AUSTRALIAN COMMISSION ON SAFETY AND QUALITY IN HEALTH CARE

Submission to the consultation on the

TGA Medicine Labelling and Packaging Review

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This document is available on the Commission web site at www.safetyandquality.gov.au

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1. Background

The Australian Commission on Safety and Quality in Health Care (the Commission) was established in 2006 to lead and coordinate improvements in the safety and quality of health care in Australia. A priority program of the Commission is medication safety. Improving the safety of medication management across the care continuum is an important focus of the medication safety program.

Similar drug names and similar packaging have been identified as contributing to medication errors in Australia both in the community (home and community residential units) and in health services.[1-5] Confusion with medicines names account for as many as 25% of reported medication errors in a large United States database.[6] Reducing errors from confusing medicines names and packaging is one of the World Health Organization's nine patient safety solutions.[7]

The Commission's *National Medication Safety and Quality Scoping Study Committee Report* identified medicines packaging and labelling as contributors to error. The report listed the following actions to reduce the risk of errors from confusing medicines naming, labelling and packaging [8] including:

- mandating testing of naming, labelling and packaging products for safety as a requirement of registration
- mandating equal prominence of active ingredient name and brand name of medicines on the label
- establishing a national process to identify problems with look alike sound alike names, packaging and labelling
- establishing a forum to liaise with industry and the Therapeutic Goods Administration
- requiring application of machine readable codes to all medicines at "unit of use" level.

The report recommended that the Commission work with the Therapeutic Goods Administration of the Department of Health and Ageing (TGA) to:

- improve safety of labelling and packaging including giving prominence to the active ingredient name equal to the brand name
- establish a process for identifying and addressing reports of errors and patient harm caused by poorly designed labelling and packaging.

To progress these recommendations, the Commission and the TGA jointly conducted the *National Round Table on Safer Naming, Labelling and Packaging of Medicines* on 24 May 2011 in Sydney. 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. The report of the round table was issued jointly by the Commission and the TGA and contains eighteen recommendations for reducing the risk of error for confusing medicines naming, labelling and packaging. These remain generally applicable in the context of naming, labelling and packaging regulatory reform.

Seven of the recommendations are specifically relevant to this review and have been noted in the response. A copy of the report forms Appendix 1 to this submission and can be found on the Commission's web site at www.safetyandquality.gov.au/our-work/medication-safety/national-round-table-on-safer-naming-labelling-and-packaging-of-medicines/

2. General comments

The Australian Commission on Safety and Quality in Health Care (the Commission) supports most of the recommendations in the review of the labelling and packaging of medicines (the Review) and applauds the TGA for initiating the review. The Commission welcomes the opportunity to provide comment on the *TGA Labelling and Packaging Review*.

The Commission supports the recommendations for equal prominence of active ingredient name and for a systematic and transparent approach to medicines naming.

However it regrets the limited focus of the review which mostly considers specific strategies to reduce the risk of patient harm resulting from confusion of names, and labelling and packaging as it relates to the medicines name. There is other critical information contained in medicines labelling in addition to the medicines name. These include the strength, form and route of administration, all of which can contribute to confusion and subsequent patient harm if not clearly expressed. Similarly, much is now known about the design of medicines labels and packaging in the context of human factors research and how it can influence the safe handling of a medicine.

In the consultation paper, the approach taken to considering the proposed regulatory changes in terms of their affect on consumers limits the scope of possible changes. For example, other significant contributors to medication error were not canvassed in the consultation paper including health professional selection errors from look-alike, sound-like medicines names (LASA names), look-alike packaging and poor design of medicines labelling and packaging. These errors result in significant error and consumer harm.

Heath professionals handle a broad range of medicines including many that require dose calculation, preparation and administration by various routes and that carry a high level of risk, such as intravenous, intrathecal, and epidural injections. Issues such as LASA names, unclear labels and look-alike packaging can contribute to errors in these processes and to patient harm. Medication errors can be devastating to the health professional involved as well as to the patient and their family. It is important that busy health professionals are not compromised by the quality of the information and the design of medicines labels and packaging.

These issues, along with a number of pre and post-marketing solutions, were identified in the 2011 *National Round Table on Safer Naming, Labelling and Packaging of Medicines* which was co-hosted by the Commission and the TGA. The solutions have been implemented in other developed countries. While is it is recognised that a number of these solutions would not be appropriate for inclusion in a therapeutic goods order, they are relevant to any reform of medicines labelling and packaging in Australia. The Commission has identified these issues within this submission (see *Section 4: Other issues and solutions*) and recommends that they are considered alongside the changes proposed in this review. The Commission is prepared to work with the TGA to assist in this process.

The Commission proposes progressing Australian labelling reform as a whole package and does so for two reasons. One is to ensure timeliness of an important strategy for reducing preventable patient harm. The second is that the cost of labelling reforms to the pharmaceutical industry should be recognised and that it be a one step reform rather than ongoing, piecemeal changes. Industry representatives at the National Round Table supported reform but requested that the cost be minimised by this approach.

The Commission has made seven recommendations in this submission for consideration as part of the review process and which are in addition to those made in the *Report of the National Round Table on Safer Naming, Labelling and Packaging of Medicines*. These recommendations, if actioned, will improve the safety of medicines use by Australian consumers and health professionals. They are listed in Table 1 below.

Finally the Commission continues to advocate consideration of the extensive work undertaken by the NHS National Patient Safety Agency in setting standards for safe naming, labelling and packaging of medicines including injectables. These are available in the two publications *Guide to the graphic design of medication packaging*, available at www.nrls.npsa.nhs.uk/resources/collections/design-for-patient-safety/?entryid45=63053 and *Guide to labelling and packaging of injectable medicines* available at www.nrls.npsa.nhs.uk/resources/collections/design-for-patient-safety/?entryid45=59831 . This submission refers to them a number of times.

Table 1: Additional recommendations for safer medicines labelling and packaging

1	Standardise expressions of strength for: • Oral liquid products as quantity per mL • Injections using both quantity/mL and total quantity per total volume in container.
2	Require that generic medicine names: • Be limited to the active ingredient name • Cannot include prefixes incorporating part, or all, of the sponsor's name with the active ingredient name.
3	Require machine readable codes on all medicines labels in the labelling and packaging regulatory changes.
4	Require that Tall Man lettering be applied to product labels of prescription medicines listed in the *National Tall Man Lettering List*.
5	Require distinctive labelling and packaging requirements for potassium, vinca alkaloids and methotrexate tablets in labelling regulatory changes.
6	Require distinctive labelling and packaging of neuromuscular blocking agents in labelling regulatory changes.
7	Action Recommendation 5 from the *Report on the National Round Table on Safer Naming, Labelling and Packaging of Medicines*: 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.

3. Response to proposed regulatory changes

3a. Prominence of the active ingredients on medicine labels.

i. Impact of increasing prominence and standardising the location of active ingredient on the medicines label

The Commission fully supports this proposed regulatory change. It accords with Recommendation 4 from the *Report on the National Round Table on Safer Naming, Labelling and Packaging of Medicines.*

These changes will make for safer management of medicines by both consumers and health professionals.

Consumers

The number of different brands of generic medicines available on the Australian market increases the risk of confusion and error.[1] This is supported by general practice reports of patients suffering adverse outcomes by taking double the dose of medicines because they have two different brands of the same drug. [9] Confusion between generic and trade names is cited as one of the key medication related risk factors associated with poor health outcomes.[10]

Displaying the name of the active ingredient with equal, or greater, prominence to the brand name will assist consumers understand that the same medicine is available in different brands and decrease the risk of patients taking two brands of the same medicine at the same time, resulting in duplication of the dose.[9]

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.

Standardising the prominence and presentation of medicines names will assist consumers find appropriate information. With the level of health literacy of the Australian population a large proportion of the population will have difficulty in obtaining specific information if it is presented in a non standard format.

To help consumers avoid confusing their medicines, NPS Better choices Better health (NPS) produces a fact sheet *Know the active ingredient* and available at www.nps.org.au/consumers/publications/factsheets/factsheets/get_to_know_your_medicines/know_the_active_ingredient2 In the section *Using medicine safely and effectively,* the first message is:

	Identify each of your medicines by the active ingredients rather than their brand name. This will help you to avoid confusing medicines and perhaps taking too much or not enough. Making the active ingredient name more prominent on medicines labels will assist consumers identify and know the active ingredient name. Helping consumers to identify easily the active ingredient of their medicine through equal or greater prominence of the active ingredient name is strongly supported by the Consumers Health Forum (CHF) which considers greater prominence of the active ingredient name on prescription medicine labels as "an important measure to help consumers avoid adverse medicines events" …and .."is consistent with the Government's current emphasis on assisting consumers to self manage their health". The CHF describes a number of situations in which not knowing the active ingredient potentially causes adverse medicines events (see Appendix 2). <u>Health professionals</u> It has been estimated that as many as a third of medication errors occur because of confusion with product labelling The Commission sought feedback from state therapeutic advisory groups on this issue. The multiplicity of brand names for generic products was cited by one respondent as the "biggest single problem" for prescription medicines labelling. Equal prominence of the active ingredient name will reduce the risk of selection errors by health professionals in dispensing, drug preparing and administering processes in pharmacies, hospitals and residential care facilities. Prescribing by generic name is encouraged and is hospital policy in some states and territories. The *National Inpatient Medication Chart* prompts prescribers to write generic names. Equal prominence of the generic name on packaging would assist prescribers to order by generic name. It would also help nursing staff responsible for administering medicines to identify the correct product from medicines kept on wards and assist pharmacy staff reduce product selection errors when dispensing and choosing products for supply to wards. A common complaint from medical practitioners (general practitioners, emergency physicians and specialists) is the confusion caused by the many brands of generic products [1]. General practitioners and hospital medical officers have reported difficulties in eliciting accurate medication histories from patients as they do not know the active ingredient name and the medical officer is not familiar with the different brands dispensed to, or purchased by, the patient [14]. This is supported by reports from consumers (see Appendix 2).

1.1 Location of active ingredient name	The proposal to locate the active ingredient name immediately below the brand name is supported. Further it is recommended that the location of the active ingredient name and key information should accord with the recommendations in NHS National Patient Safety Agency *Guide to the graphic design of medication packaging* and the NHS National Patient Safety Agency *Guide to labelling and packaging of injectable medicines (NHS label design guides).* This includes placement of the active ingredient name directly above or beside the space provided for the dispensing label.
1.2 Equal prominence on front/main panel of the label	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. The proposed regulatory changes for equal prominence are supported. In addition in is recommended that sans serif font be required for the active ingredient name. This accords with the recommendations in the NHS National Patient Safety Agency *Guide to the graphic design of medication packaging*. The active ingredient name should have equal or greater prominence on all faces of carton where printed.
1.3 Greater than three ingredients	All active ingredients should appear on the main label with a limitation applied to the minimum size of text, that is 2mm.
1.4, 1.5 Day and night preparations / generic labelling	Both proposals are supported.
ii. Proposed warning for paracetamol and ibuprofen products	
1.6 Non-prescription paracetamol labelling	The use of a safety warning to prevent harm caused by duplicate dosing of paracetamol or ibuprofen products is supported. **Paracetamol** Graudins and Gazarian report many cases of paracetamol overdose and toxicity in young children resulting from lack of knowledge by parents of the paracetamol content of commonly used over the counter products (including combination preparations).[4] The proposed wording of the warning does not adequately convey the message that two paracetamol products should not be taken together. The warning required by the MHRA in the UK should be adopted as this warning

	conveys the message more clearly. It reads: **Do not take with any other paracetamol-containing products** - for adults and children over 12 years **Do not give with any other paracetamol-containing products** - for children 12 years of age and under. The size of the font used for the warning should be at least 2mm high. It is suggested that the warning be boxed.
1.7 Non-prescription ibuprofen labelling	The proposal is supported.
iii. Other concerns about size or position of brand and active ingredient names	
Inclusion of strength with medicines name	The strength of the medicine should be prominently displayed with the medicines name. The recommendations from the *TGA Best Practice Guideline on Prescription Medicine Labelling* should be followed. That is: "Both the product name and the active ingredient names and **strength** should be prominently and equally displayed on the packet on at least three sides, including the two end panels. **Strength and quantity** should also be displayed. To assist in easy storage and reference both product and active ingredient names, and strength / quantity, should be displayed on end panels with the first name alternating between the two end panels. There should be consistency in terminology to describe strength. All products in one product line should follow the same convention. The use of 5mg/5mL and 10mg/mL for two products in a product line is strongly discouraged. Expressions of strength should be consistent throughout all labelling, including *Product Information* (PI) and *Consumer Medicine Information* (CMI).'' Standardising the medicine expression of strength on the label would assist consumers understand their medicines and reduce the risk of calculation errors and misinterpretation of strengths by health professionals. The use of strength expressed as a percentage and as a ratio (such as 1 in 1,000) are a cause of error in dose calculation. Standardising the format of drug strength information on labels of injectable medicines substantially improves human performance in selection tasks. Garnerin et al report standardised labels expressing concentration in mg per mL produced the lowest rate of selection errors.[11] It is timely that the practice of expressing oral liquid doses as quantity per 5mL be reviewed and replaced with

	quantity per mL. This would reduce an unnecessary calculation step that is currently required for a number of medicines. Most paediatric doses are calculated as a quantity per body weight. Once the dose is determined the health professional is required to calculate the dose required from a strength expressed in quantity per 5mL. This can lead to errors. Expressing dose per 5mL can also be misinterpreted as dose per mL and result in patients being administered a 5 times dosing error.
	Recommendation 1: Standardise expressions of strength for: • **Oral liquid products as quantity per mL** • **Injections using both quatity/mL and total quantity per total volume in container.**
	To reduce further the risk of error with injectable medicines, recommendations for depiction of strength contained in the NHS National Patient Safety Agency *Guide to labelling and packaging of injectable medicines* should be adopted. Different strengths of the same drug should be expressed in the same manner for example 250mg, 500mg, 1,000mg and not 1g.
Size or position of brand and active ingredient names on Injectable medicines	Recommendations from the NHS National Patient Safety Agency *Guide to labelling and packaging of injectable medicines* should be adopted for labelling injectables medicines. For example: • Creating a front panel that features key information including active ingredient name. (The examples depicted in the publication present the generic name in larger font to the brand name) • Using large, clear font • Using font size and formatting on vials and ampoules that enable the generic name to be read at one glance, this requires orientating text longitudinally on ampoules, pre-loaded syringes and some vials • Using colour to identify names on packages of high risk infusions • Specifying strength in terms of qty/mL and qty/ampoule content.

iv. Additional benefits of making active ingredient name the same size as the brand name	
	Font size is an important determinant of the readability and prominence of information and an important consideration for older users.[12] The United Kingdom's Medicines and Healthcare Products Regulatory Agency, in its *Best practice guidance on labelling and packaging of medicines,* lists relative size of text as the major determinant of due prominence for the active ingredient name but suggests colour of text and font as other factors that may be relevant. Presenting the active ingredient name in same or larger font size will aid in distinguishing the active ingredient name from brand name. Size infers importance. Given the multiple brands of medicines available it is more important for consumers to know the active ingredient name. If it is smaller, there is the risk that consumers will attach less importance to it.
Smallest size font	The font size for active ingredient name should be 16 points consistent with the recommendation in the NHS National Patient Safety Agency *Guide to the graphic design of medication packaging* with an exception for small containers such as eye drop bottles and small ampoules. The smallest font size should be 12 point.
General questions	**What do you think will be the impact of increasing the prominence and standardising the location of the active ingredient on the medicine label?** ▪ Reduced risk of overdosing through taking two products with the same active ingredient. ▪ Increased patient awareness of medicines, which may assist them in making informed decisions around what medicines work well, don't work and which ones cause them adverse effects ▪ Informed selection of medicines purchased by consumers, through enhanced knowledge of active ingredients and experience of what suits them best ▪ Some patients may be confused by the increased information **What do you think of the proposed warnings for paracetamol and ibuprofen containing products?** Given the significant number of accidental overdosing with paracetamol and ibuprofen that occurs annually, steps to reduce these risks are welcome. It is noted that additional warnings have been introduced successfully in other countries. **Are there any concerns you have with the size or position of brand names and active ingredient?** The proposed changes are welcome. Inevitably these changes will not suit everyone. It is hoped however that

	they will minimise risks for the majority. **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?** Improved legibility and an increased likelihood that the consumer would read beyond the brand name. As a result the consumer might take a more proactive role in making informed choices regarding medicines purchased. **What is the smallest size font you consider readable?** 12 point.
3b. Look-alike and sound-alike medicine brand names and look-alike packaging and branding	
1. Will proposed changes to address LASA names and LA packaging improve medication safety?	
3.1 LASA names risk assessment	*Labelling Round Table Report Recommendation 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. (* Submitting proposed naming and packaging risk assessment evidence is supported. Routine use of electronic risk screening to identify potential LASA names should be mandatory. An existing program, such as that used by Health Canada and the United States Federal Drug Administration, could be adapted for use in Australia. Introducing a standardised risk assessment process to assess the risk of confusable names in terms of likelihood and severity of harm after identification by screening is supported. It is recommended that medication safety experts are included along with the TGA and industry in the development of the process and a national group, such as that proposed for the labelling and packaging advisory committee, also be consulted in the development. **Why?** LASA names are a common cause of medication error and many examples are available in the literature. Around 25% of medication incidents reported to voluntary error reporting systems in the US errors involve name confusion. [6] Reducing errors from look-alike sound-alike medicine names is one of the World Health Organization's nine patient safety solutions.[7]

	It is important that the potential for confusion of a medicine brand name is assessed prior to the drug reaching the market. Electronic screening tools have been developed to measure similarity between drug names and are used in other jurisdictions including Canada and the US. Computerised screening tools are objective and are able to compare proposed names to a large number of existing names, a task suited to automation. The use of a screening tool will enable proposed names that are similar to existing names to be identified and then assessed for potential risk to patient safety using the proposed standardised risk assessment process. This should include testing by consumers and health professional involving simulated clinical processes. Having a standardised assessment process in Australia would streamline product review, provide a consistent assessment across the industry and provide transparency to the decision making process.
3.2 Contrast with pre-existing ARTG names	The approach of using the number of differing letters in a name to identify LASA names does not seem to be logical. Drugs with long names may have many similar letters. It would be better to identify confusable names using electronic tools mentioned in 3.1 to measure orthographic (look-alike) and phonetic (sound-alike) similarity. [13] Risk assessment should be undertaken (as outlined above) when similarity is established. The Commission supports the process of using distinctive product labelling as a risk mitigation strategy if the name is similar and clinical risk is felt to be justifiable. However, an alternative name **must** be required when similar brand names are found and determined to pose a risk to patient safety. When 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 if risk is identified. Distinctive product labelling could include the use of Tall Man lettering to distinguish similar names of drugs when risk of confusion could cause harm. (See *Other Issues and solutions* on page 20) It should be noted that distinctive labelling and colour differentiation does not address the problem of confusion of look-alike medicine names grouped together in drop down lists in electronic prescribing and dispensing systems. This is an area in which selecting incorrect medicine names is likely to increase with the introduction of electronic systems for prescribing and administering medicines in health services. In these circumstances, consideration needs to be given to changing brand names rather than using distinctive labelling.
3.3 Applications to change existing naming	This regulatory change as proposed does not address the problem of look-alike packaging. The Commission proposes acting on recommendations 7 and 8 from the *Labelling Round Table Report* to reduce

and packaging	the risk of harm from look-alike packaging. *Recommendation 7: Develop guiding principles for clinical safety assessment of labelling and packaging* *Recommendation 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*. Packaging design should take into account the needs and capabilities of the widest range of potential users. This includes: • older and partially sighted consumers and how they manage the medicine in their home • health professionals taking into consideration how they identify, classify and differentiate between medicines packaging. It is estimated that a third of medication error are caused by confusion over packaging and labelling instructions. In Australia, packaging (including similar–looking containers and packaging) has been identified as causing 30% of therapeutic errors occurring with in children in the community reported to an Australian poisons information centre. Limiting changes to packaging only if names are similar will not reduce errors from similar packaging. Selection errors occur with completely different drugs when similar labelling and packaging is used. For example Midazolam and Cis-atracurium, Coversyl and Coumadin, (see Figures 1 and 2 in Appendix 3). Regulatory reform is needed for look-alike packaging as well as LASA medicine names. Objective ways of looking for similar labelling and packaging should be introduced, such as the use of an electronic screening tool. Consumer testing of packaging (and that includes health professionals) should be part of pre-market assessment processes. The recommendations on packaging colour and design contained in the TGA's *Best Practice Guideline on Prescription Medicine Labelling* should be applied. This is particularly so when "corporate livery" is used by companies and where there are different strengths or presentations of products.
General question	**Do you think the proposed changes to address LASA names and LA packaging will improve medicine**

	safety? Why/why not? Electronic screening and use of different coloured packaging are positive steps towards labelling and packaging differentiation. Electronic means of identifying and avoiding product name similarity is likely to reduce confusion from misreading prescriptions and changes in packaging may assist in reducing selection errors during the dispensing process. Confusion may still arise when medicines are 'pre-packed' and labelled for use at ward level. In this case the visible differences in packaging will be eliminated if the preparation is no longer in the original pack. This is especially an issue when several different tablet strips may be placed into bedside drawers of patients during their inpatient stay unless blister strips are distinctly different.
3c. Look-alike medicine branding	
i. Benefits of proposed changes for consumer safety	
3.4, 3.5 Limitations on marketing, extension marketing	*Labelling Round Table Report Recommendation 3: Undertake a review of brand extension regulations and ensure that safety and quality concerns are addressed. Include elements of the TGA* Best Practice Guideline on Prescription Medicine Labelling *relating to brand extension or corporate naming in the labelling order*. The proposed changes are supported and should reduce the risk of error from look-alike medicine branding (i.e. brand extension) which can result in consumers taking the same medicine twice and doubling the dose. With a medicine such as paracetamol this can be serious. Graudins and Gazarian report many case of paracetamol overdose and toxicity in young children resulting from lack of knowledge by parents of the paracetamol content of commonly used over the counter products (including combination preparations).[4]
3.6 Brand extension	There will be less risk of consumers taking a medicine to which they have a known allergy as may occur where the same brand name contains a different active ingredient.
	The "branding" of many new generic medicines has the potential to cause confusion for patients, pharmacists and prescribers.[1 14] The proposed changes will not address problems with look alike branding of generic products in which the prefix or suffix is used to denote the brand. Examples include Apotex products, which have the prefix APO added to the active ingredient name, as in APO – Amisulpride, APO –Atorvastatin, or the Novo Nordisk range of insulin that is labelled with the prefix Novo, as in NovoRapid and NovoMix. Such prefixes may cause medication errors in electronic prescribing and dispensing systems when an incorrect product is selected from the drop-down menu or from pharmacy shelving if medicines are stored alphabetically by brand name. Ascent

	Pharmaceuticals has three different suffixes/prefixes for its generic products (GA, GN, DP). It is difficult for health professionals to ascertain which medicines a consumer is taking when they give the prefix/suffix or the sponsor's name as the name of the medicine.[14] The current level of confusion about branded generic products indicates a need to review brand names for generic products.
	Recommendation 2: Require that generic medicine names: • **Be limited to the active ingredient name** • **Cannot include prefixes incorporating part, or all, of the sponsor's name with the active ingredient.**
	The use of non-standard suffixes as part of medicine brand names can be a source of misunderstanding about duration of action and dosing intervals and can lead to errors. [14] Non-standard suffixes are used to indicate special release properties such as longer duration of action, as in sustained release (SR) or extended release (XR). The use of standard nomenclature for special release properties would reduce confusion and harm from errors resulting from misinterpretation of these suffixes.
3d. Medicine information box	
	Standardising the presentation of information on medicines labels is supported.
General questions	**To what extent do you think a standardised format for information on the labels of over-the-counter and complimentary medicines will improve access to information for these medicines?** Particularly in the case of complimentary medicines, information around active ingredients, uses and warnings, doses, directions and side effects can be difficult to access. Standardised information would therefore be an improvement. **Are there other ways that the presentation of information could be improved?** It would seem that the best location is for the information to be attached to the label, with other medicines related information, as package inserts are readily discarded. With the advances in smart technology, availability of trusted information via the internet and via apps will be increasingly sought after. **Do you think the proposed requirements for products with more than three active ingredients (directions, warnings and allergy information) is [sic] sufficient for these products? Please provide an alternative if you don't agree with current recommendations.**

	There will always be a balance between providing the information on the packet and the space available to provide the information in a legible manner. In this case, readily available access to further information would be important where the space available on the packaging is limited.
3f. Dispensing label space	
i. Support for a designated space for the dispensing label on prescription medicines	
5.1. Designated space	Making available a clearly designated space of a minimum of 70 x 30mm, the most common size of dispensing labels, is available for the dispensing label on prescriptions medicines is supported.. **Why?** Having a designated space for the dispensing label standardises the placement of consumer instructions on the package. It also avoids the dispensing label covering up important information such as the medicines name, batch number and expiry date. It is a recommendation from the TGA *Best Practice Guideline on Prescription Medicine Labelling* and is supported by consumers.
5.2 Alternative information arrangement	It is recognised that a dispensing label space will not be possible for all containers, especially small containers, and will not be appropriate for some medicines such as injectable medicines not self administered by consumers.
5.3 Small container alternative	A clear space on the label of small containers to affix the edges of a folded dispensing label is supported.
3f. Blister strip labelling	
i. Is proposed information for blister strips sufficient?	
6.1. Information repeated once every two units	It is not considered adequate that the active ingredient name, amount of active ingredient, batch number and expiry date are repeated once every two units. Each unit should be labelled with the information repeated on each unit. If the information is not repeated on all units then it is possible for the remaining tablets not to be labelled or identifiable. For example. This can occur when the pack is cut for dispensing (as occurs in hospitals) or the tablet or capsule is removed from the blister pack by consumers or nurses.

6.2 Segment labelling	This proposal is supported.
6.5 "Race track format" blister packs	It is important with "race track format" packs, and that are designed to assist consumers adhere to their medication regimen, that the label is positioned in such a way that the name, strength, batch number and expiry dates are not removed when the tablets are extruded.
ii. Other changes to blister packaging	
	Provision should be made for two-dimensional machine readable codes (bar codes) to be printed on each unit to facilitate implementation of bar code checking throughout the medication distribution chain to the patient's bedside in hospital.
	The design recommendations for primary packaging of blister packs in the NHS *Guide to the graphic design of medication packaging* should be adopted. For example, a products primary and secondary packaging should have identical or linked visual style created through, for example, colour. This will enable patients taking more than one medicine, or two or more strengths for the same medicine, to be able to identify which blister belongs to which packet as the prescription instructions are attached to the secondary packaging.
3g. Small containers	
i. Support for proposed regulatory changes	
7.1, 7.2, 7.3	All the changes are supported. In addition the requirement for at least equal prominence of active ingredient and brand name should be applied to primary label. Active ingredient name and strength on the primary label should not be less than 2mm.
3h. Pack inserts	
i. Support for proposed changes for pack inserts	
8.1.	The changes are supported. **Why?** Rationale is that stated in the consultation paper. Advertising material should not be presented alongside information on the use of products. This could deter consumers from reading important information relating to safe use of the product. For prescription medicines, this would be a form of direct to consumer advertising.

8.2.	The changes are supported. **Why?** Rationale is that stated in the consultation paper. Consumers, including health professionals, should not have to cut the primary packaging to access important information on the use of the product. There is also the risk that the information will be overlooked.
3i. Labels and packaging advisory committee	
i. Establishment of a labels and packaging advisory committee	
	The Commission fully supports the proposal to establish an expert advisory body providing advice to the TGA on general and specific matters relating to medicines naming labelling and packaging. The committee would be enhanced by including: • one or more medication safety representatives from state and territory safety and quality branches or agencies • a representative from a jurisdictional poisons information centre • a representative from the Council of Therapeutic Advisory Groups. These representatives hold information from incident reporting systems on medicines labelling issues that have occurred in the acute care sector. They can access community information relating to admissions, emergency department presentations and poisons information centre calls relating to errors caused by confusion with naming, labelling and packaging. The advisory committee would be able to provide advice on: • developing a pre-market assessment process that includes: o electronic screening for confusability of names **and** packaging o development of a process for determining likelihood and potential risk of harm from confusable naming, labelling and packaging • developing a post-marketing assessment process in which errors have been reported from confusable naming, labelling and packaging • determining the level of harm resulting from actual or potential naming, labelling and packaging

	confusion and whether alternative names, labels or packaging or differentiation of labelling and packaging is required • identifying medicines to which the application of Tall Man lettering should be considered.
General question	**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?** Outcomes from committees and other advisory groups are optimised when the following conditions apply: a) The goals and direction are clear b) The roles, responsibilities and accountabilities of each member are clear c) Processes are clear and don't give rise to undue conflict d) Collaboration with other key agencies with common interest is effective In addition to the above, task focused groups provided the best return in terms of input versus output. So, if you have the right members, structure and process, an advisory committee is likely to provide valuable insights and can assist in developing options and solutions. Outcomes may be enhanced further through an effective chair or facilitator.

4. Other issues and solutions

There are a number of strategies for improving the safety of medicines naming, labelling and packaging in Australia that have not been addressed in the consultation paper or are considered out of scope of the review. The Commission recommends these be considered alongside the current regulatory review and incorporated into the reform of medicines labelling.

The additional strategies are the use of:

1. Machine readable codes
2. Tall Man lettering
3. Colour and warning labels for specific high risk medicines
4. Best practice guideline on prescription medicine labelling

1. Machine readable codes

The use of machine readable codes to check that the correct medicine has been selected for dispensing or administration to a patient is an important innovation in patient safety. The Commission considers its absence from the review a deficiency.

The Commission recommends inclusion of machine readable codes (bar codes) on all medicines labels and has previously provided advice to the TGA on this issue.

There is a significant body of literature to support the use of bar code checking to reduce errors in the medication management processes of:

- dispensing and supplying items
- distributing and storing medicines within healthcare facilities such as ward cupboards, medication trolleys or patient bedside lockers
- administering medicines including selection, preparation and administration to the correct person and, when required, a record of the medicines administered and the health professional administering the medicines.

Within all these processes there is the risk that a wrong product can be given to the wrong patient. It is estimated that only 34% of dispensing and 2% of administration errors are caught prior to reaching a patient.[15] Bar-code checking has been shown to decrease substantially hospital dispensing and administering errors. It enables healthcare professionals to verify that they are giving the right drug in the right dose through the right administration route to the right patient at the right time. It is especially powerful when bar codes are affixed to medications at the dose unit level.[16-18] Bar code technology can be used to check that the correct formulation is administered (such as that an oral formulation is not being administered by injection) and the patient has no known allergies or adverse reactions to the medicine.

The *Report on the National Round Table on Safer Naming, Labelling and Packaging of Medicines* included a Recommendation 11 that the TGA:

> *Consult on the options of introducing two-dimensional machine readable (QR) codes on medicines packaging.*

With new developments, such as two dimensional, quick response codes, there are opportunities for additional information (such as CMI and content of pack inserts) to

be accessed through medicines packaging through smart phones and other technologies by consumers.

The implementation of electronic medication management systems for prescribing, dispensing and administering medicines that is occurring in the acute and residential care sectors will enable the introduction of bar code checking at the patient or resident bedside. It is essential that machine readable codes are included in any change to labelling regulations.

The same considerations for using bar codes on prescription medicines apply equally to non-prescription and complementary medicines, reducing the of risk of selection errors when dispensing or administering the product. Some non-prescription medicines and complementary medicines are used within hospitals and residential care facilities, and are also subject to product recalls, and would therefore benefit equally from bar coding.

Recommendation 3: Require machine readable codes on all medicines labels in the labelling and packaging regulatory changes.

The recommendation on the location of the bar code in the TGA *Best Practice Guideline on Prescription Medicine Labelling* should be adopted, that is it should be in a location that is not be covered up by the pharmacist's dispensing label.

2. Tall Man lettering

The use of Tall Man lettering has been identified as a strategy to reduce the risk of medication error and harm from LASA medicines names. It is disappointing that it has not been included as part of this review and the Commission request reconsideration of this decision.

The Commission has developed and maintains a National Tall Man Lettering List of medicines to which Tall Man lettering is applied. The drug name pairs and groups have been assessed as confusable and likely to cause harm if confused. Tall Man lettering is recommended for use on printed labels used for inpatient dispensing, shelving in pharmacies, ward medicines cupboards, and in electronic medicines management systems and drug libraries for infusion pumps. The Commission supports extending this recommendation to medicines packaging. It could be one of the mechanisms employed to make labelling of LASA names distinctive.

The use of Tall Man lettering on manufacturer labels has been taken up by medicines regulators in other countries. For example, the FDA maintains a list of medicine names that require Tall Man lettering to be applied on medicines labels. The NHS National Patient Safety Agency *Guide to the graphic design of medication packaging* recommends the use of Tall Man lettering on manufacturer labels.

Recommendation 4: Require that Tall Man lettering be applied to product labels of prescription medicines listed in the *National Tall Man Lettering List*.

3. Colour and warning labels for specific high risk drugs

The TGA *Best Practice Guideline on Prescription Medicine Labelling* includes additional labelling and packaging recommendations for the high risk drugs potassium, vinca alkaloids and methotrexate tablets. These recommendations should be included in the regulatory changes.

Recommendation 5: Require distinctive labelling and packaging requirements for potassium, vinca alkaloids and methotrexate tablets in labelling regulatory changes.

Neuromuscular blocking agents

Inadvertent administration of neuromuscular blocking agents in error for another anaesthetic agent is a recurring error in Australian hospitals. It can have devastating consequences and has been the subject of at least one coronial inquiry. In Canada and the US, the labelling and packaging of neuromuscular blocking agents is required to be made distinctive through the use of the colour red and warning labels. It is recommended that a similar labelling and packaging requirement be introduced in Australia.

Recommendation 6: Require distinctive labelling and packaging of neuromuscular blocking agents in labelling regulatory changes.

4. Best practice guideline on prescription medicine labelling

Report on the National Round Table on Safer Naming, Labelling and Packaging of Medicines Recommendation 5 was to:

> *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.*

The review is an opportunity for considering a number of items that could improve the safety of medicines labelling and that are contained in the *Best Practice Guideline on Prescription Medicine Labelling*. These include recommendations on:

2. Batch number and expiry date

3. Storage conditions

4. Bar codes

5. Product strength

6. Dose form

7. Packaging colour and design: as they relate to “corporate livery”

9. Specific Australian issues as they relate to labelling and packaging of potassium, vinca alkaloids and methotrexate.

10 General issues: with respect to using positive statements on labels e.g “For intravenous use only”

Evidence that the design and content of medicines labels can influence the safe use of medicines is growing in the context of knowledge about the role of human factors in this area. Medication incidents are the second most common incident reported in health services and with many of the incidents resulting from LASA names and poorly designed labelling and packaging. Reform of medicines labelling in Australia should also include a review of the *Best Practice Guideline on Prescription Medicine Labelling* www.nrls.npsa.nhs.uk/resources/collections/design-for-patient-safety/?entryid45=63053 and the *Guide to labelling and packaging of injectable medicines* www.nrls.npsa.nhs.uk/resources/collections/design-for-patient-safety/?entryid45=59831 as outlined in the *Report on the National Round Table on Safer Naming, Labelling and Packaging of Medicines*. This review should be undertaken alongside the TGA *Medicines Labelling and Packaging Review* to enable industry to make the required labelling and packaging changes in a one step process.

Recommendation 7: Action Recommendation 5 from the *Report on the National Round Table on Safer Naming, Labelling and Packaging of Medicines*.

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

List of round table attendees

Name	Position	Organisation
Ms Carol Bennett	Chief Executive Officer	Consumers' Health Forum
Mr Graham Bedford	Program Manager, Medication Safety	Commission
Ms Nicki Burridge	Publications Coordinator	Society of Hospital Pharmacists of Australia
Ms Elizabeth de Somer	Regulatory Affairs Manager	Medicines Australia
Ms Anne Develin	National Manager, Regulatory Affairs	Pharmacy Guild of Australia
Ms Margaret Duguid	Pharmaceutical Advisor	Commission
Ms Paula Elliott	Quality & Accreditation Coordinator – ACT Community Health	Royal College of Nursing of Australia/Australian Nursing Federation
Ms Karen Kaye	Executive Manager, Quality Use of Medicines	NPS: Better Choices Better Health
Dr Megan Keaney	Principal Medical Advisor	Therapeutic Goods Administration
Mr Daniel Lalor	Project Manager, Medication Safety	NSW Clinical Excellence Commission
Mr Bill Lawrence AM	Acting Chief Executive	Commission
Dr Jocelyn Lowinger	National Coordinator	Council of Australian Therapeutic Advisory Groups
Ms Kate Lynch	Chief Executive	Generic Medicines Industry Association
Ms Judith Mackson	Chief Pharmacist	NSW Health
Ms Alison Marcus	Consumer representative	Consumers' Health Forum
Mr Toby Mathieson	Program Manager, Electronic Medication Management	NEHTA
Mr Alastair McDougall	Pharmacist Consultant Pharmacy Improvement Program	Health Support Services, NSW Health
Prof Andrew McLachlan	Chairman	National Medicines Policy Committee
Mr Albert Regoli	Sydney Director	Pharmaceutical Defence Limited
Dr Harry Rothenfluh	Head, Office of Medicines Authorisation	Therapeutic Goods Administration
Dr Brendan Shaw	Chief Executive	Medicines Australia
Dr Deon Schoombie	Executive Director	Australian Self Medication Industry
Ms Kay Sorimachi	Director Policy and Regulatory Affairs	Pharmaceutical Society of Australia
Ms Danielle Stowasser	Clinical Adviser, Quality Use of Medicines	NPS
Dr Linda Swan	Member	National Medicines Policy Committee

The full report is available from the Commission web site at www.safetyandquality.gov.au/wp-content/uploads/2012/05/National-Round-Table-on-Safer-Naming-Labelling-and-Packaging-Report.pdf

Equal prominence of active ingredient and proprietary names on labels for prescription medicines

March 2009

Overview

The Consumers Health Forum of Australia (CHF) ***strongly supports greater prominence of the active ingredient than the proprietary name*** on prescription medicines labels. This is an important measure in helping consumers achieve Quality Use of Medicines and avoid adverse medicines events.

CHF consumer engagements show that while the level of consumer knowledge about the difference between medicines' active ingredients and brand names has improved in recent years, there is significant ignorance, misinformation and confusion in the community. We 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. Having greater prominence of the active ingredient than the brand name on labels for prescription medicines is consistent with the Government's current emphasis on assisting consumers to self-manage their health.

Consumer experiences where confusion of brand and generic names have resulted in adverse events, or there was potential for an event to occur

CHF has received numerous reports of potentially serious errors with different preparations of paracetamol in both community and hospital settings. The following case studies illustrate this point:

- In the community setting, errors made by people with reasonable health literacy. This indicates that even when consumers have taken responsibility in seeking out health information, they need structural supports, including adequate medicines labelling, to complement their self-management strategies.

- The report of errors in a hospital setting involving junior nursing staff, who were not aware that two preparations both contained paracetamol. 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, particularly at a junior level, also need clear active ingredient labelling on medicines.

- Consumers unable to answer questions from their health care provider about whether they are taking particular medicines because sometimes the brand name is used in the question, and sometimes the active ingredient. This is a serious issue in terms of preventing adverse medicine events. Having both names in the label

would promote better communication between health providers and consumers, which is very important in avoiding medicines interactions and overdoses.

- Consumers undertaking Home Medicines Reviews and finding out that they are taking multiple prescriptions of the same active ingredient, but have not realised because of the different brand names of each. While this is attributable in part to the problems associated with having different sources of prescriptions, this is a circumstance that is common to many people with ongoing health conditions (for example, through being prescribed medicines by the different health professionals involved in their care, including while in hospital). The most practical way forward would be for the active ingredient to be given greater prominence than the brand name at every stage of health care, including on medicines' labels. As one consumer noted:

  "With having haemophilia it is common for you to have to see different doctors and when they take a history the list of medications is always asked for. It is common to know the medication by its brand name… however the doctor usually will know it by its initial name or active ingredient. I take a tablet called Aldactone (that is the brand name). Doctors know this drug as spirolactone and I have noticed them looking up the brand name in Mims. There are also other drug brand names for spirolactone, and the individual brand name often correlates to the amount of active ingredients i.e. Brand name A is a 25mg tablet of active ingredients whilst brand name B is 50mg of active ingredients.

- Seniors who come home from hospital with tablets marked clearly with the active ingredient, but think that their 'old' tablets are not the same because they think of them with their brand name. They therefore take both medicines, thus risking an overdose.

- Consumers report difficulty in finding the active ingredients on a bottle or packet of medicine, as the direct consumer as well as a parent looking for active ingredients. An example of this is a consumer reporting having had a lot of problems with compound medicines such as flu and cold preparations, as these preparations could have paracetamol or aspirin, which has negative health consequences for some people.

Views on improving recognition of active ingredients on medicines labels

Consumer views as to how greater prominence of active ingredients could be achieved on medicines labels include:

- The active ingredient label must be clearly visible, and the labelling format of active ingredient and brand name must be consistent. One consumer view is:

  "Make the position for the list of active ingredients consistent on every type of medication. That is one of the major problems, you don't know if it is on the front, back or sides. Where ever it is agreed for the list to be placed it has to be consistent."

- The labelling needs to be very clear, with a font and colour able to be seen easily:

"At the moment the list of active ingredients (LAI) is usually so small I have no hope of reading the label without my glasses. I know that at some point an individual has to take responsibility, such as making sure you have your glasses, but the minimum size font could be set at a size that can be read by most people with an allowance for some degree of vision impairment."

- CHF has also received feedback that people are having difficulty with medicines labelling when trying to pick a product which is safe for children. For some consumers. the issue is not only having equal prominence of brand name and active ingredient, but also needing to have information on the *quantity* of active ingredient to be clearly marked on the label:

  "I want to make sure the medicine is appropriate for children and what is in it. A typical ingredient I wish to know is whether cold and flu medication contains paracetamol and/or pseudoephedrine, and how much. I want to make sure the child is getting the appropriate amount of active ingredients, say paracetamol, and also know that we should <u>not</u> give any additional paracetamol tablets. I also want to avoid tablets containing pseudoephedrine."

- 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. Points below illustrate this:

  - The active ingredient and brand name should be co-branded, with the active ingredient first and in larger font than the brand name. This is done with a view to improving consumer awareness of the medicines they are taking.

  - Only the active ingredient should be used on the label (i.e. not equal prominence). This comment is based on the view that it is the active ingredient that consumers need to recognise in order to manage their medicines safely.

  - The active ingredient needs to be in bold black at the top, with the brand name smaller and in plain (unbolded) print underneath.

Conclusion

Consumers believe that there must be greater opportunity for the recognition of active ingredients on their medicines. The greater prominence of active ingredient than proprietary name on medicines labels needs to be recognised as integral to consumers' quality use of medicines. This is illustrated well by one consumer comment:

"There needs to be a change in culture whereby the consumer understands their medication by active ingredient and amount of active ingredient instead of by brand name only, which is the usual case. I often hear elderly people, at pharmacy or chemist shop being confused because the brand name is different – and the chemist can have a great deal of trouble trying to explain the change."

Comments such as these indicate that current medicines labelling may be creating additional work for health care professionals. This is likely to translate into additional time and financial costs for consumers. Supporting consumers to become more educated about their medicines through having greater prominence of active ingredient than proprietary names will foster their skills in self-management and allow them to be equal partners in their own healthcare.

Background information

The Consumers Health Forum of Australia Inc (CHF) is the national voice for health consumers. As an independent non-government organisation, CHF helps shape Australia's health system by representing and involving consumers in health policy and program development.

Health consumers have a unique and important perspective on health as the users and beneficiaries of health care and, ultimately, those who pay for it. CHF takes consumers' views to government and policy makers, providing an important balance to the views of health care professionals, service providers and industry to achieve a health system that reflects the needs of all stakeholders.

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

Current priorities include safety and quality in health care, safe and appropriate use of medicines and health care for people with chronic conditions. CHF also facilitates the appointment of consumer representatives on over 200 national health-related committees.

CHF believes all consumers should receive affordable, safe, good quality health care at the time they need it. The best outcomes are achieved when consumers are involved in decisions about and management of their own health care. Consumers should receive health care information when they need it in a form they can understand, particularly about using medicines.

Established in 1987, CHF receives funding from the Australian Government Department of Health and Ageing and membership fees. It seeks external funding for priority projects.

With its ability to access a variety of health consumer networks and extensive knowledge of consumer issues, CHF is a respected and influential contributor to the Australian health debate.

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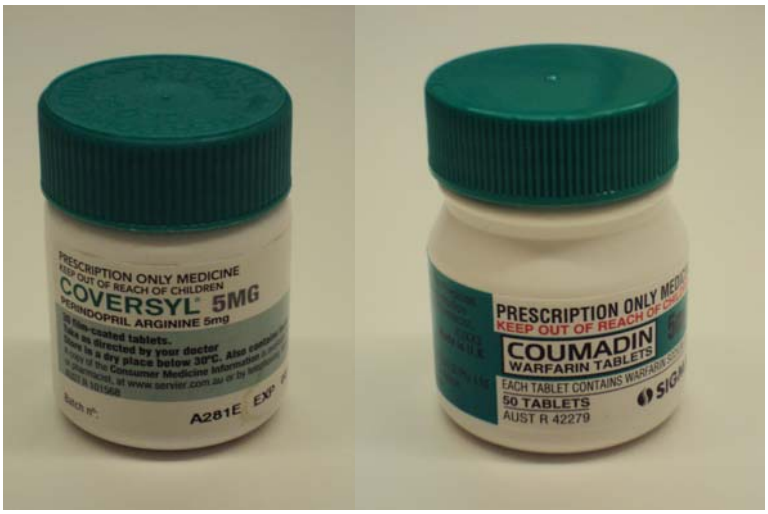
Appendix 3

Examples of confusing packaging which resulted in harm or near misses in Australia

Figure 1: The two drugs pictured below (cis-atracurium, a paralysing agent and midazolam, a benzodiazepine used for sedation) are used quite commonly in anaesthesia. The glass ampoules of both the drugs look quite similar (midazolam is the top ampoule) and hence the potential for confusion.

A near miss was reported by a health service to the Commission and which involved cis-atracurium which was administered instead of midazolam. Fortunately this was immediately recognised and addressed otherwise the patient would have been paralysed and unable to breathe.

Figure 2: The drug packaging below resulted in confusion in community pharmacies with consumers incorrectly dispensed Coumadin instead of Coversyl and vice versa.



6. References

1. Carney SL, Gazarian M, Denholm JT, et al. What's in a name? Brand name confusion and generic medicines. *MJA* 2011;195:650-51.
2. Taylor DMcD, Robinson J, MacLeod D, et al. Therapeutic errors among children in the community setting:nature, causes and outcomes. *J Paediatrics and Child Health* 2009;45:304-09.
3. Taylor DMcD, Robinson J, MacLeod D, MacBean C, et al. Therapeutic errors involving adults in the community setting: nature, causes and outcomes. *ANZ J Public Health* 2009;33(4):388 - 94.
4. Graudins LV, Gazarian M. Promoting Safe Use of Paracetamol in Children. *J Pharm Pract Res* 2006;36(4):297-300.
5. Guchelaar H-J, Kalmeijer MD, Jansen M. Medication error due to ambiguous labelling of a commercial product. *Pharm World Sci* 2004;2004(26):10-11.
6. Bermann A. Reducing Medication Errors through Naming, Labeling and Packaging. *Journal of Medical Systems* 2004;28(1):9-29.
7. WHO Collaborating Centre for Patient Safety Solutions. Look-Alike, Sound-Alike Medication Names. *Patient Safety Solutions*: World Health Organisation, 2007.
8. Australian Commission on Safety and Quality in Health Care. National Medication Safety and Quality Scoping Study Committee Report. Sydney: ACSQHC, 2009.
9. McLachlan AJ Ramzan I Milne RW. Requently asked questions about generic medicines. *Australian Prescriber* 2007;30(2):41-43.
10. Sorensen l, Stokes JA, Purdie DM , et al. Medication management at home: medication related risk factors associated with poor outcomes. *Age and Ageing* 2005;34:626-32.
11. Garnerin P, Perneger T, Chopard P, et al. Drug Selection error in relation to medication labels: a simulation study. *Anaesthesia* 2007;62:1090-94.
12. Hellier E Edworthy J Derbyshire N Costello A. Considering the impact of medicine label design characteristics on patient safety. *Ergonomics* 2006;49(5-6):617-30.
13. Kondrak G, Door B. Automatic identification of confusable names. *Artif Intell Med* 2006;36(1):29-42.
14. Graudins LV, Dooley MJ. Generic medicines literacy - minimising the potential for patient confusion. *MJA* 2010;193(7):427.
15. Bates D. Using information technology to reduce rates of medication errors in hospitals. *BMJ* 2000(18 March 2000):788-91.
16. Foote SO CJ. Medication administration: the implemenation process of bar-coding medication administration to enhance medication safety. *Nursing Economics* 2008;26(3):207-10.
17. Franklin BD OGK, Donyai P et al. The impact of a closed-loop electronic prescribing and administration system on prescribing error, administration errors and staff time: a before-and- after study. *Quality and Safety in Health Care* 2007;16(4):279-84.
18. Poon E, Cina J, Churchill W, Patel N, Featherstone E, Rothschild J, et al. Medication Dispensing Errors and Potential Adverse Drug Events before and after Implementing Bar Code Technology in the Pharmacy *Annals of Internal Medicine* 2006;145(6):426-34.
19. Shrank WH Agnew-Blais J Choudry NK et al. The variability and quality of medication container labels. *Archives of Internal Medicine* 2007;167(16):1760-65.
20. National Patient Safety Agency and Helen Hamlyn Research Centre NHS. *Design for patient safety A guide to the graphic design of medication packaging*. 2 ed: National Pateint Safety Agency, 2007.
21. National Patient Safety Agency NHS. *Design for Patient Safety A guide to Labelling and packaging of injectable medicines*. 1 ed: National Patient Safety Agency 2008.