bureau of Consumer Affairs in September 1995. This paper noted that "For some consumer products, labelling requirements are complicated and sometimes confusing with several regulators each making different demands on the label. This is particularly the case for products which are drugs, poisons and chemicals. The label that results when manufacturers comply with the regulations and add their own 'sales' information can be one which is difficult for consumers to use."

3. In 1996, the Department of Industry, Science and Tourism undertook research to consider whether a performance-based approach to product labelling regulation could improve label information for consumers and help reduce administrative complexities and expenses faced by business. For the purposes of this project, the Department used the following definitions to distinguish performance-based (i.e. outcomes-based) labelling from prescriptive approaches:

- Prescriptive requirements specify the manner in which a product is to be labelled (e.g. labels on a hazardous substance shall contain particular words, sized and positioned as specified).
- Performance-based/outcomes-based requirements give specified outcomes but leave open the means of meeting the outcomes (e.g. labels on hazardous substances must be easily legible and draw the attention of the user to all hazards involved in their use).

The Department also drafted a document, *Features of Good Regulatory Practice for Product Labelling*, which provided guidelines on good regulation for regulators, including those moving towards a performance-based approach to product labelling regulation.

Regulation:
The Therapeutic Goods Administration (TGA) regulates all aspects of medicines, including mandating the type of information that has to be included on labels.

The *Therapeutic Goods Act* 1989 requires that the 'presentation' of all therapeutic goods be considered as part of the approval process. 'Presentation' is defined as:

> *"presentation", in relation to therapeutic goods, means the way in which the goods are presented for supply, and includes matters relating to the name of the goods, the labelling and packaging of the goods and any advertising or other informational material associated with the goods.*

Section 3 (5), also requires the TGA to consider whether a presentation is unacceptable:

> *(5) For the purposes of this Act, the presentation of therapeutic goods is unacceptable if it is capable of being misleading or confusing as to the content or proper use or identification of the goods and, without limiting the previous words in this subsection, the presentation of therapeutic goods is unacceptable:*
>
> *(a) if it states or suggests that the goods have ingredients, components or characteristics that they do not have; or*
> *(b) if a name applied to the goods is the same as the name applied to other therapeutic goods that are supplied in Australia where those other goods contain additional or different therapeutically active ingredients; or*
> *(c) if the label of the goods does not declare the presence of a therapeutically active ingredient; or*
> *(ca) if the therapeutic goods are medicine included in a class of medicine prescribed by the regulations for the purposes of this paragraph--if the medicine's label does not contain the advisory statements specified under subsection (5A) in relation to the medicine; or*
> *(d) if a form of presentation of the goods may lead to unsafe use of the goods or suggests a purpose that is not in accordance with conditions applicable to the supply of the goods in Australia; or*
> *(e) in prescribed cases.*

All medicines approved by the TGA must comply with the publication *Therapeutic Goods Order No. 69 – General requirements for labels for medicines* (TGO 69)[1]. In addition, the *Standard for the Uniform Scheduling of Medicines and Poisons* (SUSMP)[2], and the

[1] http://www.comlaw.gov.au/ComLaw/Legislation/LegislativeInstrumentCompilation1.nsf/all/search/4898DEE2DB28BC14CA25759E0022D7DA
[2] http://www.frli.gov.au/ComLaw/Legislation/LegislativeInstrument1.nsf/0/D41CD6A80FAF293ECA25778800280D92?OpenDocument

document *Required Advisory Statements for Medicine Labels*[3] may require inclusion of warning statements on the labels of certain substances. The TGA may also require further warnings be added to labels as part of the registration/listing process for specific products.

The TGA agrees that the label is the single most important piece of information for non-prescription medicines, and that the information should help consumers select and use suitable products. It is therefore critical that the information is presented in a way that can be understood and acted on by the consumer.

To this end, in April 2000 the TGA issued its first consultation document, *Labelling project 99/00 – Effective by design. A discussion paper on possible reforms to the regulation of the labelling of medicines in Australia*[4].

This was followed in March 2002 by the consultation report, *Review of the labelling requirements for medicines: Consumer-focused Labelling – a way forward?*[5]. This report reflected a positive approach to performance-based or consumer-focused labelling and made a series of recommendations, one key one being the development of an industry code on preparing consumer-focused labelling.

> *"Recommendation 5: A consumer-focused approach to the labelling of medicines should be established using a similar approach to that adopted for CMI. The performance-based elements should be co-regulated under an industry code of practice with mandatory requirements set out in the Medicines Labelling Order. The TGA should work with stakeholders to examine how the performance-based principles may be applied with the aim of improving the performance of labels for the benefit of consumers."*

Activity:
An outcome of this consultation was the development of an industry code of practice for the OTC medicines industry by the ASMI and CRI, with TGA's close involvement and cooperation. The code was drafted using the knowledge gained from the development and application of the performance-based guidelines, *Writing about medicines for people: Usability Guidelines for Consumer Medicine Information*, and subsequent research into the development of performance-based labelling for OTC medicines.

The *Labelling Code of Practice: Designing usable non-prescription medicine labels for consumers*[6] was published in 2004 and is freely available on the ASMI website.

The Labelling Code of Practice provides a set of consumer-focused principles for developing labels with the consumer in mind. It notes that labels designed using consumer-focused principles help consumers to:

- identify products, differentiate and choose an appropriate product for their needs;
- find and appropriately action instructions for using the product safely and effectively; and
- know where to find further information if they need to know more about the product.

Guidelines providing detailed advice for developing usable labels were also developed and are available for purchase from CRI.

[3] http://www.tga.gov.au/meds/rasml.htm
[4] http://www.tga.gov.au/consult/2000/label.htm
[5] http://www.tga.gov.au/docs/html/labelrev.htm
[6] http://www.asmi.com.au/documents/Industry/labelling_code_of_practice.pdf

Effective 1 July 2004, TGO 69 was amended by TGO 69A[7] to require all non-prescription product labels to be developed using the criteria put forward in the Labelling Code of Practice. The Introduction to TGO 69 states:

> *"The purpose of a medicine label is to provide information about the product such as its identity, potency, content, storage, expiry date, registration status and sponsor. Medicine labels also include other information not required by the Order, but which may be required by other legislative instruments or for commercial purposes. These include items such as signal headings (eg. prescription only, pharmacist only), bar codes and sponsor's logos.*
>
> *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.*
>
> *Although there may be various means of achieving the aim stated above, products with labels that have been designed in accordance with the industry code of practice entitled Labelling Code of Practice: Designing usable non-prescription medicine labels for consumers, published by Communications Research Institute of Australia Inc. should achieve this aim."*

GlaxoSmithKline was presented the Pharmaceutical Industry QUM Award at the 2004 National Medicines Symposium for the project to redesign Panadol labelling using consumer-focused principles. ASMI was Highly Commended for identifying the importance and necessity of medicine labelling in achieving understanding, acceptance, trust and responsible use of self-medication products.

A case study[8] detailing the process for redesigning the Panadol label is available on the CRI website. Additional examples of redesigning non-prescription medicine labels are provided in the document *Performance-based design*[9] on the CRI website.

These two documents only highlight the work being done by CRI for ASMI member companies. However, it is important to note that many more companies have revised or are revising their labels to better incorporate consumer-focused labelling principles.

Following development of the Labelling Code of Practice and associated Guidelines, ASMI together with CRI have presented several training workshops for industry.

In 2004, the TGA also published guidelines for 'umbrella' or 'family' branding[10], which occurs when different products are marketed under the one brand name. The guideline requires that, before making a decision, the TGA must take into account the following factors when assessing whether the use of an existing brand name for a new product with different active ingredients is acceptable:

- the strength of association of the brand name with a particular active ingredient and/or therapeutic use;

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[7] http://www.tga.gov.au/docs/html/tgo/tgo69a.htm
[8] http://communication.org.au/publications/case-histories/medicine-labelling-for-consumers/60,33.html
[9] http://communication.org.au/publications/case-histories/performance-based-design/86,33.html
[10] *Australian Regulatory Guidelines for OTC Medicines* (ARGOM), Chapter 5A, Presentation – Product Name: http://www.tga.gov.au/docs/pdf/argom_5.pdf

- whether the presentation of the new product is sufficiently different to the existing product range to alert consumers to the fact that this is a different product, despite the similarity in product name;
- consideration of the safety consequences if a consumer took the new product as if it were the existing product and vice-versa;
- consideration of the efficacy consequences if a consumer took the new product as if it were the existing product and vice-versa;
- the scheduling classification of the product, i.e. if professional advice is available and/or required at the point of sale;
- the sponsor's proposals for advertising/consumer education/health professional education; and
- evidence of consumer testing demonstrating adequate differentiation between the products.

This is on top of TGA's general requirement to assess the 'presentation' of all new therapeutic goods.

The labelling workshops run by ASMI and CRI include guidance on developing and testing labels to determine if consumers can differentiate between various products under the one brand name.

It should be noted that the TGA is in the process of redrafting the 'umbrella' branding guideline as part of the ARGOM Review Project. We anticipate that the draft guideline will be released for broad stakeholder consultation later this year.

Further to the above labelling activities, ASMI, in 2008, redesigned its website to include a section specifically for consumers[11]. It includes general information on various topics, including labelling, packaging, Consumer Medicine Information, and side effects of medicines. It is to be expanded this coming year with educational materials on issues such as how to read and understand information presented on a label, and fact sheets on therapeutic categories.

In summary, there are already many legislative/regulatory requirements in place to control labelling and packaging of non-prescription products. In addition, the last 20 years has seen the involvement of industry and government in various initiatives with the aim of ensuring that non-prescription labels are clearly written and designed consistent with QUM principles so that consumers and health professionals can appropriately select and safely and effectively use the most suitable product.

Please do not hesitate to contact me if you would like any additional information.

Yours sincerely

Mary Emanuel
QUM Manager

[11] ASMI 'Consumer Information' website: http://www.asmi.com.au/consumer/default.aspx

ASMI Response

TGA Medicine Labelling and Packaging Review

Appendix 4

Australian Commission on Safety and Quality in Health Care 2011, *Report on the National Round Table on Safer Naming, Labelling and Packaging of Medicines*, ACSQHC, Sydney.

Australian Government
Department of Health and Ageing
Therapeutic Goods Administration

AUSTRALIAN COMMISSION ON SAFETY AND QUALITY IN HEALTH CARE

Report on the

National Round Table on Safer Naming, Labelling and Packaging of Medicines

24 May 2011

Report on the National Round Table on Safer Naming, Labelling and Packaging of Medicines 2011 24 May 2011.

Suggested citation
Australian Commission on Safety and Quality in Health Care (year), *Report on the National Round Table on Safer Naming, Labelling and Packaging of Medicines 24 May 2011*, ACSQHC, Sydney.

Acknowledgment
Many individuals and organisations have freely given their time, expertise and documentation to support the development of this report. In particular, the Commission wishes to thank the Therapeutic Goods Administration of the Department of Health and Ageing and other members of the *Safer Naming, Labelling and Packaging Round Table Organising Committee* for their significant contribution to management of the round table and the drafting of this document. The involvement and willingness of all concerned to share their experience and expertise is greatly appreciated.

This document can be downloaded from the ACSQHC web site: www.safetyandquality.gov.au

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Acronyms

ACSQHC	Australian Commission on Safety and Quality in Health Care
CATAG	Council of Australian Therapeutic Advisory Groups
CHF	Consumers' Health Forum
NCCTG	National Coordinating Committee on Therapeutic Goods
NEHTA	National Electronic Health Transition Authority
NHMRC	National Health and Medical Research Council
NMPC	National Medicines Policy Committee
NPS	NPS – Better Choices, Better Health
PBA	Pharmacy Board of Australia
TGA	Therapeutic Goods Administration of the Department of Health and Ageing

Executive summary

There is evidence from Australia and overseas countries that confusing naming, and inadequate labelling and packaging of medicines contributes to medication errors and patient harm.

There have been considerable efforts by numerous organisations to improve the quality of medicines naming, labelling and packaging in Australia. Organisations involved include:

- Therapeutic Goods Administration of the Department of Health and Ageing (the TGA),
- Medicines industry including representative organisations;
- Academic and other researchers; and
- Safety and quality organisations.

Despite these efforts, concern about the contribution of naming, labelling and packaging practices to the safety and quality of medicines continues to be voiced by both consumers and health care professionals. This has been acknowledged by members of the medicines industry, the National Medicines Policy Committee and the TGA.

It was a combination of these issues that led the Australian Commission on Safety and Quality in Health Care (the Commission) to accept a recommendation from its Medication Reference Group to convene a national round table on safer naming, labelling and packaging of medicines.

The Commission and the TGA jointly conducted a round table on safer naming, labelling and packaging of medicines in Sydney on 24 May 2011. The aim of the round table was to develop a coordinated approach to improving medicines naming, labelling and packaging in Australia by agreement and coordination amongst key stakeholders.

Clinicians, consumers, regulators and the pharmaceutical industry participated in the roundtable and:

- Considered existing issues with the naming, labelling and packaging of medicines;
- Identified potential solutions to existing issues;
- Prioritised issues and potential solutions;
- Recommended a course of work that could be undertaken and identified those responsible for each action.

At the meeting the TGA announced that a review of medicines labelling and packaging requirements would be conducted.

The meeting identified eighteen recommendations along with those responsible for their action. The recommendations are listed below in Table 1 with an update on the status of the recommendations at 21 September 2011.

The Commission and the TGA undertook to review the recommendations and work with the roundtable participants in developing a national approach to reducing the risk of confusing naming and labelling contributing to patient harm.

Table 1: Recommendations

Recommendation	By	Status at 21 September 2011
A. Pre-marketing solutions		
1: Consider screening all medicines names to identify look-alike, sound-alike medicines names using a computerised system. An alternative name should be used when similar proprietary names are identified and the risk of harm from confusion of the products is high.	TGA	Included in TGA review on medicines labelling and packaging
2: Develop guiding principles for clinical safety assessment of confusable medicines names, both brand and active ingredients. The principles should include the use of prospective risk assessment tools. Distinctive product labelling should be used to differentiate products when potentially confusable names are identified.	TGA Industry	Included in TGA review on medicines labelling and packaging
3: Undertake a review of brand extension regulations and ensure that safety and quality concerns are addressed. Include elements of the TGA's *Best Practice Guideline on Prescription Medicine Labelling* relating to brand extension or corporate naming in the labelling order.	TGA	Included in TGA review on medicines labelling and packaging
4: Include a requirement for equal prominence of active ingredient name on medicines labels within the labelling order.	TGA	Included in TGA review on medicines labelling and packaging
5: Review the *Best Practice Guideline on Prescription Medicine Labelling.* Develop standards for content and design of labelling that consider international work on medicines labels design and mandate elements within the labelling order.	TGA	Included in TGA review on medicines labelling and packaging
6: The Commission will maintain links with the *International Medication Safety Network* (IMSN) to learn of international activity on improving the safety of medicines naming and labelling.	ACSQHC	Commission is a member of IMSN
7: Develop guiding principles for clinical safety assessment of labelling and packaging.	TGA	Included in TGA review on medicines labelling and packaging
8: Investigate technical solutions to identifying look a-like packaging prior to product registration. The solutions should be validated by health professionals and consumers to demonstrate equivalence to user-testing by health care professionals and consumers prior to their introduction. This could include future research into the feasibility of an electronic system to screen proposed label designs against existing labels.	TGA NPS NMPC NHMRC	Under consideration for inclusion in the TGA review on medicines labelling and packaging

B. Post-marketing solutions		
9: Set standards that require the use of machine readable code (barcode) readers by health professionals selecting medicines for dispensing and administering.	Health professional national councils / boards Professional indemnity organisations Professional organisations	ACSQHC will work with key organisations
10: Obtain uniformity of state and territory requirements for barcode checking in the dispensing process.	PBA NCCTG	ACSQHC will work with key organisations
11: Consult on the options of introducing two-dimensional machine readable (QR) codes on medicines packaging.	TGA	Included in TGA review on medicines labelling and packaging
12: Develop and communicate guidance on using Tall Man lettering to reduce risk of selection errors from confusable medicine names.	ACSQHC NEHTA	ACSQHC will communicate guidance in final quarter 2011
13: Develop guidance for jurisdictions on principles of pharmaceutical purchasing for safety.	CATAG ACSQHC	ACSQHC will work with CATAG
14: Educate consumers on medicines names, label content and where to locate further information.	NPS CHF Industry	Current *Be Medicine-wise* campaign includes knowing the active ingredient name.
15: Progress consistency of medicines names used on product labels and in electronic medication management systems through use of Australian Medicines Terminology (AMT) for medicines naming.	TGA NEHTA	TGA currently liaising with NEHTA

C. Detecting and reporting problems		
16: Enhance mechanisms for consumers, organisations and health professionals to report errors and harm attributable to confusing names and labelling to a central repository so that remedial action can be taken. This would include the Adverse Medicines Line.	TGA NPS	TGA will enhance current systems for reporting adverse medicines events.
17: Collate and analyse reports from multiple sources of medication errors caused by confusing naming and labelling and review for signals.	ACSQHC TGA NPS	ACSQHC will coordinate establishment of a process with NPS and TGA
18: Develop a process for alerting jurisdictions, organisations and health professionals of potential and actual errors that have occurred. This would include suggested risk mitigation strategies such as systems changes and practice improvements.	ACSQHC TGA NPS	ACSQHC will coordinate establishment of a process with NPS and TGA

1. Introduction

Background

Issues related to the naming, labelling and packaging of medicines are long-standing in Australia as well as in overseas countries. There is sufficient evidence to suggest that the existence of similar sounding or looking medicines names contributes to medication errors. Analysis of large incident reporting systems indicate that up to 25% of reported medicines errors involved name confusion (Berman, 2004). Lists of similar medicines names that have caused medication errors are regularly published and updated by indemnity insurers and other organisations and case reports are regularly published in the literature to highlight errors caused by name confusion. Reducing errors from look-alike sound-alike medication names is one of the nine patient safety solutions developed by the World Health Organization to help reduce health care-related harm.

It is acknowledged that similarity in non-proprietary names is difficult to avoid due to Australia's general adherence to *International Non-Proprietary Names* (INN) as promoted by the World Health Organization. However, similarity in proprietary (brand) names is avoidable. In addition, inconsistency in the use of suffixes in the names of medicines causes confusion amongst health care professionals and consumers. Brand extension, and corporate naming are also cited as causes of error and the use of names in formats such as Brand Plus and Company-generic (or generic-Company) create opportunities for confusion amongst health professionals and consumers.

There has been considerable effort by numerous groups, including the Therapeutic Goods Administration of the Department of Health and Ageing (TGA), various members of the medicines industry, researchers and safety and quality organisations to improve the quality of medicines naming, labelling and packaging in Australia. Despite these efforts, concern about the contribution of naming, labelling and packaging practices to the safety and quality of medicines use is still voiced by both consumers and health care professionals. These concerns have been acknowledged by members of the medicines industry and the TGA.

It was a combination of these issues that led the Australian Commission on Safety and Quality in Health Care (the Commission) to accept the recommendation from its Medication Reference Group to convene a national round table on safer naming, labelling and packaging of medicines.

A round table on safer naming, labelling and packaging of medicines was co-hosted by the Commission and the TGA in Sydney on 24 May 2011. The aim of the round table was to develop a coordinated approach to improving medicines' naming, labelling and packaging in Australia by agreement and coordination amongst key stakeholders.

Roundtable objectives

The objectives of the roundtable were to provide a forum for clinicians, consumers, regulators and the pharmaceutical industry to:

- Consider existing issues with the naming, labelling and packaging of medicines;
- Identify potential solutions to existing issues;
- Prioritise issues and potential solutions;
- Recommend a course of work that could be undertaken, identifying those responsible for each action; and
- Agree on a governance process for any recommendations.

Participants included representatives from the National Medicines Policy Committee, NPS *Better Choices Better Health*, state/territory governments, medicines industry organisations, professional organisations, learned colleges and consumer representatives.

Scope of the discussion

The discussion focused on issues relating to manufacturers' labels. Labels applied by health care professionals such as pharmacist's dispensing labels were also recognised as a source of error and patient harm but were not included in the discussion. A separate body of work will be pursued in this area by the Commission.

Discussion was limited to prescription and non prescription (over-the-counter) medicines. Complementary medicines were excluded.

The contribution of packaging to medication error was limited to packaging as it related to product appearance. Issues related to access (child-proof packaging) and other mechanisms to enhance safety were considered outside the scope of the workshop.

Setting the scene

Participants were provided with pre-reading material which gave an overview of current initiatives relating to safe naming, labelling and packaging of medicines occurring in Australia and the gaps in current activities where additional effort is required (see Appendix 1). This was circulated in advance of the round table so that participants could contribute more fully to the round table discussions. Key stakeholders were consulted on the pre-reading material and contributed significantly to its structure and content.

To build on the pre-reading material, the round table opened with three presentations which gave perspectives on safer naming, labelling and packaging of medicines.

Consumer perspective

Participants at the round table were provided with a consumer perspective on packaging and labelling by Ms Carol Bennett, Chief Executive Officer of the Consumers' Health Forum. In her presentation *Don't Judge a Medicine by its Label: The consumer perspective on packaging and labelling* she discussed:

- Role of packaging and labelling in informing consumers on how to use a product, store it and alerting them to any risks;
- Consumer concerns about labelling with directions too small to read and difficulties in discerning the active ingredient name;
- Consumer-friendly design in packaging and labelling; and
- Consumer recommendations on safe labelling and packaging. (See Table 2)

She noted that the existence of voluntary best practice guidelines had not been effective in changing the safety of medicines labelling in Australia. The variation in the layout of the text made it difficult for consumers to understand the content of labels. Lack of prominence of the active ingredient name was a major issue from this perspective. She provided examples of two existing products with consumer-friendly labelling and packaging designs.

Ms Bennett referred to the Consumer Health Forum's 2010 report of consumer views on medicines naming, labelling and packaging issues which are provided below.

Table 2: Consumer recommendations on safe naming and labelling

1. The full name of the medicine should appear on at least three non-opposing faces of the pack to aid accurate identification of the drug.
2. Where the common name appears after the brand name, it should be given due prominence. Generally this will be determined by the relative size of the text, but other factors may be relevant, such as colour of text and the font used.
3. The critical information, such as 'directions for use', should appear in as large a font as possible to maximise legibility, on at least one face of the presentation. It should not be broken up or separated by non-critical information.
4. Adoption of innovative pack design incorporating the use of colours or symbols to help identify medicine and its intended use should be encouraged.
5. Where possible, packs should include space for the placement of the dispensing label. It is recommended that this should be a blank white space in which there is no text of any kind, to aid legibility of the dispensing label.
6. Where possible, positive statements should appear on medicines labelling to avoid ambiguity of the message.
7. Undertaking a user test to ensure the maximum clarity of the critical information is desirable and recognised as best practice.
8. Colour for the text and the font style on blister packs should be chosen carefully, as the legibility of the text on the foil is already impaired.
9. The active ingredient should be displayed in equal size and prominence as the brand name.
10. Information relating to the quantity of active ingredient per dose or unit must be displayed clearly on the packaging.
11. An independent audit of compliance with all Commonwealth legislation and regulation should be undertaken.
12. A single point of reporting for consumers to access information, report concerns and adverse effects should be established. Alternatively, the existing Adverse Medicine Event Line operated by NPS could be better promoted and used to collect data on adverse events attributable to packaging and labelling.

Safety and quality perspective

Mr Daniel Lalor, Medication Safety Project Manager at the NSW Clinical Excellence Commission, presented on current concerns and potential solutions. The current concerns were extracted from:

- Brief prepared by the NPS in 2010 for the Department of Health and Ageing on the issues of medicines naming, packaging and labelling;[1] and
- 2010 report from the Consumer's Health Forum on consumer's views on medicines labelling and packaging issues[2].

[1] NPS - Better Choices Better Health. Briefing on naming, packaging and labelling of medicines, 2011 http://www.tga.gov.au/pdf/submissions/review-tga-transparency-1101-submission-nps.pdf. Accessed 17 August 2011

[2] Consumers' Health Forum. Achieving Best Practice in the Packaging and Labelling of Medicines:Report from National Consumer Workshop. 2011. https://www.chf.org.au/pdfs/rep/rep-689 PackagingandLabellingReport-Jan11.pdf Accessed 17 August 2011

Safety and quality issues identified in these reports are listed below in Table 3.

Table 3: Safety and quality issues with current naming and labelling practice

- The existence of names that look or sound alike, causing patients to receive the wrong medicines;
- The existence of labelling that looks alike, causing patients to receive the wrong medicines;
- Ability of consumers and health professionals to identify the active ingredients on labelling (and relative prominence of trade and generic names);
- Lack of space for over-labelling (including application of pharmacy labels and warning labels);
- Consumers with difficulty reading information on medicines labels; and
- Inconsistent use of terminology and abbreviations especially when describing modified release, or combination products.

Potential solutions included

1. Pre-market review and confusability testing of names to reduce look-alike naming, labelling and packaging;
2. Improving safety of medicines labels and packaging;
3. Checking machine readable codes (barcodes) in dispensing and administration processes; and
4. Using Tall Man lettering to minimize selection errors by health professionals.

Safe labelling could be achieved by learning from research and simulation, hazard labelling and using design to reduce potential for error. The work of the Danish Society for Patient Safety, and the UK National Patient Safety Agency with the Helen Hamlyn Research Centre, were presented as positive examples of applying design principles to improve the safety of medicines labels.

Regulatory perspective

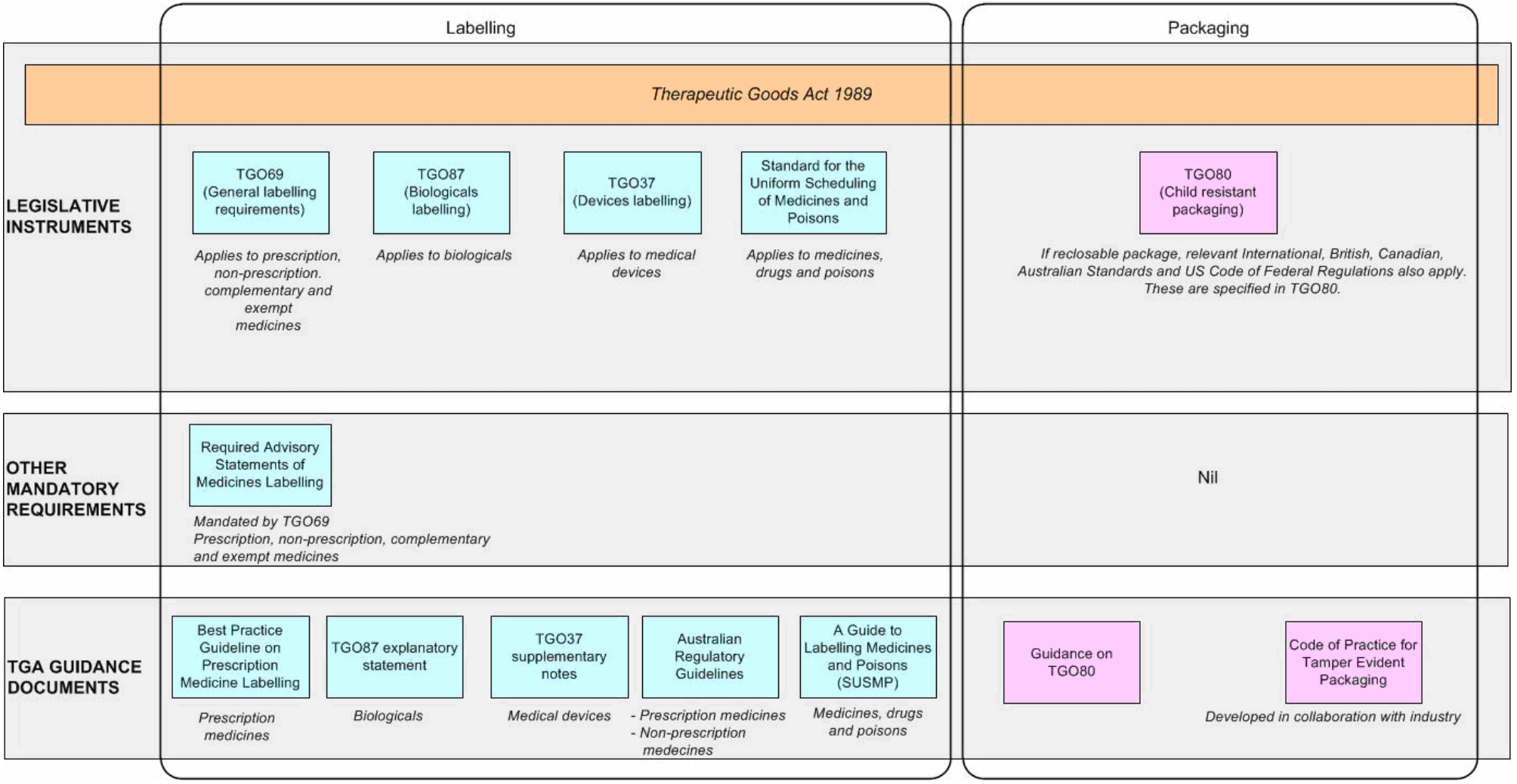
Dr Harry Rothenfluh, Office of Scientific Evaluation of the Therapeutic Goods Administration, provided an overview of the TGA labelling and packaging regulatory framework and the three levels of regulation that covered labelling and packaging (see Figure 1 overleaf).

He announced that the TGA would conduct a review of all the regulations relating to naming, packaging and labelling of prescription, non-prescription (OTC) and complementary medicines. There would be broad consultation with stakeholders throughout the review which was expected to take approximately two years.

Post meeting note: The TGA review will focus on addressing key consumer health risks identified from previous consultation and feedback from various stakeholders on labelling and packaging of medicines. In the first phase of the review an internal working group will develop a number of proposals which will be presented to an external reference group for further discussion and advice. These proposals will then be released for broader public consultation in early 2012. Feedback from that consultation will guide the revision of current labelling and packaging requirements. The recommendations from the roundtable that have been identified as the responsibility of the TGA will be addressed in the review.

Figure 1 overleaf shows the TGA Labelling and packaging regulatory framework

TGA LABELLING AND PACKAGING REGULATORY FRAMEWORK



2. Key issues

Key areas of concern identified in the pre-reading material were discussed and considered. Participants proceeded to identify priorities through discussion sessions.

Whilst it was acknowledged that there were differences in the requirements for labelling for prescription and non-prescription medicines, many of the issues were seen to be common.

2.1 Medicines naming

Look or sound alike names

Look-alike or sound-alike (LASA) names were recognised as an important contributor to medication errors.

Pre-market testing of names prior to registration, and employing a range of approaches to manage the risk of existing products with LASA names, was identified as an important strategy for reducing the risk of consumers receiving the wrong medicines.

A process was required for collecting evidence on instances of consumers receiving the wrong product as a result of LASA names and the related outcomes. This evidence should be considered in determining the need for a name change or employing risk mitigation strategies such as Tall Man lettering.

Multiple names for medicines

The existence of active ingredient and brand names for the same chemical entity was confusing for consumers. There was a need for consumers to be aware that medicines may have different names.

Inconsistent use of the International Non Proprietary Name (INN) to express the active ingredient name could result in the same medicines having different active ingredient names on the label. This was confusing for consumers and health professionals.

Importance of using the term "active ingredient"

There was confusion with the use of the term "generic" to describe the active ingredient of the product. This extended to the use of "generic brand" to describe the brand name of a non-originator product.

Umbrella branding and the use of brand extension

Product brand extension carries a risk of confusing consumers and health professionals which can create opportunities for errors and adverse events.

The current system for regulating product brand extension was not considered to be transparent nor applied consistently.

Prefixes and suffixes used in brand names

The variety of different prefixes and suffixes used in product naming was seen as a cause of confusion and potential error. This included the incorporation of a common prefix or suffix in the medicine name that included part of, or all, the manufacturer's name on a range of different products. The large range of suffixes used to describe modified release or combination products, and the lack of uniformity in terminology and abbreviations, was reported to contribute to error and cause consumers to experience difficulty in interpreting the information on medicines labels.

2.2. Labelling and packaging

Prominence of the active ingredient name

Equal prominence of the active ingredient name on labels was considered an essential requirement for safe labelling of prescription and non-prescription products and a priority for consumers. Inconspicuous active ingredient names affect the ability of consumers and health professionals to identify the medicine active ingredient(s).

Prominence included the position, colour and size of the name on the label. Consistent placement of the active ingredient name on the label/package was considered important.

Look- alike labelling (and packaging)

The use of company themed (look alike) labelling and packaging across a range of products has been reported to contribute to error and patients receiving the wrong medicines.

Inconsistent label content and layout

Inconsistent formats and placement of content on labels e.g. medicines name, prominence of active ingredient name, strength, expiry date lead to difficulties for consumers and health professionals in reading the content and checking expiry dates.

Standardization of presentation of strength

Standardising the expression of the strength of the medicine on the label would assist consumers' understanding of their medicines and reduce the risk of calculation errors and misinterpretation of strengths by health professionals. It was recommended that expression of strength be standardised, for example in oral liquid products to quantity/mL and for injections both quantity/mL and total amount/total volume in container.

Space for over-labelling

It was noted that often there is no designated space for over-labelling (including application of pharmacy dispensing labels and warning labels) on containers. This risks dispensing labels covering up information important for consumer safety such as the expiry date and batch number.

Assessing risk of labelling and packaging changes

When manufacturers make a labelling or packaging change there is a risk that the change may lead to confusion with another product on the market, especially if the label or packaging is similar and products are stored adjacent to one another on the pharmacy or ward shelves.

A risk assessment should be undertaken when packaging changes are made and the consequences of the change considered prior to release of the product.

2.3. Detecting and reporting problems

Mechanisms for notifying the relevant authorities about naming, labelling or packaging issues

There was a lack of clarity around processes for consumers, health professionals and organisations (e.g. professional indemnity organisations, health departments) to report issues with the naming, labelling or packaging of medicines and how the reporting may provoke remedial action. This was considered a serious gap.

There are multiple methods of reporting medication errors and adverse events that may be attributed to confusion with medicines naming and labelling. These include hospital incident systems, the consumers Adverse Drug Event telephone line, the TGA adverse drug reaction reporting system and professional indemnity organisations. None of these systems are linked and individuals and organisations alerted to problems do not know where to report. There is also no established mechanism for informing those responsible for instigating changes.

2.4 Priority issues

Naming

- Pre-market testing of names prior to registration to reduce risks from LASA names;
- Clinical risk assessment of LASA names;
- Active ingredient and brand names for same medicine;
- Standardising naming;
    - Uniform use of term “active ingredient”;
    - Standard terminology and abbreviations for describing modified release and combination products;
- Implementing strategies to manage the risk of products with LASA names;
- Health literacy and consumer awareness of medicine names.

Labelling and packaging

- Equal prominence of active ingredient name on the label;
- Umbrella branding and brand extension;
- Risk assessment of labelling and packaging;
    - Prior to registration;
    - Post marketing following a change in labelling, packaging;
- Availability of tools for industry to undertake risk assessments;
- Standard and consistent labelling:
    - Standard placement of the active ingredient name;
    - Standard presentation of the unit of measure/strength;
    - Standard placement of warning information;
    - Consistent use of INN as active ingredient name;
    - Inclusion of space for over-labelling with pharmacy dispensing labels and warning labels;
    - Use of symbols to assist consumers interpret label content;
- Safe design of medicines labelling and packaging.

Detecting and reporting problems

- Quantifying the contribution of LASA names and poorly designed labelling and packaging in causing errors and patient harm;
- Developing a mechanism for notifying the relevant authorities about naming, labelling or packaging issues.

3. Potential solutions

Unsafe naming, labelling and packaging is a multifactorial problem and potentially present throughout the pharmaceutical supply chain from manufacturing, at point of prescribing and dispensing through to administration by health care professionals and consumption by the consumer.[1] Any approach to reducing the risks associated with medicines naming, labelling and packaging in Australia therefore needs to be multifaceted and involve a number of organisations and players from a range of disciplines.

Reducing the use of look-alike sound-alike (LASA) names and improving the content and design of labels should be major components of any strategy to improve the safety of medicines naming, labelling and packaging. Other interventions can also contribute to overall risk reduction such as the use of bar-code verification in the medication management pathway and the use of Tall Man lettering in electronic prescribing, dispensing and administration systems. These strategies should be part of a national, multifaceted approach to reducing the risks associated with confusable medicine names and labels.

It is recognised that a considerable amount of work has already occurred in Australia to identify problems in medicines naming, labelling and packaging as well as potential solutions. The results of these consultations should be used along with and international evidence to inform any national approach to minimizing error and patient harm.

The TGA's *Review of Labelling and Packaging* will be an opportunity to introduce changes to improve the safety of medicines naming, labelling and packaging. However it is not necessary for change to be driven by regulation alone. Provided there is clear guidance on the requirements for medicines naming and labelling, there is no reason why the pharmaceutical industry cannot use self-regulation to introduce best practice in medicines naming and labelling in Australia. Indeed, industry participants at the round table urged other participants to ensure a safe and predictable framework for naming, labelling and packaging against which they could test products prior to formal regulatory assessment.

It was acknowledged that there was a cost to manufacturers in making changes to labelling and any changes would require a regulatory impact statement. To minimise the cost to industry, any reform should be a one step process rather than piecemeal changes.

The potential solutions to the problems identified as priority issues in Section 2 are divided into two groups:

1. Pre-marketing solutions

- Pre-market assessment prior to registration of the product to identify potential problems with confusing naming and labelling; and
- Strategies to manage any risks identified during the assessment.

2. Post marketing solutions

- Strategies to mange risks identified after the product is on the market.

1. Aronson JK. Medication errors: What are they, how do they happen and how to avoid them. *Quarterly Journal of Medicine.* 2009;102:513-521.

3.1 Pre-marketing solutions

Medicines naming

Pre-market testing of names prior to registration can be used to identify LASA names. An alternative name can be used if risk of confusion is likely to cause harm.

While sponsors have the flexibility to use an alternative brand name, this is not the case for non-proprietary names. When names cannot be changed, such as INNs, a clinical risk assessment should be used to identify the potential for confusion and the likely severity of the outcome. Where this is high, strategies should be put in place to mitigate the risk. These are discussed in section 3.2.

Screening for look-alike, sound-alike names

LASA names can be identified through computer programs designed to identify names that look or sound similar. Such systems are used by regulators overseas.

When similar proprietary names are found and determined to pose a risk to patient safety e.g. the clinical context of the use of two products is similar and the risk of harm from confusion of the products is high an alternative name should be used.

Recommendation 1: Consider screening all medicines names to identify look-alike, sound-alike medicines names using a computerised system. An alternative name should be used when similar proprietary names are identified and the risk of harm from confusion of the products is high.

Organisation responsible: TGA

The screening tool could be used by sponsors as well as the TGA as part of their product assessment process.

Risk assessment of similar names

A clinical risk assessment should be part of the label approval process when potentially confusable names are used. This should include an estimate of the severity of the outcome if two products with similar names are confused. This would apply to proprietary and active ingredient names.

A standard process should be used as, for example, the model used by the FDA where the risk assessment is completed by the pharmaceutical manufacturer during product development.

Risk assessment could be conducted by the TGA or standard risk assessment tools could be used by product sponsors during product development.

Where the clinical risk of using potentially confusable names is considered justifiable, or where there is similarity amongst non proprietary names, risk mitigation strategies should be employed to reduce the risk of error. This may include the use of distinctive labelling. Distinctive labelling must comply with labelling standards to avoid variability in labelling that could have unintended consequences.

Recommendation 2: Develop guiding principles for clinical safety assessment of confusable medicines names, both brand and active ingredient. The principles should include the use of prospective risk assessment tools. Distinctive product labeling that complies with labeling standards should be used to differentiate products when potentially confusable names are identified d.

Organisation responsible: TGA, Industry

Product brand extension and umbrella labelling

Product brand extension and umbrella labelling are cited as causes of error and confusion amongst health professionals and consumers. The current system for approving brand extension names was not considered robust or transparent.

Recommendation 3: Undertake a review of brand extension regulations to ensure that safety and quality concerns are addressed. Include elements of the TGA's *Best Practice Guideline on Prescription Medicine Labelling* relating to brand extension or corporate naming within the labelling order.

Organisation responsible: TGA

Labelling and packaging

Prominence of active ingredient name

Equal prominence of the active ingredient name on labels was considered an essential requirement for safe labelling of prescription and non-prescription products and a priority for consumers. Prominence includes the position, colour and size of the name on the label as well as consistent placement of the active ingredient name on the label/package.

Recommendation 4: Include a requirement for equal prominence of active ingredient name on medicines labels within the labelling order.

Organisation responsible: TGA

Labelling standards

Standards for labelling need to include requirements for consistency in the content as well as the layout.

Common errors could be reduced through adopting a standard format for labels in which there was consistent naming, active ingredient name prominence, expression of strength and content placement.

A fundamental review of the *Best Practice Guideline on Prescription Medicine Labelling* was required and elements included in the labelling order.

International work on design of medicine labels, such as the UK National Patient Safety Agency and the Helen Hamlyn Research Centre Principles for Designing Medicines Labels and the work of the Danish Society for Patient Safety, should be used to inform Australian standards for medicines labelling following validation in the Australian setting.

Recommendation 5: Review the TGA's *Best Practice Guideline on Prescription Medicine Labelling.* Develop standards for content and design of labelling that consider international work on medicines labels design and mandate elements within the labelling order.

Organisation responsible: TGA

Standard for consistent labelling would include:

- Prominence and placement of the active ingredient name;
- Standard presentation of the unit of measure/strength;
- Standard placement of warning information;
- Consistent use of INN as active ingredient name;
- Inclusion of space for over-labelling with pharmacy dispensing labels and warning labels;
- Use of symbols to assist consumers interpret the label content.

The development of a new standard for medicines labelling requires broad consultation.

It was recognised that making changes to standard labelling requirements entailed a significant cost to industry. Labelling standards need to:

- Provide clarity on labelling requirements;
- Be consistently applied;
- Have universal applicability;
- Require a transition period for introduction; and
- Be implemented as a single reform and not in a piecemeal approach.

It is important that Australia remains aware of any overseas activity to improve the safety of medicines naming and labelling.

Recommendation 6: The Commission will maintain links with the *International Medication Safety Network* to learn of international activity on improving the safety of medicines naming and labelling.

Organisation responsible: ACSQHC

Clinical safety assessment

Using health care professionals and consumers to identify look-alike packaging before products are approved for registration occurs in other countries. A nationally consistent evaluation process for risk assessment of naming, labelling and packaging is required to address concerns of any subjectivity in the assessment. There are cost implications for industry to be considered.

Recommendation 7: Develop guiding principles for clinical safety assessment of labelling and packaging.

Organisation responsible: TGA

Recommendation 8: Investigate technical solutions to identifying look a-like packaging prior to product registration. Such solutions should be validated by health professionals and consumers to demonstrate equivalence to user-testing by health care professionals and consumers prior to their introduction. This could include future research into the feasibility of an electronic system to screen proposed label designs against existing labels.

Organisation responsible: TGA, NPS, NMP Committee, NHMRC

3.2 Post marketing solutions

If risks to patient safety are identified after products have been approved for use and are available on the Australian market, other approaches are required to reduce the risk of the wrong medicines being prescribed, dispensed or administered. These solutions are generally aimed at reducing errors by introducing systems that minimise reliability on human abilities. Such solutions need to be tested and evaluated prior to implementation. They may have practice implications for health practitioners that need to be taken into account when introducing systems changes.

Systems solutions currently available include:

- Barcode verification in dispensing and administration processes
- Use of Tall Man lettering; and
- Purchasing for safety policies.

Barcode verification

Barcode verification of the medicine against the medicine prescription is considered an important strategy to reduce patient harm from medication selection errors.

Barcode checking has been shown to reduce the risk of wrong medicines, wrong dose, wrong form and wrong route errors in dispensing and in medicines administration processes in hospitals.

The Pharmacy Board of Australia requires pharmacists to use barcode scanners when dispensing medicines in pharmacies and pharmacy departments.

Recommendation 9: Set standards that require the use of machine readable code (barcode) readers by health professionals selecting medicines for dispensing and administering.

Organisations responsible: Health professional national councils/boards

Recommendation 10: Obtain uniformity of state and territory requirements for the use of barcode checking in the dispensing process.

Organisations responsible: Pharmacy Board of Australia, NCCTG

Two dimensional machine readable codes such as quick response (QR) codes offer benefits over one dimensional linear codes and should be considered for use on medicines labels. Use of them is not restricted by the space constraints of a linear code and they have greater readability.

QR codes can be linked to trusted sources of information and, in the future, could be used by consumers and health professionals to source information such as consumer medicines information or product information through technology such as an application on a “smart phone”.

Recommendation 11: Consult on the option of introducing two dimensional machine readable (QR) codes on medicines packaging.

Organisation responsible: TGA

Tall Man lettering and other techniques

Tall Man lettering, and other techniques, should be used to reduce the risk of the wrong product being selected by assisting health practitioners differentiate look a-like and sound a-like names. Guidance was required on the use of Tall Man lettering within technology and other areas such as pharmacy or hospital ward shelves to maximise its benefits.

This would include the education of health professionals on the role of Tall Man lettering in reducing risk of wrong product selection and in judicious use of Tall Man Lettering to ensure its effectiveness.

Recommendation 12: Develop and communicate guidance on using Tall Man lettering to reduce risk of selection errors from confusable medicine names.

Organisations responsible: ACSQHC, NEHTA

Purchasing for safety

Most jurisdictions have centralised tendering processes for pharmaceuticals used in public hospitals. Several jurisdictions include an assessment of the safety of labelling and packaging of products within their purchasing policies to reduce the risk of harm from unsafe product labelling. All states and territories should be encouraged to "purchase for safety" and to coordinate their efforts to maximise purchasing power against unsafe products.

Recommendation 13: Develop guidance for jurisdictions on principles for purchasing for safety in pharmaceutical purchasing.

Organisation responsible: Council of Australian Therapeutic Advisory Groups, ACSQHC

Consumer education

Improving health literacy about medicines labelling and medicines having different names is an important strategy for reducing risk of harm to consumers from confusing naming and labelling. The NPS is currently conducting the *Be Medicinewise* consumer campaign educating consumers to know the active ingredient name of their medicines and where to find the active ingredient name on the package/label.

Recommendation 14: Educate consumers on medicines names and label content and where to locate further information.

Organisation responsible: NPS, CHF manufacturers

This could be done through social marketing as well as placing text on the label on where to obtain further medicines information.

Additional information, such as Consumer Medicines Information, could also be supplied through machine readable (QR) codes on the medicines label and accessed through technology such as "smart phones".

Medicines terminology in electronic medication management systems

There is need for consistency in medicines terminology used in electronic medication management systems (i.e. electronic systems used for prescribing, dispensing and documenting administration of medicines) and the medicine name on the product label. Australian Medicines Terminology (AMT) is the preferred terminology for electronic medication management systems.

Recommendation 15: Progress consistency of medicines names used on product labels and in electronic medication management systems by using the Australian Medicines Terminology (AMT) for medicines naming.

Organisations responsible: TGA, NEHTA

4. Detecting and reporting problems

Currently there is no national authority to report incidents or errors attributed to confusing naming, labelling or packaging. This is so in relation to incident or error reporting by public and private hospitals, state and territory health departments, professional indemnity organisations and individuals (including consumers). The result is that there is no accurate way of quantifying the contribution of LASA names and poorly designed labelling and packaging to errors and patient harm in Australia or of identifying remedial action that is required. This is a major gap in national medication safety and quality.

Mechanism for reporting errors caused by confusing names and labelling

A mechanism is required for consumers, organisations and individual health professionals to report medication errors and adverse events associated with LASA names or confusing or inadequate labelling and packaging to a central database.

The system should be user friendly (such as a standard reporting template) to encourage consumers and health professionals to report.

Recommendation 16: Enhance mechanisms for consumers, organisations and health professionals to report errors and harm attributable to confusing names and labelling to a central repository so that remedial action can be taken. This would include the consumers' Adverse Medicines Line.

Organisation responsible: TGA

Addressing reports of errors caused by confusing naming and labelling

A national, coordinated approach to reviewing reports of errors attributed to confusing naming and labelling is required in order to identify signals and to respond with remedial action.

Recommendation 17: Collate and analyse reports of medication errors from confusing naming and labelling from multiple sources and review for signals.

Organisation responsible: ACSQHC, TGA, NPS

Recommendation 18: Develop a process for alerting jurisdictions, organisations and health professionals across the health sector of potential and actual errors that have occurred. This would include suggested risk mitigation strategies such as systems changes and practice improvements.

Organisations responsible: ACSQHC, TGA, NPS

5. Follow up actions

The Commission and the TGA undertook to review the recommendations and work with the round table participants to develop a national approach to reducing the risk of confusing naming and labelling contributing to patient harm.

Appendix 1

Australian Government
Department of Health and Ageing
Therapeutic Goods Administration

AUSTRALIAN COMMISSION
ON SAFETY AND QUALITY IN HEALTH CARE

National Round Table on Safer Naming, Labelling and Packaging of Medicines

24 May 2011

Pre-reading material

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Introduction

The Australian Commission on Safety and Quality in Health Care (the Commission) and the Therapeutic Goods Administration (TGA) are jointly conducting a national roundtable on the safe naming, labelling and packaging of medicines on 24 May 2011 in Sydney.

The aim of the roundtable is to improve patient safety in relation to medicines' naming, labelling and packaging through agreement and coordination amongst key stakeholders. Invitees include the National Medicines Policy Committee, the NPS, medicines industry organisations, professional organisations, learned colleges and consumer representatives.

The roundtable will provide an overview of current initiatives relating to safe naming, labelling and packaging of medicines occurring in Australia and the gaps in current activities where additional effort is required. Participants will be asked to identify and agree on the top priorities and potential projects to address these gaps, as well as identify and obtain agreement from key stakeholders with the capacity to undertake elements of the work identified.

Pre-reading material

Roundtable participants are requested to read this pre-reading material prior to attending the roundtable. The material includes background documents and an overview of the TGA's labelling and packaging regulatory framework.
This document has been circulated in advance of roundtable to enable participants to contribute to the content of the discussions to be held on the day, and where appropriate, to consult with key stakeholders within their organisations and networks about the content of the paper and proposed discussions.

Feedback on the background documents
Participants are encouraged to provide feedback on the background documents are and requested to:

1. Indicate whether if any major issues regarding the contribution of medicines naming, labelling and packaging to patient safety and quality use of medicines have been omitted.
2. Identify any work that has been done, or is currently being done, that may address any of the issues raised and that has not been mentioned and that should be considered in the roundtable discussions.
3. Identify any other issues that should be discussed at the roundtable.

Any feedback should be sent to Justine Marshall at Justine.Marshall@safetyandquality.gov.au by 20th May 2011.

Safe Labelling and Packaging of Medicines Roundtable

Background Documents

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Background

Issues related to the naming, labelling and packaging of medicines are long-standing. There have been considerable efforts may by numerous groups, including the Therapeutic Goods Administration (TGA), various members of the medicines industry, researchers and safety and quality organisations to improve the quality of medicines naming, labelling and packaging in Australia. Despite these efforts, concern around the contribution of naming, labelling and packaging practices to the safety and quality of medicines use is still voiced by both consumers and health care professionals. These concerns have been acknowledged by members of the medicines industry and the TGA.

This roundtable discussion has been convened to provide a forum for clinicians, consumers, regulators, and the industry to:

- Discuss existing issues with the naming, labelling and packaging of medicines;
- Identify potential solutions to existing issues;
- Prioritise issues and potential solutions;
- Recommend a course of work that could be undertaken, identifying those responsible for each action; and
- Agree on a governance process for any recommendations.

Purpose

The purpose of this document is to provide a summary of issues related to the naming, packaging and labelling of medicines, without duplicating work that has previously been completed. This document will aim to provide a synopsis of the key issues and in naming, labelling and packaging, and present some key work that has been done in the field.

It is intended that by providing this information in advance of the roundtable discussion, extensive periods of time will not need to be spent establishing what problems exist with naming, labelling and packaging. In addition, the document is intended to highlight work, past or planned, that aims to address some of the identified issues.

This document, and the associated discussion, will focus on issues relating to manufacturers' labels rather than those applied by health care professionals. Whilst it is acknowledged that the quality of labels applied by health care professionals is variable and can have a significant impact on the quality use of medicines, these issues are separate to those related to manufacturers' labels. A separate body of work will be pursued in this area. Additionally, the concept of packaging, as it relates to functions beyond product appearance, will not be extensively explored. Issues related to access (child-proof packaging) and other mechanisms to enhance safety are acknowledged, but are outside of the scope of this discussion.

Problem Statement

During 2010, the NPS prepared a brief for the Department of Health and Ageing on the issues of medicines naming, packaging and labelling. This briefing compiled qualitative and quantitative data as well as anecdotal reports on issues related to the naming, packaging and labelling of medicines. This briefing paper can be seen at http://www.tga.gov.au/pdf/consult/tga-transparency-review-submission-1012-

nps.PDF as part of the NPS response to the review to improve transparency of the TGA . The paper provides a good overview of issues from the perspective of both the consumer and the health care practitioner.

NPS also commissioned a report from Consumer's Health Forum (CHF) who convened a national workshop to determine consumer's views on medicines labelling and packaging issues. The CHF report can be seen here https://www.chf.org.au/pdfs/rep/rep-689-PackagingandLabellingReport-Jan11.pdf.

Key areas of concern extracted from these two documents are:

- The existence of names that look or sound alike, causing patients to receive the wrong medicines;
- The existence of labelling that looks alike, causing patients to receive the wrong medicines;
- Ability of consumers and health professionals to identify the active ingredients on labelling (prominence of generic name);
- Lack of space for over-labelling (including application of pharmacy labels and warning labels);
- Consumers experiencing difficulty in reading information on medicines labels; and
- Inconsistent use of terminology and abbreviations especially when describing modified release, or combination products.

Naming Medicines

There is sufficient evidence to suggest that the existence of similar sounding or looking medicines names contributes to medication errors. Regular case reports in the literature highlight errors caused by name confusion, lists of similar medicines names are regularly published and updated by indemnity insurers and other organisations and analysis of large incident reporting systems in indicate that up to 25% of reported medicines errors involved name confusion (data from the United States Pharmacopoeia, see Berman, 2004). Reducing errors from look-alike sound-alike medication names is one of the nine patient safety solutions developed by the World Health Organisation to help reduce the toll of health care-related harm. It is acknowledged that similarity in non-proprietary names is difficult to avoid due to Australia's general adherence to International Non-proprietary Names (INN) as promoted by the World Health Organisation. However, similarity in proprietary (brand) names is avoidable. In addition, inconsistency in the use of suffixes in the names of medicines causes confusion amongst health care professionals and consumers. Brand extension, and corporate naming are also cited as causes of error. The use of names in formats such as Brand Plus and Company – generic (or generic-Company) create opportunities for confusion amongst health care professionals and consumers.

Work to date

The *Best Practice Guidelines on the Naming and Labelling of Medicines* produced by the Therapeutic Goods Administration (TGA) state that names should be distinct from other names and that user testing, computerised screening and hand-writing analysis should be conducted by companies when selecting names. .

These guidelines are not mandatory and there is no standard process defined for the conducting of these tests by industry. There is also no standardised tool provided for the electronic screening of medicines names and there continues to be products introduced onto the Australian market that have similar names.

In Canada and the United States of America, there has been a move to standardise the process of name assessment. Medicines regulators in both countries use a computer program (Phonetic Orthographic Computerised Assessment – POCA) to screen proposed names against names of medicines already in use. Both jurisdictions also make this software available to medicines industry to allow them to identify issues early in the name development process. Transparency of process had previously been an issue for the industry. In addition to computerised assessment, the Federal Drug Administration (FDA) is trialling a standardised process of user testing. Under this model, the FDA has outlined what it believes to be best practice in the testing of proposed proprietary names. Product sponsors are encouraged to complete this testing and send the results to the FDA as part of their product submission process. In this way, it is hoped, product review by the FDA will be streamlined, consistent assessment will be done across the industry and transparent decision making processes will be applied by the FDA.

Other aspects of the best practice guidelines on the naming and labelling of medicines discourage the use of umbrella branding and brand extension. The guidelines also make mention of the use of suffixes.

Potential solutions

Identification of look-alike, sound-alike medicines names during the product assessment process could be conducted using a computerised system, potentially that of the FDA/Health Canada (work under investigation by the TGA).

Where similar proprietary names are found and determined to pose a risk to patient safety, alternative names should be chosen by the product sponsor. Where clinical risk is felt to be justifiable, risk mitigation strategies, such as distinctive product labelling, should be used.

Where similarity exists between non-proprietary names, a clinical risk assessment should be undertaken. Risk mitigation strategies such as the use of distinctive labelling could be considered at this point. Risk assessment processes could either be conducted by the TGA as part of their assessment processes, or standard risk assessment tools could be used by product sponsors during product development. Known risk management tools such as Failure Mode Effects Analysis or other prospective risk assessment tools could be applied.

Where risks to patient safety have been identified after products have already been approved for use and are available on the Australian market, other solutions are necessary. Considerable evidence has been collected to support the use of barcode verification in dispensing and administration processes and there is evidence to support the use of techniques such as Tall Man lettering to help differentiate these similar names.

It needs to be determined whether any elements of the best practice guidelines related to brand extension or corporate naming should be included in the labelling order and, if so, what a reasonable position would be.

Labelling Medicines

A number of issues have previously been identified with medicines labelling. Such things as creation of corporate look for a range of products, leading to confusion, the prominence of brand versus generic name, and the choice of font sizes and the readability of information presented have been identified as barriers to the quality use of medicines. The same data stating that approximately a quarter of medication errors relate to name states that labelling issues contribute to a third of medication errors (data from the United States Pharmacopoeia, see Berman, 2004). Some Australian data from incident reporting systems and professional indemnity insurers has shown that significant errors are caused by issues with medicines labelling.

Work to date

The TGA *Best Practice Guideline on Prescription Medicine Labelling* addresses many of these issues and describes how individual elements of a medicines label should be constructed. These guidelines highlight many of the problems that exist with medicines labelling and provide guidance for how they can be avoided.

The National Patient Safety Agency (NPSA) in the UK move beyond simply providing a set of statements about what information should be included on a medicines label and how it should be presented. The NPSA have worked with the Helen Hamlyn Research Centre (Royal College of Art, London) to produce design guides for medicines labels. These guides (one for general medicines, one for injectable medicines and one for dispensing labels) provide guidance on, and examples of, the use of colour, fonts and the layout of information required on medicines labels.

The Danish Society for Patient Safety has also undertaken a body of work around improving the design of medicines labelling. In 2007, the organisation opened a competition for the design of medicines labelled that could reduce error by reducing similarities between medicines names and labels. A new design of labels was chosen and applied to products manufactured by the government owned pharmaceutical supplier providing medicines to Danish hospitals (http://patientsikkerhed.dk/fileadmin/user_upload/documents/Sikker_medicinering/Amgros_Pres_ENG_long.pdf) .

Identification of products through barcode scanning is viewed as a highly effective mechanism for preventing medication errors. The vast majority of medicines carry a barcode. This should be universal. Barcodes are often present only at the original pack level. GTIN numbers needs to be allocated down to unit of use level if the benefits of using barcode checking throughout the pharmaceutical chain in hospitals to the individual patient level. It is also timely to review the information carried within that barcode. For the purposes of product recall or pharmacovigilance, tracking batches of particular medicines may be desirable.

Purchasing for safety has also become a focus for a number of state health departments. The quality of medicines labelling and packaging has been a consideration in the assessment of tenders for recent state pharmaceutical contracts. This move provides a financial incentive for industry to produce labels that are perceived as contributing to the safe and quality use of medicines. However the practice of purchasing for safety is not uniformly implemented in all jurisdictions and there is no national guidance available on the safety issues that need to be considered when purchasing medicines.

Potential solutions

It is possible that key elements of the *Best Practice Guideline on Prescription Medicine Labelling* could reasonably be moved into the labelling order.

The work of the NPSA and the Helen Hamlyn Research Centre in outlining the design principles that should be employed when designing medicines labels could be adopted or adapted for use in Australia. The principles contained within these documents are already largely supported by the *Best Practice Guideline on Prescription Medicine Labelling* and could be included in the labelling order where appropriate. In the same way as the Danish Society for Patient Safety engaged the design industry, it may be possible to engage local design firms in work to improve medicines labels.

Given the extensive number of products on the market, similarity between packaging of products made by different manufacturers remains a possibility. By engaging health care professionals in the labelling assessment process, it may be possible to identify look-alike packaging before product labels are approved. Additional research should be considered on whether there is the potential to create an electronic system similar to that used for name assessment that could screen proposed label designs against existing labels to detect look-alike products.

Detecting and Reporting Problems

Detection or quantification of issues related to the naming, labelling or packaging of medicines has proved difficult. There has been no standardised method developed that can detect the number of errors or incidents that relate to the medicines naming, labelling or packaging. Spontaneous reporting systems do exist and provide the little evidence that we currently have on issues related naming, labelling or packaging in Australia.

All jurisdictions in Australia now support and encourage the use of incident reporting systems to collect data related to health care related errors and incidents. Data collected using these systems, however, is generally related only to issues with care provided by public health systems, and is largely related to in-hospital care. The reporting systems used across Australia are non-uniform and the systems are generally not suitable for extracting aggregate data related to incidents related to naming, labelling or packing of medicines. When issues are identified in these state-based systems, there is no clear mechanism for reporting these to pharmaceutical industry, the TGA or other Commonwealth agencies as appropriate.

Similar systems are coordinated by professional indemnity insurers who collect information about incidents and errors made by their members. These organisations face similar difficulties in notifying the relevant authorities about issues that may exist with naming, labelling or packaging of medicines.

The deficiency of the current system has been highlighted by recent issues related to Coversyl and Coumadin. Anecdotally, pharmacists have complained about the similarities in the labelling and packaging of these products for some time. Additionally, a number of significant incidents have been identified due to hospitalisation of patients inadvertently warfarinised. The absence of a standardised mechanism for reporting these issues contributed to a significant delay in remedial action to address this labelling and packaging similarity.

To date, there is no mechanism for members of the public to raise issues related to errors in their care that may have been caused by medicines naming, labelling or packaging.

Whilst data from voluntary reporting systems do not allow for quantification of error rates, they provide a mechanism for flagging potential issues with products. Mechanisms for collecting this data at a national level should be investigated as should the process of alerting health professionals of potential and actual errors that have occurred. This could also include suggested risk mitigation strategies.

Special Notes on Non-Prescription Medicines

It is acknowledged that issues related to naming, labelling and packaging are not identical in the prescription and non-prescription medicine industries. It is also acknowledged that there have been considerable efforts made in the self medication industry to improve the quality of medicines labelling. An industry-wide move to outcome or performance based labelling (whereby label effectiveness is assessed against the ability of consumers to interpret the information presented on the label), supported through the development of guidelines and an education program has been a move toward improved labelling.

The outstanding issues for the self medication industry include the potential for product labelling and packaging to look similar both within and across brands and the potential for look-alike and sound-alike names to cause confusion between products.

Other Potential Issues

There is an increasing effort to standardise the way in which medicines are described, particularly in terms of electronic systems. The main body of work in this field has been conducted by NEHTA and is based on a need to have a common language between information systems when communicating electronically. However, there needs to be a clear link made between what standards are used by NEHTA and others and what manufacturers include on their labelling.

Inconsistencies between nomenclature or format of drug names or dose expressions and product labelling are thought to be a contributor to medication errors due to difficulties in reconciling information from electronic systems to that present on physical products. Discussion may need to be had between industry, NEHTA and others about conventions used. The evidence used to inform NEHTA about how best to present such information should be also be applied by industry in constructing labels.

Planned Activity

There is ongoing work in Australia at various levels . to improve naming, labelling and packaging of medicines and reduce the risk of confusion and patient harm

1. The TGA is undertaking a review of labelling issues. Information related to this will be provided by the TGA.
2. The NPS Be Medicinewise campaign will be a major consumer education campaign. Key objectives of the campaign will include educating consumers on;
    a. Knowing their medicines; and
    b. Being able to interpret medicines labels to identify the active ingredient.
3. The Australian Commission on Safety and Quality in Health is preparing a standard list of medicines names in Tall Man lettering.
4. Procurement initiatives in various states.

Recommended Reading

The NPS briefing on naming, packaging and labelling of medicines
http://www.tga.gov.au/pdf/consult/tga-transparency-review-submission-1012-nps.PDF

Consumers Health Form, Achieving Best Practice in the Packaging and Labelling of Medicines: Report from the National Consumer Workshop
https://www.chf.org.au/pdfs/rep/rep-689-PackagingandLabellingReport-Jan11.pdf

Lambert BL, Lin SJ, Tan HK. Designing Safe Drug Names. Drug Safety, 2006; 28(6):495-512.
http://tigger.uic.edu/~lambertb/journal_art/Designing.pdf

NPSA in collaboration with the Helen Hamlyn Centre, Royal College of Art: *A guide to the graphic design of medication packaging* (second edition) (2007)
http://www.nrls.npsa.nhs.uk/resources/collections/design-for-patient-safety/?entryid45=63053

NPSA in collaboration with the Helen Hamlyn Centre, Royal College of Art: *A guide to labelling and packaging of injectable medicines* (first edition) (2008)
http://www.nrls.npsa.nhs.uk/resources/?entryid45=59831 1. NPS - Better Choices Better Health. Briefing on naming, packaging and labelling of medicines, 2011.

Berman A. Reducing Medication Errors Through Naming, Labelling, and Packaging. J Med Syst 2004;28:9-29.

WHO Collaborating centre for Patient Safety Solutions. Look - alike Sound - alike medication names. Patient Safety Solutions , Volume 1, Solution 1, May 2007.
http://www.who.int/patientsafety/solutions/patientsafety/PS-Solution1.pdf

TGA Best practice guideline on prescription medicine labelling
http://www.tga.gov.au/industry/labelling-pm-best-practice.htm

Attachment 1

TGA labelling and packaging regulatory framework

Australian Government
Department of Health and Ageing
Therapeutic Goods Administration

TGA labelling and packaging regulatory framework

May 2011

TGA Health Safety Regulation

About the Therapeutic Goods Administration (TGA)

- The TGA is a division of the Australian Government Department of Health and Ageing, and is responsible for regulating medicines and medical devices.
- TGA administers the *Therapeutic Goods Act 1989* (the Act), applying a risk management approach designed to ensure therapeutic goods supplied in Australia meet acceptable standards of quality, safety and efficacy (performance), when necessary.
- The work of the TGA is based on applying scientific and clinical expertise to decision-making, to ensure that the benefits to consumers outweigh any risks associated with the use of medicines and medical devices.
- The TGA relies on the public, healthcare professionals and industry to report problems with medicines or medical devices. TGA investigates reports received by it to determine any necessary regulatory action.
- To report a problem with a medicine or medical device, please see the information on the TGA website.

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TGA labelling and packaging regulatory framework

The legislative framework

Legal requirements

The *Therapeutic Goods Act 1989* (the Act) specifies that therapeutic goods must not be imported, supplied or exported if they do not meet applicable standards. A number of Therapeutic Goods Orders (Orders) specify standards relating to the labelling and packaging of therapeutic goods (see Attachment 1).

The *Standard for the Uniform Scheduling of Drugs and Poisons* (the Poisons Standard) is also adopted by state and territory legislation in relation to poisons labelling and other Commonwealth regulatory authorities, such as the Office of Chemical Safety. In relation to the regulation of therapeutic goods, the Poisons Standard applies to decisions about whether a medicine should be listed or registered on the Australian Register of Therapeutic Goods (ARTG) and decisions relating to the advertising code.

The *Required Advisory Statements for Medicine Labels* (RASML) document was developed to enable the transfer of all mandatory label advisory statements from the *Standard for the Uniform Scheduling of Drugs and Poisons* (SUSDP) and the Therapeutic Goods Regulations 1990 (the Regulations) to a new document, separate from but linked to *TGO 69 – General requirements for labels for medicines* (the Labelling Order).

The Labelling Order makes it mandatory for medicine labels to include any label advisory statements specified in RASML. By physically separating the documents, the advisory statements can be updated at regular intervals to reflect decisions of the Advisory Committee on Medicines Scheduling, without issuing an entirely new Labelling Order each time.

Guidance documents and codes of practice

The TGA, as a Commonwealth regulatory authority has an obligation to provide explanatory material to assist the regulated community in understanding their legal obligations. Each legislative instrument therefore has an associated guidance or explanatory document.

As a result of the tampering crises in the consumer medicines industry in 2000, the Therapeutic Goods Administration (TGA) established an Industry Government Crisis Management Committee (IGCMC). This Committee developed strategies aimed at preventing, or minimising the effect of, similar occurrences in the future. This included the development of an industry code of practice that sets out the requirements for tamper evident packaging, the *Code of Practice for the Tamper-Evident Packaging of Therapeutic Goods* (the TEP Code of Practice). This code of practice was adopted on a voluntary basis by the Australian Self Medication Industry Association (ASMI), Medicines Australia (MA), the Complementary Healthcare Council (CHC) and the Medical Industry Association of Australia (MIAA) in December 2000.

The TGA also provides detailed information to sponsors in relation to applications to register a therapeutic good on the ARTG. In the case of prescription medicines, this includes the Australian Regulatory Guidelines for Prescription Medicines and detailed instructions about information that must be included in the common technical document (CTD). A CTD is an internationally harmonised application package to register a therapeutic good on the ARTG. This facilitates the preparation of preclinical pharmacology and clinical data in a format that can be submitted to therapeutic goods regulators around the world. Module 1 of the CTD requires a sponsor to supply information elements that reflect local legislative requirements. In Australia, this is where specific labelling and packaging information is provided. Detailed guidance about labelling and packaging requirements, in addition to the guidance documents shown in Attachment 1, is provided by on the TGA internet site (http://www.tga.gov.au/pdf/pm-ctd-module1-1101.pdf).

TGA regulation of product labelling and packaging

Pre-market regulatory processes

The TGA pre-market evaluation process includes an assessment of the product against mandatory labelling and packaging requirements and those requirements documented in the TEP Code of Practice. Evaluators provide their assessment and appropriate recommendations to the clinical delegate with responsibility for the product application. Before a therapeutic good can be approved for marketing, the delegate must be satisfied that all legislative requirements, including those relating to labelling and packaging, have been met.

In relation labelling, the TGA evaluators check that the label contains information specified by the legislation, including:

- the product name;
- name(s) of all active ingredients and their quantity;

- in some cases, excipient information;
- batch number;
- expiry date;
- relevant warning/advisory statements;
- storage conditions;
- directions for use;
- in most cases the indications for which the product is used; and

that the information is in the English language and in durable, legible lettering that is not less than 1.5 millimetres in height (except for the ARTG number which must be no less than 1 millimetre in height).

TGA evaluators also assess:

- the scientific evidence that is provided in support of the proposed shelf life (expiry dates);
- whether the product name looks or sounds like another ARTG entry;
- the content of the Patient Information (also known as Consumer Medicines Information) documents against the requirements specified in Schedule 12 and regulation 9A of the Regulations;
- ensure that medicines containing active ingredients listed in TGO80 are packaged in a manner that is designed to be resistant to opening by children; and
- that the elements of the TEP Code of Practice have been met.

Please note that the above is not intended to be a complete listing of legislative requirements in relation to medicine labelling and packaging. Non-mandatory specifications, such as space for Pharmacy dispensing labels and packaging colour and design are also considered and changes recommended to the sponsor of the therapeutic good.

Post-market regulatory processes

Once a therapeutic good has been entered on the ARTG, it becomes subject to TGA's ongoing post-market monitoring and surveillance processes, which include the following activities:

Adverse event monitoring: The TGA assesses adverse event information to identify risks that may come to light only after more people use the therapeutic good, and takes appropriate action. This may include product recalls, safety alerts, revision of contra-indications and advisory statements.

Audits of manufacturing sites: To ensure the ongoing quality of the approved therapeutic good, the TGA conducts regular inspections of sites where they are manufactured, including overseas manufacturers. The frequency of the audits is based on product risk (see http://www.tga.gov.au/industry/manuf-audit-frequency.htm).

Product testing: The TGA conducts random and targeted laboratory testing of approved therapeutic goods.

Problems reporting: The TGA provides an on-line facility for consumers and health professionals to report problems related to therapeutic goods. This may include information about problems relating to labelling or packaging issues. Information received is assessed and appropriate follow up or compliance action taken.

The TGA is also closely engaged with other therapeutic goods regulators. This is particularly important as potential problems may be detected first in larger populations or in countries where a therapeutic good is approved for marketing earlier.

The TGA has a range of compliance and enforcement powers to take appropriate action should any potential non-compliances with labelling and packaging requirements be detected.

Reviewing the TGA labelling and packaging framework

As with any regulatory framework, there is a need for ongoing review to ensure it keeps up with technical developments and continues to be able to manage emerging risks.

The TGA is currently conducting a scoping exercise in relation to a review of the labelling and packaging regulatory framework. Once the scope and priorities have been determined, the TGA will engage with relevant stakeholders. It is anticipated that this will include consumer, professional and industry representative bodies, other government agencies and the jurisdictions.

It is a requirement of Australian Government agencies that a Regulatory Impact Statement (RIS) is prepared for any proposed changes to Commonwealth legislative instruments that are likely to impact on business or the not-for-profit sector, unless that impact is of a minor or machinery of government nature and does not substantially alter existing arrangements. The primary role of the RIS is to improve government decision-making processes by ensuring that all relevant information is presented to the decision maker.

The Office of Best Practice Regulation in the Department of Finance and Deregulation is responsible for the quality control of RISs and must clear the RIS before it is submitted to the decision maker.

Therapeutic Goods Administration

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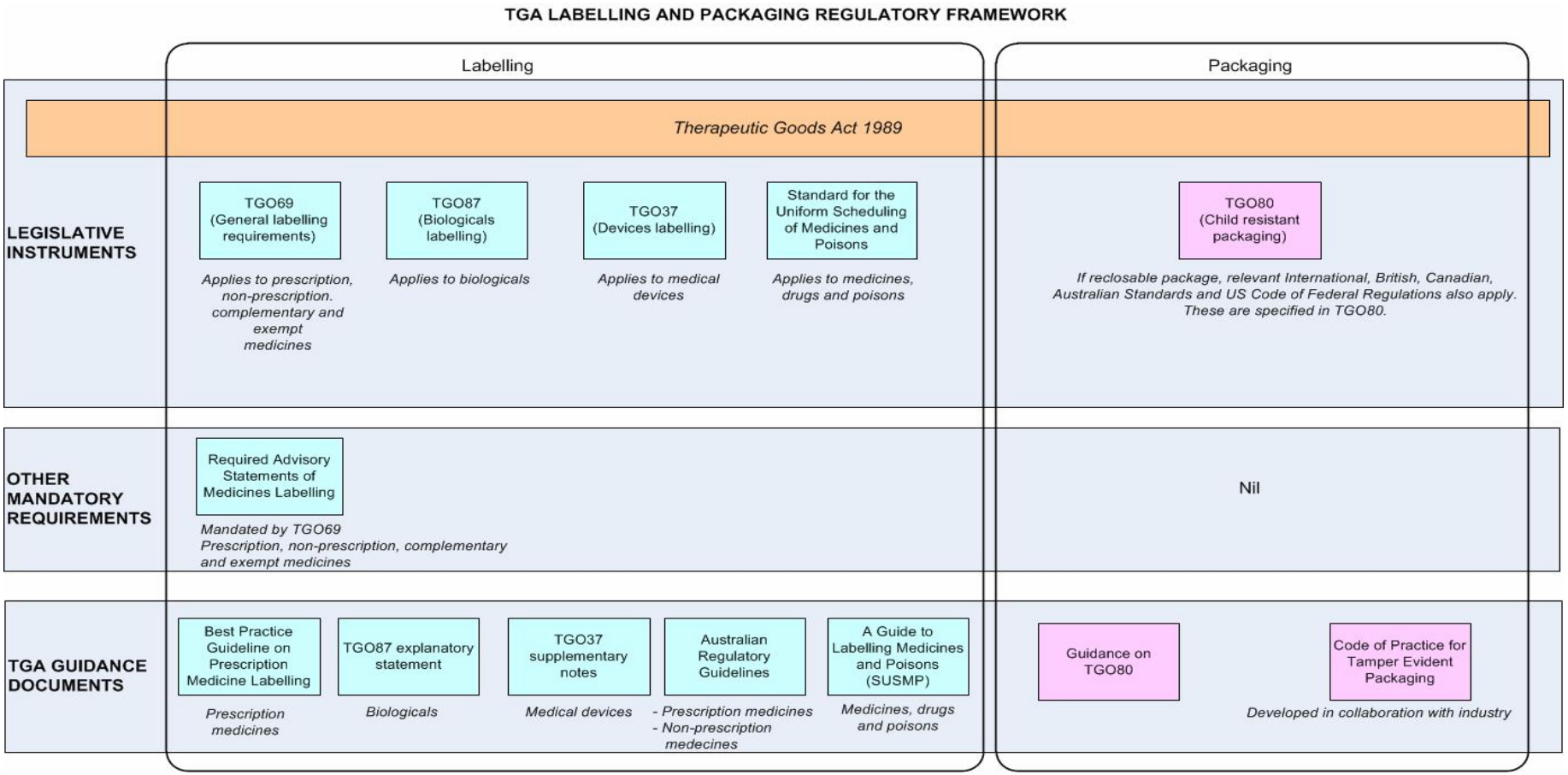
Reference/Publication #

Attachment 2



Appendix 2

Australian Government
Department of Health and Ageing
Therapeutic Goods Administration

AUSTRALIAN COMMISSION ON SAFETY AND QUALITY IN HEALTH CARE

Safer Labelling and Packaging of Medicines Roundtable
Sydney, 24 May 2011
Facilitator – Mr John Ramsay
List of Participants

Group	Name	Position	Organisation
A	Ms Carol Bennett	Chief Executive Officer	Consumers' Health Forum
A	Mr Graham Bedford	Program Manager, Medication Safety	ACSQHC
A	Ms Nicki Burridge	Publications Coordinator	Society of Hospital Pharmacists of Australia
A	Ms Elizabeth de Somer	Regulatory Affairs Manager	Medicines Australia
A	Ms Anne Develin	National Manager, Regulatory Affairs	Pharmacy Guild of Australia
B	Ms Margaret Duguid	Pharmaceutical Advisor	ACSQHC
B	Ms Paula Elliott	Quality & Accreditation Coordinator – ACT Community Health	Royal College of Nursing of Australia/Australian Nursing Federation
B	Ms Karen Kaye	Executive Manager, Quality Use of Medicines	NPS – Better Choices Better Health
B	Dr Megan Keaney	Principal Medical Advisor	Therapeutic Goods Administration (TGA)
A	Mr Daniel Lalor	Project Manager, Medication Safety	NSW Clinical Excellence Commission
	Mr Bill Lawrence AM	Acting Chief Executive	ACSQHC
B	Dr Jocelyn Lowinger	National Coordinator	Council of Australian Therapeutic Advisory Groups
A	Ms Kate Lynch	Chief Executive	Generic Medicines Industry Association
A	Ms Judith Mackson	Chief Pharmacist	NSW Health
B	Ms Alison Marcus	Consumer representative	Consumers' Health Forum
A	Mr Toby Mathieson	Program Manager, Electronic Medication Management	NEHTA

B	Mr Alastair McDougall	Pharmacist Consultant Pharmacy Improvement Program	Health Support Services, NSW Health
A	Prof Andrew McLachlan	Chairman	National Medicines Policy Committee
B	Mr Albert Regoli	Sydney Director	Pharmaceutical Defence Limited
A	Dr Harry Rothenfluh	Head, Office of Medicines Authorisation	Therapeutic Goods Administration
B	Dr Brendan Shaw	Chief Executive	Medicines Australia
B	Dr Deon Schoombie	Executive Director	Australian Self Medication Industry
B	Ms Kay Sorimachi	Director Policy and Regulatory Affairs	Pharmaceutical Society of Australia
A	Ms Danielle Stowasser	Clinical Adviser, Quality Use of Medicines	NPS
B	Dr Linda Swan	Member	National Medicines Policy Committee

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ASMI Response

TGA Medicine Labelling and Packaging Review

<u>Appendix 5</u>

Consumers Health Forum Australia 2010, *Community Quality Use of Medicines and Diagnostics Project: Achieving Best Practice in the Packaging and Labelling of Medicines: A consumer information and discussion paper*, CHF, Canberra.

Consumers
Health Forum
of Australia

Community Quality Use of Medicines and Diagnostics Project

Achieving Best Practice in the Packaging and Labelling of Medicines: A Consumer Information and Discussion Paper

October 2010

Community Quality Use of Medicines and Diagnostics Project

Achieving Best Practice in the Packing and Labelling of Medicines: Consumer Information and Discussion Paper

Introduction

The Consumers Health Forum of Australia (CHF) is the national peak body representing the interests of Australian healthcare consumers. CHF works to achieve safe, quality, timely healthcare for all Australians, supported by accessible health information and systems.

CHF began working in collaboration with NPS: Better Choices, Better Health in 2000 to provide a consumer perspective on issues relating to the quality use of medicines (QUM). CHF welcomes the opportunity to continue working with the NPS and has recently commenced work on the 2010-11 Community Quality Use of Medicines and Diagnostics (CQUM) Project.

Key objectives of the contract include:

- Providing strategic advice regarding consumer perspectives on QUM issues
- Supporting consumers to contribute to, and participate in, QUM Working Groups and Symposiums
- Engaging with consumers to develop QUM messages on specific topics
- Communicating with consumers and other relevant stakeholders regarding QUM.

A key element of the current collaboration between CHF and the NPS involves consumer consultation on the packaging and labelling of medicines.

The purpose of this Paper is to consult with consumers on the issues relating to the packaging and labelling of medicines. The Paper also provides a snapshot of the current literature, research and policy debate surrounding the packaging and labelling of medicines, both in Australia and internationally. CHF has also undertaken extensive work in the area of packaging and labelling, and key publications include:

- *Engaging Consumers in Quality Use of Medicines*
- *Making Consumer Quality Use of Medicines Happen*
- *Know the Active Ingredient*
- *Position Statement: Quality Use of Medicines*
- *Prominence of Active Ingredients on Labels for Prescription Medicines*
- *Information Paper: Community Quality Use of Medicines*
- *Seniors and Medication Safety*

The research in this area has been broad but consistent in its findings. This research has informed the issues and areas of interest outlined in this paper, although discussion is not limited to the points raised below. CHF encourages responses from consumers from a wide variety of backgrounds and experience, recognising that consumer perspectives are vital in creating effective health policy.

Responses to this paper will inform the agenda for a CHF consultative workshop on the packaging and labelling of medicines, to be held in November 2010.

The Role of Packaging and Labelling

Packages and labels make an important contribution to the safe and effective use of medicines. In this Paper, *packaging* refers to the way medicine is stored and dispensed, for example, in blister packs or bottles. *Labelling* refers to the design and appearance of the medicine, for example, the size of the font and placement of directions.

The presentation of medicines is intended to be the first line of communication with medicine users. This fact, coupled with several studies that indicate that poor packaging and labelling of medicines contributes to errors in medicine dispensing, underlines the importance of achieving a best practice approach to packaging and labelling.

In the literature, there is a broad consensus that the role of medicine labelling is to enable identification of the goods and to provide consumers with sufficient information to choose appropriately for self-medication products, and to use the products safely and effectively throughout the lifetime of the product. This begins at purchase, and continues during use and storage, through to disposal.

It is expected that the trend towards greater self-medication will continue. This means that the consumer is increasingly reliant on the packaging of medicines when deciding to purchase and electing to use medicines without professional evidence. Where there is professional intervention, the role of packages and labels changes.

In recognition of this, Figueiras et al[1] contend that labelling should address the different risks associated with the different categories of medicines. The risks are related to whether the decisions of end-users in the use of the product have been guided by professionals and/or consumer information leaflets, as well as the nature of the ingredients and the purpose of the medicine. For all take-home medicines, the consumer takes the responsibility for use and storage once purchased, but for the consumer to take this responsibility, labelling of medications must provide sufficient information.

Ward, Buckle, and Clarkson[2] note that the lack of access to the same amount of, and ability to interpret, information about medicines by consumers compared to manufacturers and health professionals is an 'asymmetry' of information. Part of the purpose of packaging and labelling is to address this asymmetry and to empower consumers to use the medicines appropriately.

For the consumer, it must be clear what the product is, what it is used for, how to use it, how to store it, and any risks or hazards associated with the use of the product. The labelling should also enable self-medicating consumers to make appropriate choices and compare products. This means that the consumer must be presented with information enabling them to elect whether or not to take a particular medicine, whether the medicine is the right one for their condition and whether it is the right one for them.

The label must provide information to a person dispensing or administering the product, such as a pharmacist or nurse, to enable them to select the correct product. The label should also provide all necessary information about storage and shelf life to ensure the maintenance of

[1] Figueiras, M.J., Cortes, M.A., Marcelino, D., and Weinman, J. (2010) Lay Views About Medicines: The Influence of the Illness Label for the Use of Generic Versus Brand. *Psychology and Health*. 22: 1-8.
[2] Ward, J., Buckle, P., and Clarkson, P.J. (2010) Designing Packaging to Support the Safe Use of Medicines at Home. *Applied Ergonomics*. 41: 682-694.

product quality. Other information, such as a batch number, is important for tracking purposes and to demonstrate that the medicine has been registered or listed.

Packaging and labelling should enable a consumer to elect whether to take or not take a particular medicine. Consumers need to have some way of choosing a particular product over another by reference to information that may not be generally available. It should be the role of the label to provide this information.

Current Issues in the Regulation of Packaging and Labelling

Current Legislation
The current regulation of packaging and labelling is based on the Commonwealth Therapeutic Goods Act. To comply with the Act, medicines' instructions must:

- be written in English, be clear and be legible
- be measured in metric units. Where the medicine is one of a series of strengths containing the same active ingredient in the same dosage form, the labels may state the quantity of active ingredient in terms of the highest or lowest metric unit of measurement in the series of strengths. (For example, a range of expressions of the active ingredient may be stated as 0.5 milligram, 1 milligram and 5 milligrams rather than 500 micrograms, 1 milligram and 5 milligrams.)
- include the product name, the names of all active ingredients in the goods and the quantity or proportion of all active ingredients
- list the quantity of the goods (except for medicines for injection)
- include warning statements, where these apply to the medicines
- include the batch number of the goods preceded by the batch number prefix
- display the expiry date of the goods preceded by the expiry date prefix
- list the applicable storage conditions
- list the directions for use of the goods
- list the name and address of the sponsor or supplier of the goods
- include a statement of the purpose or purposes for which the medicine is intended.[3]

TGA Review of Packaging and Labelling
The first comprehensive review of the labelling of medicines in Australia was undertaken by the Therapeutic Goods Administration (TGA) in 2000. The paper, *Effective by Design*, was commissioned by the National Drugs and Poisons Schedule Committee (NDPSC).[4] It defined three broad categories of labels as:

- labels for consumers of over-the-counter medicines
- labels for dispensers and administrators of prescription medicines
- labels for dispensed medicines for use by consumers.

The paper asks what labelling could be expected to achieve, and concluded that the role of labelling may sit somewhere in the risk management of the supply of medicines in the community.

The paper found that industry regards the labelling requirements as complex, while consumers seek better and more easily understandable information from labels. Its findings suggested that the regulations may impede industry in meeting the objectives for labels in

[3] *Therapeutic Goods Act 1989* (Commonwealth)
[4] Therapeutic Goods Administration (2000) *Effective by Design*. Department of Health and Aged Care: Canberra.

supporting safe and effective use of medicines. It recommended a check of the system to ensure it met the benefits originally sought, for handlers or users of medicines.

Consumer Concerns About Labelling

Two years later, the TGA published a paper outlining the responses it had received in relation to *Effective by Design.*[5] The most frequent complaint from consumers is that the print on labelling is too small to read. This problem may be compounded if the text is using unfamiliar language, and consumers called for an increase the print size on labels. Another common complaint was that the practical information on the label was not easy to understand. Consumers identified a need for practical interpretation of label instructions, such as information about how to maintain medicines at recommended storage temperatures when at work or outdoors.

Consumers also expressed the need for the pharmacological category to be placed on prescription medicines. It is difficult, particularly for older people or others who may be taking a number of different prescribed medicines, to know which medicine is for a particular condition.[6] The TGA noted that the problem is exacerbated by generic substitution; for example, where a patient has been taking a particular brand name for some time, and suddenly receives a medicine with an unfamiliar name. The TGA also highlighted the confusion among consumers about what they should be able to expect to find on medicine labels, and where to find this information if it seems to be missing from the label.

Additional written instructions can also be difficult to access. In spite of legal requirements, a recent study by Vitry et al[7] suggests that pharmacists do not regularly dispense written directions, such as Consumer Medicine Information (CMI). The study surveyed consumers leaving a community pharmacy, but fewer than half were buying prescription medicines requiring written instructions. Of these, only 6.4 percent received written instructions such as CMI.

Key Questions

1. What information do you expect to find on the packages and labels of medicines?

2. Have you experienced problems reading the directions for use provided with your medicines?

3. Have you ever incorrectly interpreted the directions for use on your medicines, or been uncertain about how to use a medicine after reading the directions for use?

4. Have you experienced any problems or confusion with the naming or branding of your medication?

5. Have you ever discussed these issues with your doctor, pharmacist or another health professional? If so, what was the response?

You are welcome to include examples and cite personal experiences.

[5] Therapeutic Goods Administration (2002) *Review of the Labelling Requirements for Medicines: Consumer Focused Labelling – A Way Forward?* Department of Health and Ageing: Canberra.
[6] Ibid.
[7] Vitry, A., Gilbert, A., Mott, K., Rao, D., and March, G. (2009) 'Provision of Medicines Information in Australian Community Pharmacies.' *Pharmacy World and Science*. 31: 154-157.

Consumer-Friendly Design in Packaging and Labelling

Regulation of Design
Both design and content issues are important. Rogers et al[8] looked at the effectiveness of the regulation of design. They concluded that regulations often identify required outcomes, but do not detail how those outcomes must be achieved (for example, requiring that labels on substances must be legible and draw the attention of the user to all hazards involved in their use, rather than stipulating minimum letter height).

Order of Label Information
Much of the research on design and appearance comes from Canada and the United States. Vigilante and Wogalter[9] examined the presentation of over-the-counter label components to find out consumer preferences and whether placement of warnings could influence behavioural compliance. The Non-Prescription Drug Manufacturers Association of Canada (NDMAC) also examined the order in which information should be presented.[10] In these studies, consumers preferences for the order of label components have been for indications to appear first, followed by side effects and contra-indications, then content and ingredients.

Bouldin and Smith et al[11] also provide an interesting confirmation of the preferred ordering of label information in their study on the labelling of herbal products in the United States. These studies indicate that consumers, especially those with poor literacy skills, are helped if the information is positioned in a standard order on the label, and simple, standardised wording is used. This would mean that the phrases can be found and recognised easily. Too much variation in the label layout or text may work against improved label useability.

Use of Symbols and Diagrams
In the Canadian and American research, there was little support from stakeholders regarding the use of symbols on labels, and the authors concluded that there is little evidence to suggest that the use of warning symbols improves label useability. The North American studies seem to imply that symbols and pictograms take up too much space on the label.

Overall, support for the use of pictures and symbols is mixed. According to Sojourner and Wogalter,[12] consumers show an equal preference for text only or partial pictorial presentation, rating both formats more effective and easier to understand than a pictorial-only format.

On the other hand, a current study led by the University of Western Australia[13] and commissioned by the National Health and Medical Research Council (NHMRC) is showing strong support for pictures and symbols, especially amongst seniors and consumers from

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[8] Rogers, D., Shulman, D., Sless, D., and Beach, R. (2010) *Designing Better Medicine Labels Report to Pharmaceutical Health and Rational Use of Medicines*. Communications Research Institute of Australia: Melbourne.
[9] Vigilante, W.J. and Wogalter, M.S. (1997) 'The Preferred Order of Over-the-Counter (OTC) Pharmaceutical Label Components.' *Drug Information Journal*. 31: 973-988.
[10] Nonprescription Drug Manufacturers Association of Canada (2006) *NDMAC Technical Research Paper for Improving Label Comprehension*. Nonprescription Drug Manufacturers Association of Canada: Ottawa.
[11] Bouldin. A., Smith, M., Banahan, B., and McCaffrey, D.J. and Croom, E.M. (2000) 'Herbal Supplement Information for the Consumer.' *Drug Information Journal*. 34: 1339-1353.
[12] Sojourner, R.J. and Wogalter, M.S. (1998) 'The Influence of Pictorials on the Comprehension and Recall of Pharmaceutical Safety and Warning Information.' *International Journal of Cognitive Ergonomics*. 2: 93-106.
[13] McKenzie, A. (2010) 'Medicines in People's Lives: Creating Opportunity.' *National Medicines Symposium*. (Presentation) Melbourne, Victoria.

culturally and linguistically diverse backgrounds. This is because they can be used to illustrate how to best use a product. The findings so far suggest that the pictures and symbols used in the labelling of over-the-counter medicines are more effective than the descriptions used on prescription medications, which are sometimes vague.

Identifying Features

In CHF consultations, the size, colour and other identifying features of medicines have all been cited as difficult design issues for consumers. The size of the font on medicines packaging is often too small, particularly for those with vision impairment.[14] The lack of visible identification on many medicines was also raised as a problem for many consumers, with the small font of identifiers on the medicines being very difficult for some seniors to read. Many seniors have also experienced difficulty in opening medication packaging, and this remains an ongoing issue.

Industry Perspectives

The Australian Self Medication Industry Association (ASMI) encourages its members to adhere to a Voluntary Code of Practice, which is focused on outcomes rather than the provision of specific information or design principles.[15]

The Code stipulates that labels should enable consumers to:

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

However, the section of the Code relating specifically to components is largely an articulation of the existing regulations (for example, displaying the ingredients, expiry date and directions for use).[16]

Although the pharmaceutical industry has historically resisted calls for more robust regulation of medicines packaging and labelling, CHF believes there are opportunities to develop recommendations acceptable to industry. For example, the Generic Medicines Industry Association of Australia (GMiA) has supported more robust labelling regulation,[17] and many manufacturers of over-the-counter medications have also adopted the use of consumer-friendly symbols, pictures and directions. [18] ASMI has also called for more national consistency in the regulation of medicines,[19] which could build a foundation for a cooperative national approach to best practice labelling regulation.

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[14] Consumers Health Forum of Australia (2009) *Seniors and Medication Safety*. Consumers Health Forum of Australia: Canberra.
[15] Communication Research Institute of Australia (2004) *Labelling Code of Practice*. Communication Research Institute of Australia: Canberra
[16] Ibid.
[17] Therapeutic Goods Administration (2005*) Best Practice Guideline on Prescription Medicine Labelling*. Therapeutic Goods Administration:
[18] McKenzie, Op. cit.
[19] Australian Self Medication Industry (2010) *Review of Labelling Law and Policy*. Australian Self Medication Industry: Sydney.

Key Questions

6. What kind of information should be highlighted on a package or label? (for example, content, ingredients, side-effects, etc)

7. Do you support the use of standardised design principles, such as requiring that labels on substances must be legible for packaging and labelling? Why or why not?

8. Do you support the use of pictures and symbols on the packaging and labelling of medicines? Why or why not?

9. Do you find it difficult to open the packaging of any medications?

10. If so, can you suggest a strategy to address this?

You are welcome to include examples and cite personal experiences.

Visibility of Active Ingredients

Most medicines have two names: the active ingredient name and the brand name. The active ingredient name identifies the key chemical in the medicine that makes it work, while the brand name is the name given to the medicine by its manufacturer.

CHF has conducted consumer consultations on this issue, and has strongly supported a greater prominence of the active ingredient than the proprietary name on prescription medicine labels. This is an important measure in helping consumers avoid adverse medicines events. CHF consumer engagements have indicated that, while the level of consumer knowledge about the difference between medicines' active ingredients and brand names has improved in recent years, there is still significant misinformation and confusion in the community.[20]

Consumers are concerned about the implications that this lack of knowledge has for consumers' ability to use their medicines in ways that are safe and appropriate. Greater prominence of the active ingredient on labels for prescription medicines is consistent with the Australian Government's current emphasis on assisting consumers to self-manage.

Consumers have consistently reported a number of labelling and medicines instruction issues in CHF engagements. These include that the print on medicines labelling is too small, making the active ingredient in medicines difficult to find.

Preliminary consultations with consumers have unearthed reports of potentially serious errors with different preparations of paracetamol in both community and hospital settings. In the community setting, errors made by people with reasonable health literacy indicate that even consumers who take responsibility in seeking out health information need improved medicines labelling to complement their self-management strategies. [21]

[20] Consumers Health Forum of Australia (2009) *Prominence of Active Ingredient and Proprietary Names on Labels for Prescription Medicines*. Consumers Health Forum of Australia: Canberra.
[21] Ibid.

In one CHF consultation, a consumer reported errors in a hospital setting involving junior nursing staff who were not aware that two preparations both contained paracetamol.[22] It is worth noting that one of these incidents involved a patient who had previously taken a paracetamol dose and had significant liver impairment. These incidents indicate that health professionals also need clear active ingredient labelling on medicines in order to avoid potential adverse events.

Including both the brand name and active ingredient names on the label would promote better communication between health providers and consumers, which is very important in avoiding medicines interactions and overdoses.

Additionally, both consumers and carers have reported difficulty in finding the active ingredients on a bottle or packet of medicine.[23] Examples of this include problems with compound medicines such as flu and cold preparations, as these preparations often contain paracetamol or aspirin. These ingredients may not be appropriate for some people, or they could inadvertently take two preparations with the same active ingredient.

Key Questions

11. Have you ever experienced difficulty finding the active ingredients of your medications?

12. Do you support greater prominence of the active ingredient? Why or why not?

You are welcome to include examples and cite personal experiences.

Other Consumer Issues in Packaging and Labelling

A lack of understanding about the difference between generic and brand name medicines is often raised as an issue, as is the need for consumers to check with their health care provider about the possible benefits and risks of switching from using a brand name medicine to a generic version.[24] The appearance of generic medicines is also identified as an issue for seniors who had previously used a brand name medicine, and were used to managing their medicines according to their size, colour or shape.

In general, many CHF consultations have indicated that packages do not include adequate instructions, and therefore do not promote consumers' safety. Consumers are particularly frustrated by the common advice on medicines packs, 'use as directed.' CHF engagements with consumers have repeatedly shown that this advice is inadequate, and that more comprehensive instructions need to be included on, or inside, medicines packaging.[25]

The limited amount of information on complementary medicines has also been cited as a barrier for consumers, with many reporting that they would like to see a complete list of ingredients, as well as their quantities on packaging. Consumers have also noted that the

[22] Ibid.
[23] Consumers Health Forum of Australia (2009) *Information Paper: Community Quality Use of Medicines*. Consumers Health Forum of Australia: Canberra.
[24] Consumers Health Forum of Australia (2009) *Seniors and Medication Safety*. Consumers Health Forum of Australia: Canberra.
[25] Ibid.

inconsistencies on complementary medicines labels make it very difficult to compare brands.[26]

Strategies related to medicines packaging and information identified by CHF in the past include the need for all medicines information to:

- be written in a minimum of 12-point font size
- be written in everyday language (not Latin or medical language)
- supplied with every medication.

Consumers said that it would be helpful if generic medicines looked similar to the brand name which they are replacing, and if medicines with different purposes which could be easily confused looked different to one another.

A key strategy nominated by consumers to promote QUM has been the use of 'Webster' packs (or similar dose administration aides) that show starting and finishing dates, days of the week and expiry date. These are regarded as most helpful when there is continuity of people's personal packs, with the same size, shape, marks and colour. However, the use of Webster packs does not remove the need for effective packaging and labelling to promote quality use of medicines for consumers.

Key Questions

13. Do you believe the labelling of your medicines includes adequate instructions?

14. Do you consider the amount of information provided about complementary medicines to be adequate? If not, what other information should be provided?

15. Are there any other issues you would like to raise?

You are welcome to include examples and cite personal experiences.

International Evidence and Possible Recommendations

United States

In the United States, the labelling of medicines is regulated by the Fair Packaging and Labeling Act.[27] To comply with the Act, label must state:

- the identity of the product
- the name and place of business of the manufacturer, packer, or distributor
- the net quantity of contents in both metric and imperial units.

As the Act governs all food and consumable products and is not restricted to medicines, the regulations are permissive and have not been significantly reviewed. However, some prescription medications are accompanied by more comprehensive Medication Guides.[28]

[26] Ibid.

[27] *Fair Packaging and Labeling Act 1966* (US)

[28] Wolf, M.S. Davis, T.C. Shrank, W.H. Neuberger, M. and Parker, R.M. (2006) 'A Critical Review of FDA-Approved Medication Guides.' *Patient Education and Counselling*. 62:316-322.

Medication Guides, like CMI, are paper handouts that come with many prescription medicines. They are issued when the US Food and Drug Administration (FDA) determines that:

- certain information is necessary to prevent serious adverse effects
- patient decision-making should be informed by information about a known serious side effect with a product, or
- patient adherence to directions for the use of a product is essential to its effectiveness.

The benefits to the US approach to packaging and labelling are that the regulations are easy for the manufacturers to comply with, and the importation of products is relatively straightforward. However, the reliance on prescription-only Medication Guides and lack of comprehensive labelling information means that consumers cannot always access crucial information, such as the active ingredient. There is also evidence to suggest that the Medication Guides are not widely read or easily understood by consumers.[29]

United Kingdom

In the United Kingdom, packaging and labelling is regulated by the Medicines and Healthcare Products Regulatory Agency (MHRA), which oversees both medicines and medical devices. In 2003, the MHRA undertook a comprehensive review of the medicines labelling.[30] The aim of the review was to make improvements to medicines labelling, to add clarity to the information, to assist consumers to select the correct medicines, use them safely and to minimise medication errors.

The following recommendations, which were based on consumer input and research, could be applied to Australian packaging and labelling regulations:

1. The full name of the medicine should appear on at least three non-opposing faces of the pack to aid accurate identification of the drug.

2. Where the common name appears after the brand name, it should be given due prominence. Generally this will be determined by the relative size of the text, but other factors may be relevant, such as colour of text and the font used.

3. It may be necessary in some cases to express the strength as quantity per unit volume and also as the total quantity per total volume. Reference to the total quantity per total volume should be highlighted.

4. The critical information should appear in as large a font as possible to maximise legibility, on at least one face of the presentation. It should not be broken up or separated by non-critical information.

5. Innovative pack design that may incorporate the judicious use of colour is to be encouraged to ensure accurate identification of the medicine.

6. Where practicable, packs should include space for the placement of the dispensing label. It is recommended that this should be a blank white space in which there is no text of any kind, to aid legibility of the dispensing label.

[29] Ibid.

[30] Medicines and Healthcare Products Regulatory Agency (2003) *Best Practice Guidance on Labelling and Packaging of Medicines*. Medicines and Healthcare Products Regulatory Agency: London.

7. Only positive statements should appear on medicines labelling to avoid ambiguity of the message.

8. Undertaking a user test to ensure the maximum clarity of the critical information is desirable and recognised as best practice.

9. Colour for the text and the font style on blister packs should be chosen carefully, as the legibility of the text on the foil is already impaired due to the nature of the material.

CHF Recommendations

Additionally, based on the research and preliminary consumer consultations discussed in this paper, CHF provides the following additional recommendations:

10. Labelling needs to be very clear, using a font and colour that can be read easily.

11. Information relating to the *quantity* of active ingredient per dose or unit must be displayed clearly on the packaging.

12. Many consumers believe that equal prominence of active ingredient and brand name on medicines labels does not go far enough to address the potential for adverse events and better recognition of active ingredients in their medicines. Suggested strategies to address this are outlined in Question 17.

Key Questions

16. Do you disagree with any of the recommendations listed above?

17. In relation to recommendation 12, how do you think the active ingredient should be displayed on medicines labels?
    a. The active ingredient and brand name could both be used, with the active ingredient first and in larger font than the brand name.
    b. Only the active ingredient should be displayed on the label.
    c. The active ingredient could be displayed bold black at the top, with the brand name smaller and in plain (unbolded) print underneath.
    d. Other (please specify).

17. Are there any other recommendations you would like to suggest?

Next steps

Responses to this paper will inform the agenda for a consultative workshop on the packaging and labelling of medicines, to be held in November 2010. CHF will report the outcomes of these consultations to the NPS, as well as drawing upon the consumer feedback to inform our ongoing policy work in the medicines area.

The questions asked in this paper are intended as a guide. Comments do not need to be restricted to the questions or points that have been raised. Consumers are encouraged to include examples and provide personal experiences.

Further information

Further information about CHF's Community Quality Use of Medicines and Diagnostics project can be found on the CHF website www.chf.org.au. Alternatively, interested persons can contact Maiy Azize, Project Officer at m.azize@chf.org.au or (02) 6273 5444 (STD calls will be returned).

Responses are due by Friday 29 October 2010**.**

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Consumers Health Forum of Australia

The Consumers Health Forum of Australia (CHF) is the national peak body representing the interests of Australian healthcare consumers. CHF works to achieve safe, quality, timely healthcare for all Australians, supported by accessible health information and systems.

CHF does this by:

1. advocating for appropriate and equitable healthcare
2. undertaking consumer-based research and developing a strong consumer knowledge base
3. identifying key issues in safety and quality of health services for consumers
4. raising the health literacy of consumers, health professionals and stakeholders
5. providing a strong national voice for health consumers and supporting consumer participation in health policy and program decision making

CHF values:

- our members' knowledge, experience and involvement
- development of an integrated healthcare system that values the consumer experience
- prevention and early intervention
- collaborative integrated healthcare
- working in partnership

CHF member organisations reach millions of Australian health consumers across a wide range of health interests and health system experiences. CHF policy is developed through consultation with members, ensuring that CHF maintains a broad, representative, health consumer perspective.

CHF is committed to being an active advocate in the ongoing development of Australian health policy and practice.

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ASMI Response

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Appendix 6

Case Studies in relation to blister strips

Proposed change (proposal 6.1.)

For blister strips, other than those that have a "race track" blister strip format to facilitate the quality use of the medicine (such as oral contraceptives), the following requirements are proposed:

> *6.1 The brand name of the medicine, the active ingredient and amount of active ingredient, batch number and expiry date must be repeated at least once every two units.*

Background

TGO 69 already requires the brand name, active ingredient and amount of active ingredient to be on the blister and companies comply with this requirement by reproducing this information in relation to every 2 dosage units regardless of the ability to segment.

Proposal 6.1 therefore amounts to a new requirement to include the batch number and expiry date at least once in relation to every two dosage units. As the current practice is to include the batch number and expiry date once per blister tray, this new requirement means that information which varies from batch to batch will now have to be repeated numerous times per blister tray.

For the reasons outlined below this new requirement is extraordinarily onerous.

Although obvious it is important to note that the batch number and the expiry date changes each and every time the product is made.

Ordinarily sponsors will use foils that have been pre-printed with the fixed data (i.e. active ingredient, active amount etc) and then apply the variable data at the time of manufacture.

This allows the pre-printed foils to be purchased in economic quantities and allows flexibility at the time of manufacture of the finished product.

Options (Generally)

In order to meet the proposed new requirements, manufacturers have three options:

1. Pre-print the foil with batch and expiry date at an external printer.
2. Print the variable data on the packing line: There are two equipment options:
   2.1. Printing blank foil on the finished product packing line
   2.2. Overprinting the batch and expiry data on pre-printed foil.

With option 1, the manufacturer will order much smaller quantities of foil at a time and will need to specify in advance the variable information to be included on the foil.

With option 2.1, the manufacturer can use bulk quantities of blank foil but will require specialised equipment and facilities. Manufacturing times (and costs) may increase due to foil print registration control.

With option 2.2, the manufacturer can use similar foil quantities to those currently purchased, but will need specialised equipment to maintain high speed lines.

Registration

All options require registration of the information directly over the two blister pockets. Currently foil layouts are typically designed on the diagonal, which minimises the impact of registration slip. The design will still repeat every two dosage units.

The requirement to include the batch and expiry every two dose units requires a design where all the information must be presented directly over the two blister pockets. This requires either automated control built into the blister packing equipment to ensure accurate registration of the foil or manual control and adjustment, both of which increase the costs of production.

Blister Size

The inclusion of this additional information regardless of the way the printing is achieved will have implications for the size of the blister platform. There will be a flow-on increase in the size of the primary packaging (carton) to accommodate the new blister and then to the secondary packaging (corrugated cardboard shippers) to accommodate the primary packaging.

The following summary of costs arising from the pack size increase is therefore common to the each of the three printing options:

- Additional blister material usage per platform.
- Cost of replacement of blister forming and sealing tools for each platform size $10K-$100K depending on the equipment type.
- Subsequent increase to primary packaging the carton.
- Resizing of carton artwork to the new dimension.
- Cost of replacement carton erecting tooling where high speed cartoners are in use.
- New secondary packaging dimensions.
- Cost of tooling where automated secondary packing equipment (shrinkwrappers and shippers).
- For overseas sourced product these changes will also be Australian unique requirements (a move away from the global pack dimensions) so the cost of the necessary new equipment and tooling changes would be amortised only over the Australian product only. Note that with Australian population size, annual volumes are low in global terms.
- Australian specific sized products also incur additional factory overhead charges with requirement for line change and associated downtime and line inefficiencies.
- Increases in overall pack dimensions also impact across the supply chain in costs of freight efficiencies, warehousing space rental, Pharmacy/Grocery shelf space limitations and implications to line fees paid for by sponsors for that space in grocery.

Case Study Option 1. - Preprinting the foil with batch and expiry

Background

The lead times for printing and slitting foil is typically between 12-16weeks, much longer than for other packaging materials (4 weeks). Foil is therefore ordered long before production of a batch is scheduled and therefore prior to the batch numbers and expiry dates being allocated. Pre-printing of the batch and expiry data on the foil adds significantly to the complexity of planning.

Estimated Cost Implications

To pre-print the foil at an external printer as is currently standard practice but with batch and expiry date, while appearing to have limited requirement for capital expenditure on equipment will have significant ongoing cost implications including:

- Increased cost of foil due to small print run quantities. e.g. $27/Kg for 100Kg order vs. $100/Kg for a 5Kg order.
- Foil Artwork and printing plates would be required for each batch at a cost of $175 per colour plate.
- Increased cost of write-off of excess and reject foil.(see detail below)
- Secure destruction of the batch specific printing plates and foils would be required.
- Cost of additional GMP label control procedures and staff.
- Cost of additional purchasing staff.
- Where print registration controls are not already automated, slower line speeds and manual control may be required to maintain registration.
- Production inefficiencies due to risks associated with changes in production schedule impacting planned expiry dates already pre-printed.

Increased Write off Impact

This option significantly increases the level of wastage and write-off of the (more expensive) printed foil. This is for two reasons:

1. Wastage allowance for foil orders typically allowed per product foil order would need to be made per batch to ensure sufficient to pack the whole batch. What is not used must be rejected.
2. High risk of write-off of the pre-printed foil for batches produced at the beginning and end of the month This is due to changes of the production schedule meaning batches planned to be manufactured one month move to another, impacting the planned expiry date already printed on the foil. This means that where the production date slips over from one month to the next, all the pre-printed foil will be need to be rejected and written off the books. The packing of the affected batches will then be delayed awaiting a revised pre-printed foil.

This option is not a long term viable option. The increased costs and the decreased efficiencies would be untenable.

Case Study Option 2.1. Blank foil printed on the product packing line

This option represents major capital expenditure to purchase equipment to print blank foil online. The equipment investment would be required for every line producing blister strips for the Australian market (it is not portable equipment that can be shared between lines).

Time and costs would be associated with installation, operational and performance qualification of the foil printing equipment before it could be considered validated and fit for service.

As this is additional equipment to an established line, it is likely to require additional space within the facility and capital building works may be required to accommodate it.

Current foil wastage rates are unchanged with this option.

Costs estimates are summarised as:

- ~$300K-$500K per pharmaceutical foil printer (price range varies for single to four colour print capability) – per blister packing line.
- Where print registration controls are not already automated, slower line speeds and manual control may be required maintain registration.
- Capital Building Works.

Case Study Option 2.2. Printing the batch and expiry data on pre-printed foil

For high line speeds, blister packing equipment can be purchased with foil and print registration capability. This equipment uses either ink jet or laser etch printing over the blister pockets. Being new equipment, specific tooling would be required for each blister platform size required.

With the additional functionality the blister packing equipment is likely to be larger than existing equipment and capital building works may be required to accommodate the additional length of the line. Significant time and costs would be associated with installation, operational and performance qualification of the equipment before it could be considered validated and fit for service.

The cost of this hi-tech equipment is estimated at ~$2M per line.

Current foil wastage rates are unchanged with this option.

Conclusion

Proposal 6.1 of the TGA Medicine Labelling and Packaging Review introduces a new requirement to repeat the batch and expiry more frequently on each blister tray.

There are only three options available to manufacturers to meet this new requirement (as discussed above).

All three options will be associated with increased costs and increased blister tray sizes. There will be enormous cost consequences both in terms of upfront capital expenditure and ongoing increased costs of packaging freight, storage and shelf space.

Each of the three options will be associated with significant practical and GMP issues.

With the majority medicines already imported, the enormous costs of an Australian specific requirement will increase the costs of manufacturing medicines for this country disproportionately to the rest of the world.

These increased costs will inevitably have an impact on the viability of the industry.

ASMI Response

TGA Medicine Labelling and Packaging Review

Appendix 7

Answers to the questions raised

NOTE: ASMI would like to register our disappointment at the questions included in the Consultation paper. The leading nature of the questions appears designed to provoke a pre-determined response. The questions presume that the proposed changes will achieve the stated objectives of the review. It is unclear how the answers to these questions will reliably inform the review.

General questions on the proposed regulatory changes for the prominence of the active ingredients on medicine labels

Q. What do you think will be the impact of increasing the prominence and standardising the location of the active ingredient on the medicine label?
A. If implemented as proposed, the impact will be significant (as discussed above).

Q. What do you think about the proposed warnings for paracetamol and ibuprofen containing products?
A. ASMI's position on this topic is discussed above.

Q. Are there any other concerns you have with the size or position of brand names and active ingredient?
A. ASMI's concerns with the proposed changes are discussed above.

Q. 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?
What is the smallest size font that you consider readable?
A. The "benefits" of the proposed changes have not been established. ASMI's concerns with the proposed changes are discussed above. ASMI contends that there are other ways of achieving due prominence apart from increasing the font size. Any change to the current minimum font size in TGO 69 needs to be consulted on (as it was not identified in the Consultation paper).

General question on the proposed regulatory changes for look-alike sound-alike names and look-alike packaging

Q. Do you think the proposed changes to address LASA names and LA packaging will improve medicine safety? Why/why not?
A. ASMI's concerns with the proposed changes are discussed above. In the absence of evidence, no assessment can be made as to the effectiveness of the proposed changes. No change to the current requirements should be made unless based on evidence from consumer testing in the context of the entire label.

General questions on the proposed regulatory changes for look-alike medicine branding

Q. What benefits, if any, do you think the proposed changes to address look-alike medicine branding will have for consumer safety?
A. ASMI's concerns with the proposed changes are discussed above. In the absence of evidence, no assessment can be made as to the effectiveness of the proposed changes. No change to the current requirements should be made unless based on evidence from consumer testing in the context of the entire label.

Q. Do you understand the proposed changes?
A. As discussed above, the Consultation Paper has confusingly amalgamated separate issues and has co-mingled prescription and non-prescription risks. Additionally, there are a range of issues with the figures included in the Consultation paper. The resulting lack of clarity has made interpretation difficult. This lack of clarity has compromised the consultation process.

Q. If you can read the labels and warnings clearly, will these changes reduce the potential for harm?
A. ASMI's concerns with the proposed LASA changes are discussed above. In the absence of evidence, no assessment can be made as to the effectiveness of the proposed changes. No change to the current requirements should be made unless based on evidence from consumer testing in the context of the entire label.

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

Q. 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?
A. ASMI's concerns with the proposed changes are discussed above. In the absence of evidence, no assessment can be made as to the effectiveness of the proposed changes. No change to the current requirements should be made unless based on evidence from consumer testing in the context of the entire label.

Q. Are there other ways that the presentation of information could be improved?
A. ASMI has put forward a range of alternatives. These all come with an important caveat: none of the proposed alternatives have been tested as the consultation timeframe was insufficient to undertake that task.

Q. 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.
A. ASMI's concerns with the proposed changes are discussed above. In the absence of evidence, no assessment can be made as to the effectiveness of the proposed changes. The alternatives put forward by ASMI all come with an important caveat: none of the proposed alternatives have been tested as the consultation timeframe was insufficient to undertake that task. No change to the current requirements should be made unless based on evidence from consumer testing in the context of the entire label.

General question on the proposed regulatory changes for dispensing label space

Q. Do you support a designated space for the dispensing label on prescription medicines? Why/why not?
A. This item has been identified as applying to prescription medicines only. ASMI offers no comment in relation to this part of the Consultation paper.

General question on the proposed regulatory changes for blister strip labelling

Q. Do you think the proposed information for blister strips is sufficient?
A. ASMI's concerns with the proposed changes are discussed above. In the absence of evidence, no assessment can be made as to the effectiveness of the proposed changes. No change to the current requirements should be made unless based on evidence from consumer testing in the context of the entire label.

Q. What other changes would you like to see for this type of packaging?
A. ASMI has put forward a range of alternatives. These all come with an important caveat: none of the proposed alternatives have been tested as the consultation timeframe was insufficient to undertake that task.

General question on the proposed regulatory changes for small container labelling

Q. To what extent do you support the proposed changes for small container labels? Please provide details.
A. ASMI's concerns with the proposed changes are discussed above. In the absence of evidence, no assessment can be made as to the effectiveness of the proposed changes. No change to the current requirements should be made unless based on evidence from consumer testing in the context of the entire label.

Q. Do you have any further suggestions for how labelling of small containers could be improved?
A. ASMI has put forward a range of alternatives. These all come with an important caveat: none of the proposed alternatives have been tested as the consultation timeframe was insufficient to undertake that task.

General question on the proposed regulatory changes for pack insert requirements

Q. Do you support the proposed changes for pack inserts? Why/why not?
A. ASMI's concerns with the proposed changes are discussed above. In the absence of evidence, no assessment can be made as to the effectiveness of the proposed changes. No change to the current requirements should be made unless based on evidence from consumer testing in the context of the entire label.

Q. Do you have any further suggestions regarding pack inserts?
A. ASMI has put forward a range of alternatives. These all come with an important caveat: none of the proposed alternatives have been tested as the consultation timeframe was insufficient to undertake that task.

General question on the proposed establishment of a labels and packaging advisory committee

Q. 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?
A. ASMI's position on this topic is discussed above.