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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.

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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 <i>Best Practice Guideline on Prescription Medicine Labelling</i> 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 <i>Best Practice Guideline on Prescription Medicine Labelling</i> . 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 <i>International Medication Safety Network (IMSN)</i> 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 <i>Be Medicine-wise</i> 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 issues².

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

	Labelling	Packaging
	Therapeutic Goods Act 1989	
LEGISLATIVE INSTRUMENTS	<div> <div>TGO69 (General labelling requirements)</div> <div>Applies to prescription, non-prescription, complementary and exempt medicines</div> </div> <div> <div>TGO87 (Biologicals labelling)</div> <div>Applies to biologicals</div> </div> <div> <div>TGO37 (Devices labelling)</div> <div>Applies to medical devices</div> </div> <div> <div>Standard for the Uniform Scheduling of Medicines and Poisons</div> <div>Applies to medicines, drugs and poisons</div> </div>	<div> <div>TGO80 (Child resistant packaging)</div> <div>If reclosable package, relevant International, British, Canadian, Australian Standards and US Code of Federal Regulations also apply. These are specified in TGO80.</div> </div>
OTHER MANDATORY REQUIREMENTS	<div> <div>Required Advisory Statements of Medicines Labelling</div> <div>Mandated by TGO69 Prescription, non-prescription, complementary and exempt medicines</div> </div>	Nil
TGA GUIDANCE DOCUMENTS	<div> <div>Best Practice Guideline on Prescription Medicine Labelling</div> <div>Prescription medicines</div> </div> <div> <div>TGO87 explanatory statement</div> <div>Biologicals</div> </div> <div> <div>TGO37 supplementary notes</div> <div>Medical devices</div> </div> <div> <div>Australian Regulatory Guidelines</div> <div>- Prescription medicines - Non-prescription medicines</div> </div> <div> <div>A Guide to Labelling Medicines and Poisons (SUSMP)</div> <div>Medicines, drugs and poisons</div> </div>	<div> <div>Guidance on TGO80</div> </div> <div> <div>Code of Practice for Tamper Evident Packaging</div> <div>Developed in collaboration with industry</div> </div>

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 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 manage 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.



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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Attachment 1	Therapeutic Goods Administration overview paper
Attachment 2	Therapeutic Goods Administration labelling and packaging regulatory framework overview

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 and are 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 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/Am_gros_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

TGA LABELLING AND PACKAGING REGULATORY FRAMEWORK

	Labelling	Packaging					
LEGISLATIVE INSTRUMENTS	Therapeutic Goods Act 1989						
	<div>TGO69 (General labelling requirements)</div> <p>Applies to prescription, non-prescription, complementary and exempt medicines</p>	<div>TGO87 (Biologicals labelling)</div> <p>Applies to biologicals</p>	<div>TGO37 (Devices labelling)</div> <p>Applies to medical devices</p>	<div>Standard for the Uniform Scheduling of Medicines and Poisons</div> <p>Applies to medicines, drugs and poisons</p>	<div>TGO80 (Child resistant packaging)</div> <p>If reclosable package, relevant International, British, Canadian, Australian Standards and US Code of Federal Regulations also apply. These are specified in TGO80.</p>		
OTHER MANDATORY REQUIREMENTS	<div>Required Advisory Statements of Medicines Labelling</div> <p>Mandated by TGO69 Prescription, non-prescription, complementary and exempt medicines</p>	Nil					
TGA GUIDANCE DOCUMENTS	<div>Best Practice Guideline on Prescription Medicine Labelling</div> <p>Prescription medicines</p>	<div>TGO87 explanatory statement</div> <p>Biologicals</p>	<div>TGO37 supplementary notes</div> <p>Medical devices</p>	<div>Australian Regulatory Guidelines</div> <p>- Prescription medicines - Non-prescription medicines</p>	<div>A Guide to Labelling Medicines and Poisons (SUSMP)</div> <p>Medicines, drugs and poisons</p>	<div>Guidance on TGO80</div>	<div>Code of Practice for Tamper Evident Packaging</div> <p>Developed in collaboration with industry</p>

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 Burrige	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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