

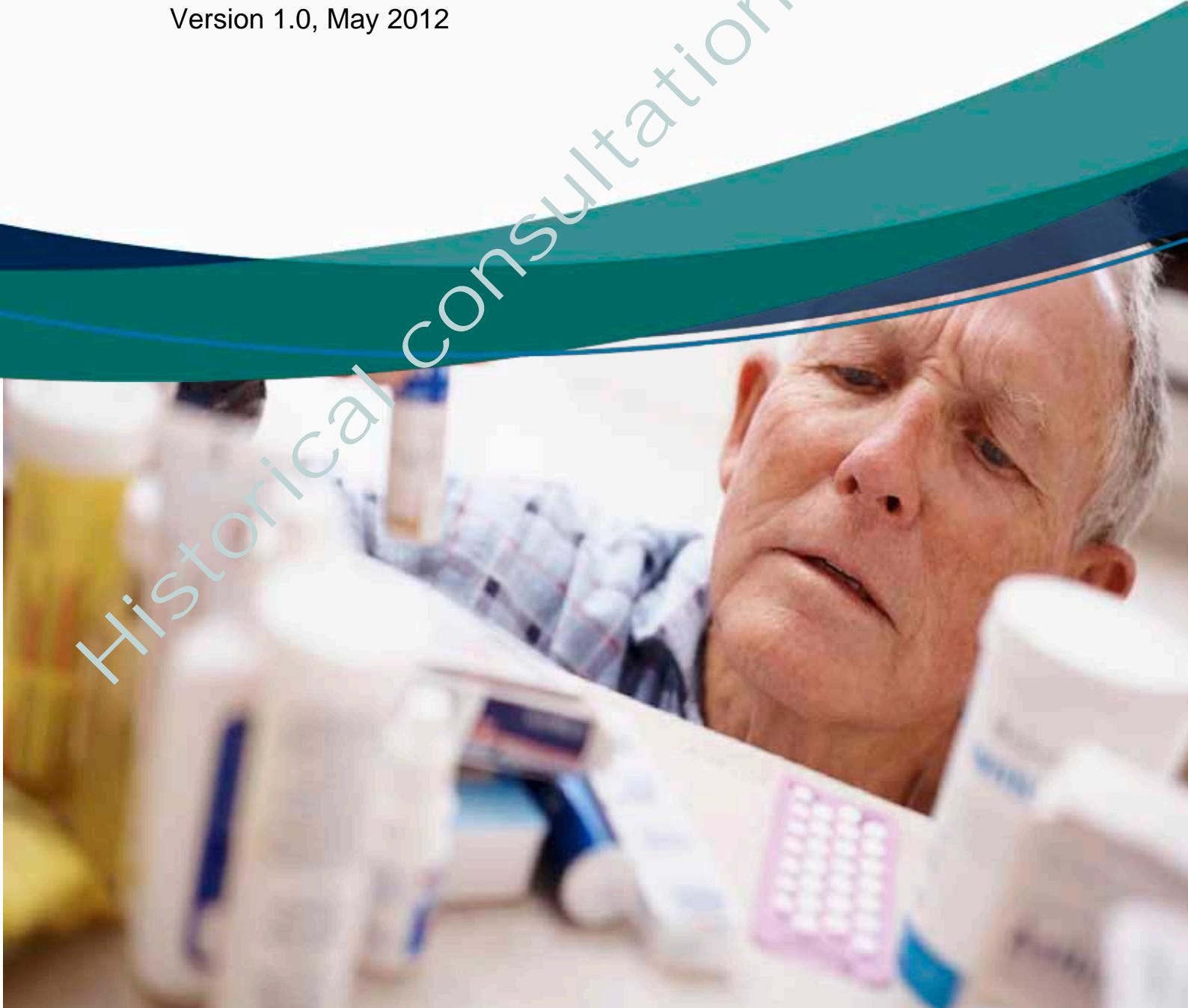


Australian Government
Department of Health and Ageing
Therapeutic Goods Administration

TGA Medicine Labelling and Packaging Review

Consultation Paper

Version 1.0, May 2012



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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Introduction

Regulation of medicines in Australia

The TGA is the Commonwealth Government agency responsible for making decisions about whether to approve a therapeutic good for supply in Australia. The TGA regulates a range of therapeutic goods, including prescription medicines, non-prescription medicines, complementary medicines, medical devices and biologicals. The focus of this consultation is the following types of therapeutic goods:

- **prescription medicines**: medicines that must be prescribed by a health care professional with prescribing rights
- **non-prescription medicines**: medicines you can buy without a prescription from pharmacies and grocery stores
- **complementary medicines**: herbal or natural products that you can buy from pharmacies, health food stores and grocery stores

Before a therapeutic good can be marketed in Australia, it must be approved by the TGA and entered on the Australian Register of Therapeutic Goods (ARTG). Where the TGA is not satisfied that a medicine meets safety, quality and, where applicable, efficacy criteria, approval is not granted. Interested persons can access and search the ARTG on the [TGA website](#).

Medicines that are registered on the ARTG have been assessed by the TGA against quality, safety and efficacy criteria. This includes all prescription medicines and non-prescription medicines, such as pain killers and hay fever medicines. Medicines that are listed on the ARTG have been assessed against quality and safety (but not efficacy) criteria. This includes most complementary medicines.

All medicines carry some risk to consumers and in making decisions about whether or not to approve a medicine, the TGA assesses whether the benefits that it could provide to consumers outweighs the risks to consumers. For example, an anti-cancer treatment may have serious side effects but may nevertheless be approved by the TGA because of its ability to treat a life-threatening condition.

Once a medicine has been approved for supply in Australia, the TGA monitors its ongoing safety and quality by conducting a range of monitoring activities, such as audits of efficacy, manufacturing facilities, collection and assessment of adverse reaction reports and laboratory testing of product samples. The TGA also works with international medicines regulators to identify signals that may indicate a safety issue associated with a medicine. Where such signals are detected, the TGA has the powers to take appropriate regulatory action, including product recalls, requiring the addition of warning statements to medicine labels or adding conditions to the continued supply of the medicine.

How the TGA contributes to the quality use of medicines by Australian consumers

The TGA administers the therapeutic goods legislative framework within the context of the [National Medicines Policy](#), which is a collaborative arrangement between the government and bodies that represent healthcare practitioners, pharmacists, medicines consumers, medicines industry and the media to improve the health of Australians by delivering on the following overarching objectives:

1. Timely access to the medicines that Australians need at a cost individuals and the community can afford
2. Medicines meeting appropriate standards of quality, safety and efficacy
3. Quality use of medicines
4. Maintaining a responsible and viable medicines industry.

The TGA's contributions to the National Medicines Policy are illustrated in Figure 1.

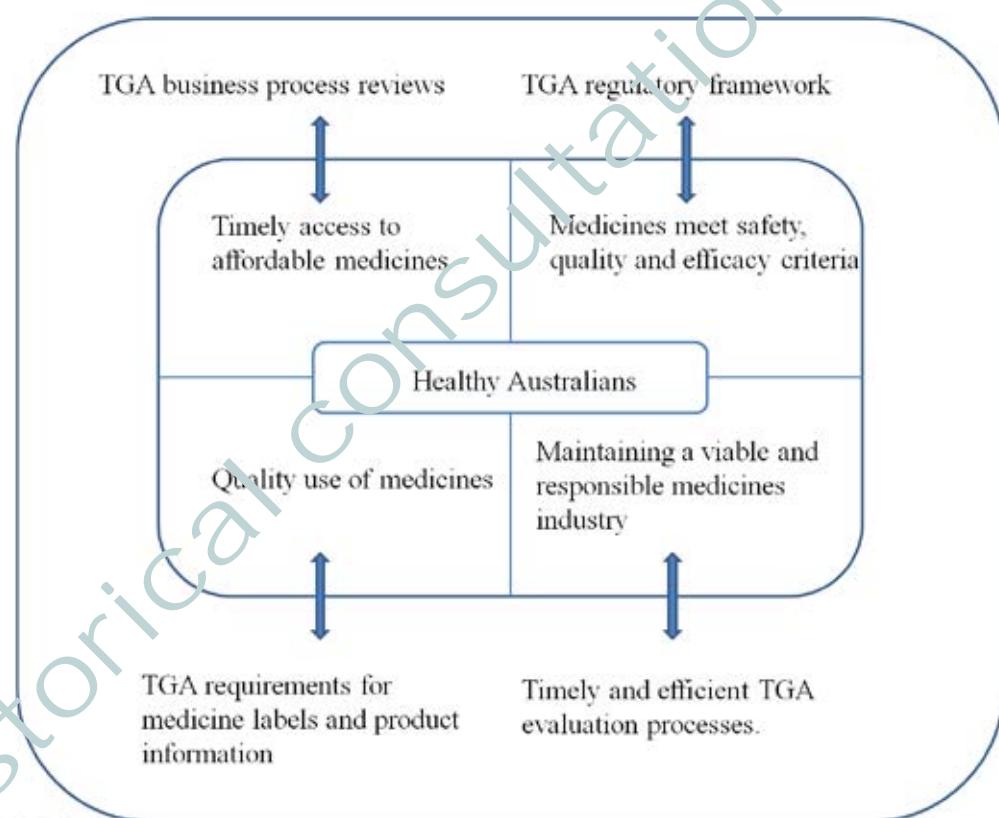


Figure 1: TGA's contribution to the National Medicines Policy

The mandatory requirements for information that must be provided to consumers on medicines labels and packaging, and the way this information is presented, make an important contribution to the safe and quality use of medicines by Australian consumers and health care professionals. In particular, the TGA assesses the potential for the information and the way it is presented to be confusing or misleading to consumers and health care professionals. The aim of this aspect of the medicines regulatory framework is

to reduce the risk of errors by health care professionals and facilitate consumer access to the information they need to:

- make informed choices where they are self-managing minor conditions, such as a headache or a cold
- safely use a medicine that they have been prescribed by a health care practitioner for the treatment of a more serious condition.

About this review

The requirements for medicine labels and packaging are specified in Therapeutic Goods Order 69 (TGO 69) *General requirements for labels for medicines*. This Therapeutic Goods Order has been in place since 2001. Since that time a number of consumer safety risks have been identified that may be avoided by improving the requirements specified in TGO 69. Some stakeholders have also indicated that the way information is presented on some medicine labels and packaging could be improved to make it easier for consumers to understand what is in their medicine and how it should be used and to decrease medication errors made by health professionals. It is therefore timely to conduct a review to assess whether the requirements specified in TGO 69 continue to be relevant to the objectives of the National Medicines Policy.

This review is primarily concerned with the presentation of the information on the medicine containers or on the boxes within which they are supplied. Of particular interest are the visual aspects that contribute to the usability of the information provided and facilitate the safe use of the medicine by health care professionals and consumers.

The key issues to be addressed by this review were determined through collation and analysis of previous consultations with key stakeholders on proposed updates to TGO 69. In preparing this paper the TGA also considered reports from consumer groups; industry feedback; and consultation with other key stakeholders. Further background to issues addressed in this review can be found in the [*Report on National Round Table on Safer Naming, Labelling and Packaging of Medicines*](#).

What is the objective of this review?

The objective of the review of the requirements for medicine labels and packaging is to develop appropriate regulatory solutions that effectively address the consumer safety risks posed by the following issues:

Information about the active ingredient(s) contained in the medicine is not always easy to find

- use of the same brand name for a range of products with different active ingredients resulting in look-alike medicine branding (this is known as brand extension or trade name extension)
- medicine names that look-alike and sound-alike that can lead to use of the incorrect medicine
- medicine containers and packaging that looks like that of another medicine
- lack of a standardised format for information included on medicines labels and packaging

- dispensing stickers that cover up important information
- information provided on blister strips
- information included on small containers
- information provided in pack inserts

What is outside the scope of this review?

The following matters are outside of the scope of this review and, although the TGA may note any submissions received on these issues for future reference, they will not be considered as part of this review.

- Recommendations 6 and 7 of [TGA reforms: A blueprint for TGA's future](#) regarding information provided on the labels of listed medicines explaining that the efficacy of these products has not been evaluated by TGA. This issue is being addressed as a part of the reform of the complementary medicines regulatory framework that is currently underway.
- Whether the presence of nanoparticles in medicines should be declared on medicines labels.
- The details of medicine-specific information to be included on labels, for example specific indications or actual directions for the use of a specific medicine, with the exception of medicines containing paracetamol and ibuprofen.
- The Required Advisory Statements for Medicine Labels (RASML).
- Therapeutic Goods Order 80 Child Resistant Packaging for Medicines.
- Code of practice for tamper evident packaging.
- The *Standard for the Uniform Scheduling of Medicines and Poisons* (Poisons Standard), which specifies the level of access to medicines and poisons as well as the requirements for the pharmacist's dispensing sticker.
- Labelling of medical devices, biologicals and other therapeutic goods not regulated as medicines.
- Electronic access to medicine information, including pack inserts and consumer medicine information.
- The use of tall man lettering. For more information regarding the tall man lettering standard developed by the Australian Commission on Safety and Quality in Health Care, please refer to the [National Standard for the Application of Tall Man Lettering](#).
- Matters covered by Industry Codes of Conduct, such as Patient Support Programs.

Have your say

This consultation paper has been prepared for a wide range of stakeholders; however care has been taken to develop a paper that can also be easily understood by a consumer audience. It is hoped that this approach will encourage consumer engagement and response and will enhance understanding of medicine labels and labelling requirements. To assist this further, a collection of animations has been developed to illustrate the proposed changes, to show more clearly what the proposed regulatory changes would mean for their medicines.

The TGA is seeking feedback on each of the proposed regulatory changes under each issue. Interested stakeholders are encouraged to provide a response to the general questions at the end of each section relating to the proposed regulatory changes. Stakeholders may respond to as many or as few of the questions as they wish and may provide additional information on issues not asked in the questions.

In addition to responses to the general questions for the proposed changes, the TGA is seeking industry specific information on each of the key issues of this consultation. In particular for each of the issues, industry and other interested stakeholders are invited to review and comment on the relevant recommendations. Responses should include:

- Whether or not you support the proposed changes. If you do not support a change, you may make suggestions for an alternative acceptable to you and provide rationales for the commentary.
- An assessment of how the proposed change will impact on you or your business. That is, what are the likely benefits or costs to you or your business (these may be financial or non-financial). If possible, please attempt to quantify these costs and benefits.

Submissions to the general questions and industry specific information should be lodged electronically to labellingreview@tga.gov.au. Or if hardcopy is preferred please mail your submissions to TGA Labelling and Packaging Review, PO Box 100, Woden, ACT, 2606.

The closing date for submissions is close of business 24 August 2012.

What will the TGA do with your comments

Submissions will be acknowledged as they are received. All submissions received will be placed on the TGA's Internet site, unless marked confidential. Any confidential material contained within your submission should be provided under a separate cover and clearly marked "IN CONFIDENCE". Reasons for a claim to confidentiality must be included in the space provided on the TGA submission coversheet.

For submissions made by individuals, all personal details, other than your name, will be removed from your submission before it is published on the TGA's Internet site.

In addition, a list of parties making submissions will be published. If you do not wish to be identified with your submission, you must specifically request this in the space provided on the submission coversheet.

At the close of the consultation period, the TGA will collate and analyse submissions on matters that are within the scope of this review. An update on progress of the review and

expected timeframes for the TGA response to the comments received will be provided on the TGA website during the consultation period.

The TGA will make any refinements or amendments of the proposed regulatory options as appropriate. The outcomes of these considerations will be published on the TGA website. At this stage, the TGA will also consider appropriate transition arrangements for the medicines industry, health care professionals and consumers.

The TGA will draft a Therapeutic Goods Order that reflects the outcomes of this consultation and, in accordance with the *Best practice regulation handbook*¹, will conduct a consultation to determine the economic impact of the proposed changes on the medicines industry.

At the completion of the required consultation processes, which also includes the Therapeutic Goods Committee, the revised Therapeutic Goods Order will be released. It will be determined at this time if any other regulatory amendments or instruments are required.

From the time the new Therapeutic Goods Order is registered as a legislative instrument there will be a transition period, at this stage proposed to be three years, for industry to comply with the revised requirements. New medicines that are approved once the new requirements come into force will be required to comply immediately.

¹ The *Best practice regulation handbook* is a publication of the Department of Finance and Deregulation and describes consultation processes that Australian government agencies must conduct when implementing regulatory changes that are not minor or routine. For more information visit <<http://www.finance.gov.au/obpr/about/>>.

Glossary of terms

Definitions of key terms used in this consultation paper are provided in this section to facilitate a common understanding of the key issues and proposed regulatory options.

Active ingredient: the ingredient of the medicine that allows the medicine to have an effect in the body.

Ampoule: a small, usually glass, container for liquid medicine preparations.

Australian Register of Therapeutic Goods (ARTG): The publicly accessible reference database of the therapeutic goods available in Australia. It provides information on therapeutic goods that can be supplied in Australia. Products may be registered or listed on the ARTG, depending on the class of therapeutic good. If a therapeutic good is not entered on the ARTG, it cannot be supplied in Australia unless access has been granted under the special access scheme.

The ARTG is available online for anyone to view and includes the following information:

- Product name and ingredients
- Sponsor and manufacturer details
- If a medicine is registered or listed

More information on searching the ARTG can be found at: [Searching the Australian Register of Therapeutic Goods \(ARTG\)](#).

Batch: a quantity of a product that is (a) uniform in composition, method of manufacture and probability of chemical or microbial contamination; and (b) made in one cycle of manufacture and, in the case of a product that is sterilised or freeze dried, sterilised or freeze dried in one cycle.

Blister strip: a sheet of plastic with pockets that contain tablets or capsules, sealed with a thin sheet of aluminium.

Brand name: means the commercial name: (a) given to goods by the manufacturer and (b) under which the goods are supplied. Also known as trade name.

Complementary medicines: also known as 'traditional' or 'alternative' medicines, include vitamin, mineral, herbal, aromatherapy and homoeopathic products.

Complementary medicines may be either listed or registered, depending on their ingredients and the therapeutic claims made.

Excipient: An inert or inactive substance used in preparing medicines.

Expiry date: the date (expressed as the month and year) after which the goods should not be used.

Listed medicines: are considered low risk medicines that are evaluated and approved for marketing in Australia based on assessment of safety and manufacturing quality.

Medicines that are listed on the ARTG have been assessed against quality and safety, but not efficacy, criteria. This includes most complementary medicines. At the time of listing, sponsors must certify that the medicine meets a range of requirements. In particular, they must certify the medicine is eligible for Listing, that the presentation is not unacceptable, that the medicine is safe for the purposes for which it is to be used, and that information or evidence is held to support any claim made in relation to the medicine. Listed medicines may only make limited therapeutic claims. Listed medicines are not permitted to include

substances that are scheduled in the [Poisons Standard](#) and can be identified by the presence of an 'AUST L' number on the medicine label.

Look-alike medicine branding: marketing of two or more products under a single brand name. Also known as brand extension or trade name extension.

Non-prescription medicines (aka over-the-counter medicine): medicine that can be purchased without a prescription as follows:

Pharmacist only medicines which are available only from pharmacies with the provision of advice from a pharmacist prior to sale.

Pharmacy only medicines which are available for self-selection within a pharmacy.

General sale medicines which are available in pharmacies, grocery and convenience stores.

Ophthalmic preparation: medicine used in the eye.

Poisons Standard: consists of decisions regarding the classification of medicines and poisons into Schedules (levels of public access) for inclusion in the relevant legislation of the States and Territories.

Prescription medicines: medicine that must be prescribed by a health care professional with prescribing rights.

Registered medicines are evaluated for quality, safety and efficacy prior to being approved for market in Australia. High risk registered products include all prescription medicines and some specified products, such as sterile injectables. Lower risk registered products include non-prescription medicines and some complementary medicines. Products containing substances scheduled in the [Poisons Standard](#) are evaluated as registered medicines. Registered medicines can be identified by the presence of an 'AUST R' number on the medicine label.

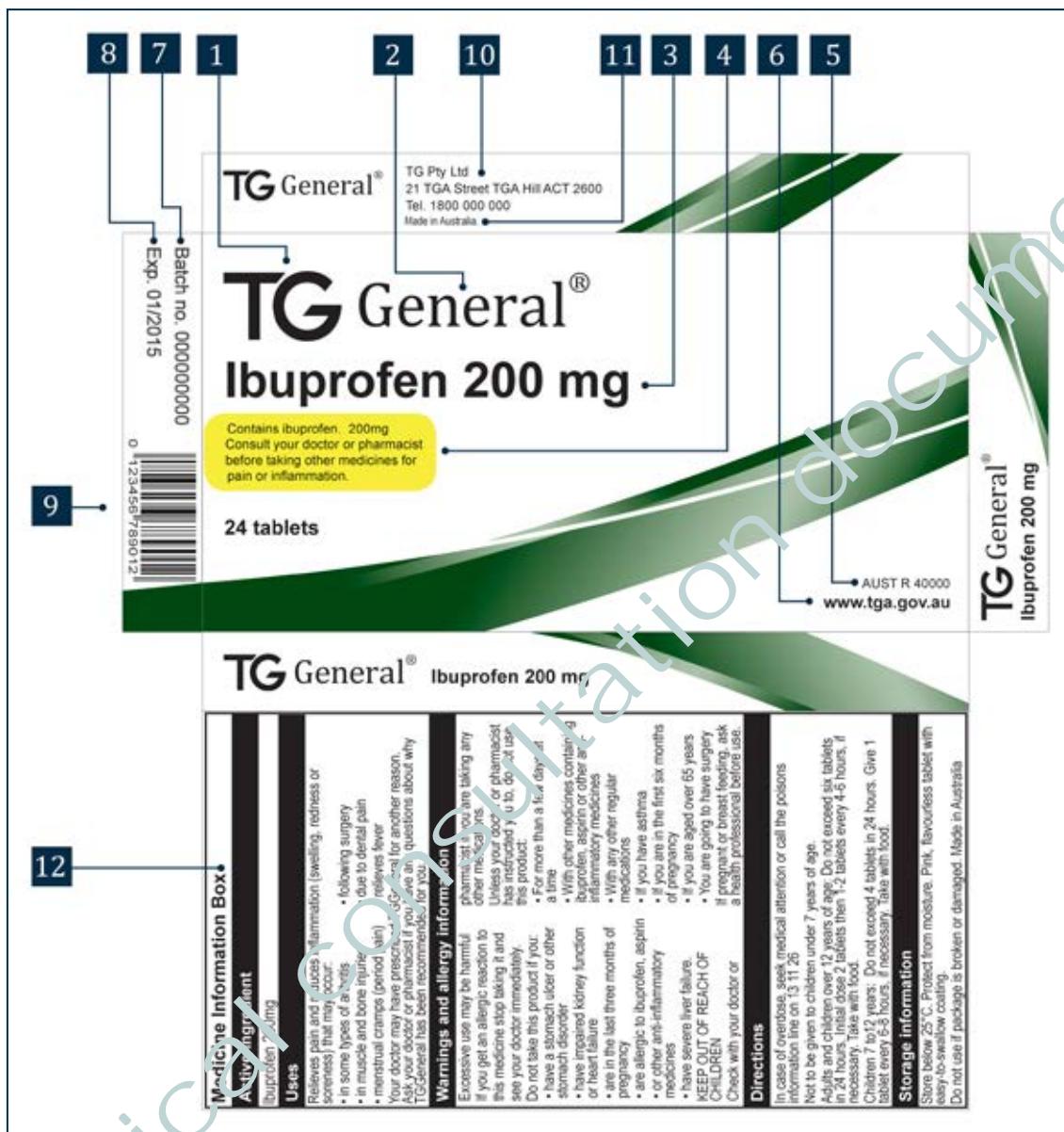
Stakeholder: a person, group or organisation who affects, or can be affected by, an organisation's actions.

A **medicine label** is a display of printed information upon, or securely affixed to, the container, any intermediate packaging and primary packaging of a medicine. The components of a medicine label are illustrated in Figure 2.

The **container** is an item that immediately covers the medicine and includes an ampoule, blister pack, bottle, sachet, dial dispenser pack, strip pack, syringe, tube, vessel, vial, wrapper or other similar item, but does not include an item intended for ingestion.

A **primary pack / packaging** means the complete pack in which the goods, or the goods and their container, are to be supplied to consumers. For example, the packaging which you see when you look at a medicine on a pharmacy shelf is called primary packaging; this may be just the container, or it may be a cardboard box that contains the bottle or blister packs.

Figure 2: The components of a medicine label.



1. TG is the company name
2. Brand name
3. Name of the active ingredient. The active ingredient is what makes the medicine work.
4. Warning label
5. The AUST R or L numbers shows that the medicines are accepted by the Therapeutic Goods Administration for supply in Australia.
6. Website address of the TGA
7. Batch number. In case of a recall the batch number will be quoted.
8. The medicine should not be used after the expiry date because it can lose its effectiveness or become unsafe.
9. Barcode
10. Address & contact details
11. Country of origin
12. Standardised Information Format: the Medicine Information Box. See recommendations 4.1 to 4.6

Prominence of active ingredients on medicine labels

What is an active ingredient?

The active ingredient is the ingredient of the medicine that allows the medicine to have an effect in the body. Examples of active ingredients include paracetamol, ibuprofen and insulin. Warning statements on medicine labels and packaging usually relate to potential side effects caused by the active ingredient. Dosage instructions on medicine labels relate to the amount of the active ingredient that should be taken to have the desired health effect.

What are the consumer health risks associated with not knowing the active ingredient?

The brand name or trade name of a medicine is the name given to the medicine by the manufacturer. Medicines that contain the same active ingredient are often marketed by different companies. For example, once a patient on a prescription medicine has expired, other suppliers can commence supplying a medicine with the same active ingredient under different brand names. These are known as generic medicines. Where a patient obtains their prescription medicine from different pharmacies, it is possible that they may be provided with different brands of the same medicine. In this case it is important to know the active ingredient so that the consumer avoids taking multiple doses of the same active ingredient.

It is equally important to know the active ingredient in over-the-counter medicines as it is common for several products with different brand names to include the same active ingredient. Next time you visit your pharmacy or supermarket, have a look at the different pain killers or cough and cold medicines and see how many include the same active ingredient. A consumer who takes several of these products at the same time may receive an overdose of the active ingredient.

Most medicines have known side-effects. One way to reduce such side-effects is to inform consumers about how many tablets or how much liquid medicine to take in any 24 hour period. Recommended doses are designed to provide the consumer with the desired health effect (e.g. relief from pain or symptoms associated with colds) while minimising the potential for side-effects to occur. Where a consumer inadvertently takes different products with the same active ingredient there is a much higher risk of side-effects occurring.²

² Murnion B.P (2010) Combination analgesics. *Australian Prescriber* Volume 33: Pages 113-5

Clear labelling showing the active ingredients on medicine packaging helps consumer safety by:

- assisting consumers to recognise when two different brands include the same active ingredient
- identifying the differences between different medicines
- identifying any ingredients that may cause allergic reactions, or interactions with other medicines
- when overseas, allowing consumers to identify alternative medicines that they can use when Australian brands are not available
- identifying the amount of active ingredient
- avoiding accidental overdose.

For more information on understanding the active ingredient(s) of a medicine, please visit <http://www.nps.org.au/bemedicinewise>.

Identification of non-prescription medicines containing paracetamol or ibuprofen

Paracetamol and ibuprofen are well known and widely used over-the-counter medicines used for pain relief. Although these medicines are generally effective and well tolerated, they do have serious side-effects when not taken in accordance with dosage instructions on medicine labels. Published evidence from a number of developed nations, including the United Kingdom, United States and Australia, is that a significant number of accidental paracetamol and ibuprofen overdoses occur annually^{3,4,5}. This type of overdosing can occur when patients take a cold and flu medication that contains paracetamol or ibuprofen and then consume another preparation, such as a liquid preparation or headache reliever, without realising that it also contains paracetamol or ibuprofen.

Accidental overdose may also occur when consumers take a paracetamol or ibuprofen product marketed for one type of pain, and then take another paracetamol or ibuprofen medicine marketed for a different type of pain.

In Ireland, the UK and the USA^{6,7,8} an additional warning statement has been included on the packets of paracetamol-containing medicines. Given the easy access to and widespread use of paracetamol and ibuprofen based medicines, it is proposed that a similar warning should be used in Australia to improve the quality use of medicines that contain these active ingredients by Australian consumers.

³ Daly, F.F.S et al (2008) Guidelines for the management of paracetamol poisoning in Australia and New Zealand – explanation and elaboration. *MJA* Volume 188: Pages 296-301

⁴ Budnitz, D.S et al (2011) Emergency department visits for overdoses of acetaminophen-containing products. *Am J Prev Med* Volume 40: Pages 585-592

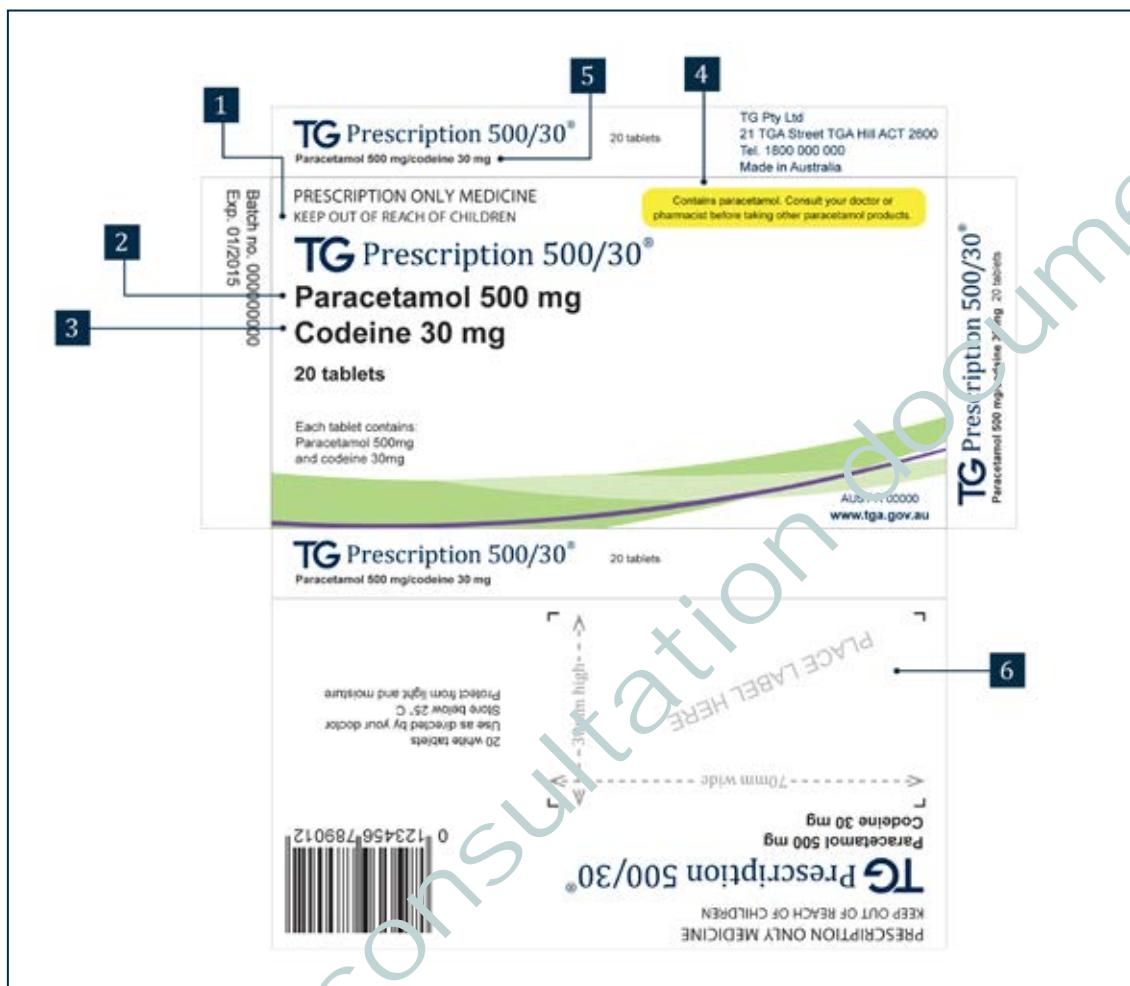
⁵ Lavonas, E.J et al (2012) Comparative risks of non-prescription analgesics: a structured topic review and research priorities. *Expert Opin Drug Saf* Volume 11: Pages 33-44

⁶ Statutory instrument 1997 No.2045: The Medicines (Sales or Supply) (Miscellaneous Provisions) Amendment (No 2) Regulations 1997 London: The Stationery Office; 1997

⁷ Statutory Instrument: S.I. 150 of 2001. Medicinal Products (Control of Paracetamol) Regulations, 2001 Dublin: Stationery Office; 2001

⁸ King, J.P et al (2011) Developing Consumer-Centered, Nonprescription Drug Labelling. *Am J Prev Med* Volume 40: Pages 593-598

Figure 3: Illustration of the recommendations for active ingredient prominence and the warning statement for products containing paracetamol.



1. Mandatory warning included on the label
2. Active ingredient directly below brand name. The first letter of the brand name is directly above the first letter of the active ingredient.
3. Active ingredient of 'registered medicines' (AUST R) has equal prominence with the brand name
4. Paracetamol warning, see recommendation 1.6
5. Active ingredient on 3 non-opposing sides.
6. Designated space for dispensing sticker.

Figure 4: Illustration for the recommendation for active ingredient prominence when there are multiple active ingredients.



1. Example of how to display active ingredient information on a label when space is limited.
2. Paracetamol warning, see recommendation 1.6

Proposed regulatory changes

The following regulatory changes are proposed.

- 1.1 The active ingredient(s) must be listed immediately below the brand name, with the first letter of the active ingredient directly below the first letter of the brand name.
- 1.2 On the front/main panel of the label, the active ingredient must have equal prominence with the brand name.
 - 1.2.1 The intention of 'equal prominence' is for the active ingredient to be as easy to locate and identify on the label as the brand name.
 - 1.2.2 The font size of the active ingredient must be at least 100% of the font size of the medicine brand name on the main/front label.
 - 1.2.3 For improved differentiation between the brand name and the active ingredient there should be a difference in font style or letter spacing or font colour.
 - 1.2.4 The active ingredient should begin with an uppercase letter but the remainder should be in lower case.
- 1.3 Where there are more than 3 active ingredients, the most abundant ingredients must appear on the main label immediately below the brand name and the names, together with the quantities of every active ingredient, are to be included on a side panel/label or on a rear panel/label for the product. (This does not apply to day and night preparations.)

- 1.4 For products containing day and night preparations that have different formulations, the composition of each tablet must be provided immediately below the brand name and the font size must be no less than 2mm in height on the main/front panel.
- 1.5 The active ingredient must be included with, and of equal prominence as, the brand name on at least 3 non-opposing faces of a carton.
- 1.6 Non-prescription medicines that contain paracetamol must include the following information on the front of the packaging. The information must be presented in bold text in letters of at least 1.5mm high and on a background that contrasts with the rest of the packaging:

“Contains paracetamol. X mg. Consult your doctor or pharmacist before taking other paracetamol products.”
- 1.7 Non-prescription medicines that contain ibuprofen must include the following information on the front of the packaging. The information must be presented in bold text in letters of at least 1.5mm high and on a background that contrasts with the rest of the packaging:

“Contains ibuprofen. X mg. Consult your doctor or pharmacist before taking other medicines for pain or inflammation.”

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

What do you think will be the impact of increasing the prominence and standardising the location of the active ingredient on the medicine label?

What do you think about the proposed warnings for paracetamol and ibuprofen containing products?

Are there any other concerns you have with the size or position of brand names and active ingredient?

If the active ingredient name is clear, directly below the brand name and in a large font, what are the additional benefits that you see by making it the same size as the brand name?

What is the smallest size font that you consider readable?

Look-alike and sound-alike medicine brand names and look-alike packaging and branding

What do we mean by look-alike and sound-alike names and look-alike packaging?

Look-alike, sound-alike (LASA) names are medicine brand names that look or sound the same as other medicine brand names when written or spoken. Look-alike medicine packaging refers to medicine containers or primary packaging that looks like that of another medicine. There are also safety concerns with medicines packaging that looks like a toy or a food.

Look-alike medicine branding occurs when two or more products are marketed under the same brand name; this may also be known as brand extension.

What are the consumer health risks associated with LASA medicine names?

Key risks to consumers from LASA brand names result when they are accidentally given the wrong medicine by a pharmacist or health care professional⁹ or they select the wrong medicine themselves due to the similarity of the name or packaging of a medicine. The consequences to consumers range from being given a medicine that is ineffective for the condition from which they suffer to potentially fatal adverse reactions to a medicine that they were not prescribed.

The issue generally relates to brand names of medicines, but may also occur with active ingredient names. Examples (taken from the NSW Pharmaceutical Defence Limited error statistics, January 2009 – January 2011) where Australian consumers have been provided with the wrong prescription medicine due to LASA names are provided in the table below.

⁹ Australian Council for Safety and Quality in Health Care (2002) Second national report on patient safety. Improving medicine safety.

Intended Medicine	Medicine Received
Aldactone 25mg (spironolactone) To treat oedematous disorders (swelling with fluid), including congestive cardiac failure.	Aldomet 250mg (methyldopa) Lowers high blood pressure.
Azopt (brinzolamide ophthalmic suspension) For treatment of elevated intraocular pressure in patients with ocular hypertension or open-angle glaucoma.	Atropt (atropine sulphate) Used to dilate pupils.
Celepram (citalopram hydrobromide) Used to treat depression.	Celebrex (celecoxib) Used to relieve the symptoms of joint pain, tenderness, swelling and stiffness.
Deralin 10mg 1 bd (propranolol hydrochloride) Used to treat various heart conditions.	Deptran 10mg 1 bd (doxepin) Used to treat depression.
Losec (omeprazole magnesium) Used to treat the symptoms of reflux oesophagitis or reflux disease.	Lasix (furosemide) Used to treat swelling of the ankles, feet, legs or even the brain or lungs.

LASA brand names also pose a risk to consumers who are on complex medical treatments involving several different medicines or who self-medicate with several different non-prescription medicines. If the names of some of the medicines they are taking look similar to each other, there is a risk they will take or use the wrong medicine.

Look-alike medicine packaging also poses a risk to consumers from being given the wrong medicine.

In the case where the medicine container or primary packaging looks like a toy, as may be the case with some inhalers, or a food, there is a risk that children may be inadvertently exposed to the medicine.

What are the consumer health risks associated with look-alike medicine branding

Look-alike medicine branding results when an existing brand name is extended to include a product that has been produced to include an active ingredient that was not previously included in the brand product range. Consumers who take the medicine based on the brand name without checking the active ingredients may suffer from adverse reactions to the newly formulated medicine. If the consumer is taking another medicine that contains the new active ingredient, they may receive an overdose.

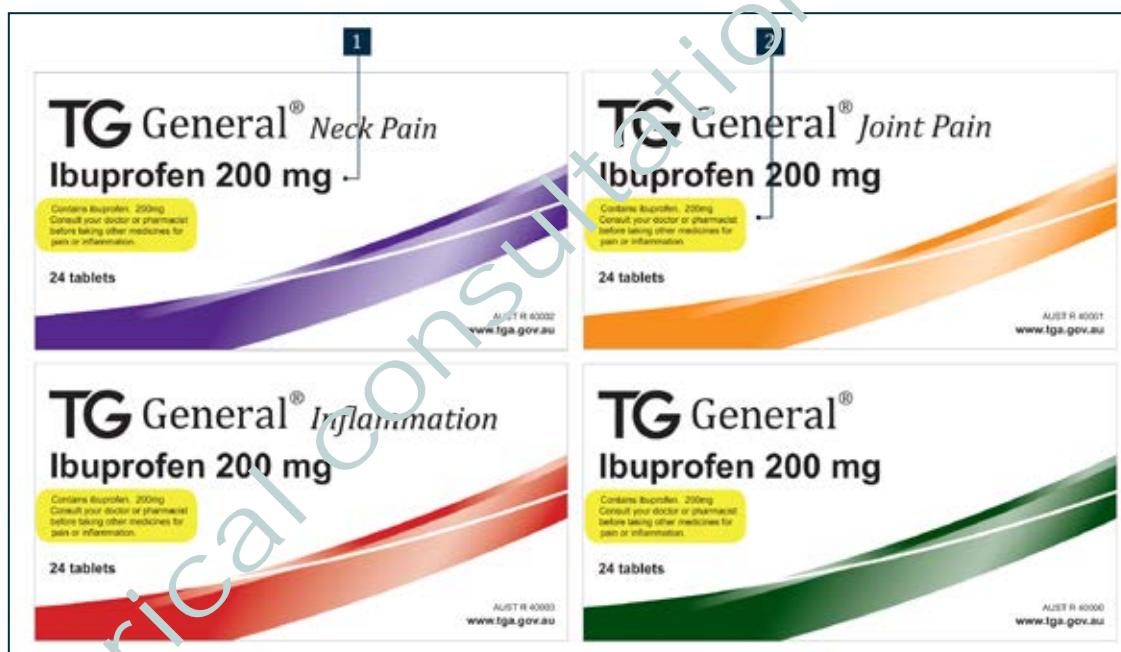
The extension of a well known brand name to new products with different active ingredients or indications is of particular concern, as consumers and health care professionals may have developed expectations about the active ingredients or intended use of the product based on the brand name.

Look-alike medicine branding also refers to the extension of a brand name to products that are designed to treat different conditions, as illustrated in Figure 5. Consumers who take the medicine based on the brand name without checking the active ingredients may take a medicine that does not provide the health benefit that the consumer is aiming to achieve and that may have a different safety profile.

Look-alike medicine branding can also arise when listed medicines are marketed under the same brand name as registered medicines, or vice versa. If a registered product is marketed under the same brand name as a listed medicine, consumers may not realise that the medicine they are taking may have an active ingredient with a different safety profile to the expected listed medicine active ingredient. In these cases there is also a risk of overdose if the consumer takes a product containing the same active ingredient but is marketed under a different name. Conversely, if a listed medicine is branded with the name of a registered product, there may be an expectation of a therapeutic benefit that is not achieved if the consumer does not realise that the two products contain different active ingredients.

Consumer health risks associated with look-alike medicine branding are generally associated with medicines that are selected by consumers, such as over-the-counter and general sale, pharmacy only and complementary medicines. However, issues may also be encountered with pharmacist only medicines and when health care professionals are selecting medications for patients.

Figure 5: An example of look-alike medicine branding.



1. The four products have the same active ingredients in the same quantities.
2. Ibuprofen warning, see recommendation 1.7.

Proposed regulatory changes - Look-alike sound-alike names and look-alike packaging

- 3.1 Sponsors of new medicines will be required to submit evidence of risk assessment of the proposed labelling and packaging. The TGA will work with industry to develop guidance for this assessment, which may include consumer testing or risk assessment checklists similar to those used in other countries. The TGA is investigating methods to electronically screen proposed brand names against already existing brand names to identify potential LASA names.
- 3.2 In relation to applications to include a new medicine in the Australian Register of Therapeutic Goods (ARTG), if the proposed medicine brand name differs from another product included in the ARTG by three letters or fewer, the presentation of the proposed medicine label and packaging must use colours and designs that contrast with the medicine label and packaging of the existing product. During the implementation of this change, the TGA will work with the medicines industry to develop guidelines to provide clarity about these proposed requirements.
- 3.3 In relation to applications to change the labelling and packaging of existing medicines, if the brand name of the medicine differs from another medicine included in the ARTG by less than three letters, the proposed changes must use colours and designs that contrast with the medicine label and packaging of the other medicine.

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

Do you think the proposed changes to address LASA names and LA packaging will improve medicine safety? Why/why not?

Proposed regulatory changes - Look-alike medicine branding

To reduce the risk of consumer confusion and medication errors caused by look-alike medicine branding, the TGA proposes the following regulatory options:

- 3.4 Products that are listed on the ARTG cannot be marketed under the same name as a registered medicine.
- 3.5 Medicines that contain the same quantity of active ingredient(s) cannot be selectively differentiated or marketed for a subset of symptoms or uses, unless the medicine has specific characteristics that make it more suitable for a particular symptom.

For example: Products cannot be marketed as "BRAND headache", "BRAND backache", "BRAND joint pain" if they include the same active ingredients in the same quantity.

3.6 The same brand name cannot be applied to products that have different active ingredients or combinations of active ingredients unless all of the following conditions are met:

- The active ingredients are closely related (e.g. different salts of the same pharmaceutical chemical), and
- The safety profile, efficacy and dosage regimen are similar.

Examples of the application of the above requirements include:

A brand name that has historically been strongly associated with a particular anti-histamine would not be permitted to be used for a new product with a different type of active ingredient, such as a corticosteroid or a different anti-histamine.

A well known combination product that contains paracetamol under a particular umbrella brand name would not be able to use this same umbrella brand name for another combination product that also contains ibuprofen.

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

What benefits, if any, do you think the proposed changes to address look-alike medicine branding will have for consumer safety?

Do you understand the proposed changes?

If you can read the labels and warnings clearly, will these changes reduce the potential for harm?

Standardised Information Format: the Medicine Information Box

What is a Medicine Information Box?

A medicine information box is a standardised format for the information required on the labels of over-the-counter and complementary medicines. It is based on the "Drug Facts" box used by the US FDA to convey this information on over-the-counter medicines, as illustrated in Figure 6.

Figure 6: An example of a medicine information box.

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

Information is presented in the same format and consistent location on primary packaging and medicine containers to help consumers find the information they need to make informed decisions about their medicines.

What are the consumer health risks associated with not having a Medicine Information Box?

Currently there is no requirement for consistent placement and presentation of key medicine information that consumers need to make informed choices about the medicines they take and how to use them safely. Inconsistent placement of information such as dosage and usage instructions, precautions (including potential allergens) and storage instructions increases the risk that a medicine may be taken or stored inappropriately.

Available evidence indicates that defined and consistent formatting and presentation of information assists medicine consumers to identify and interpret the information they need to make effective decisions about their medications¹⁰.

Grouping information and the printing of the Medicine Information Box on blank space helps consumers to locate information about the medicine and allows easy comparison of different brands of medicine.

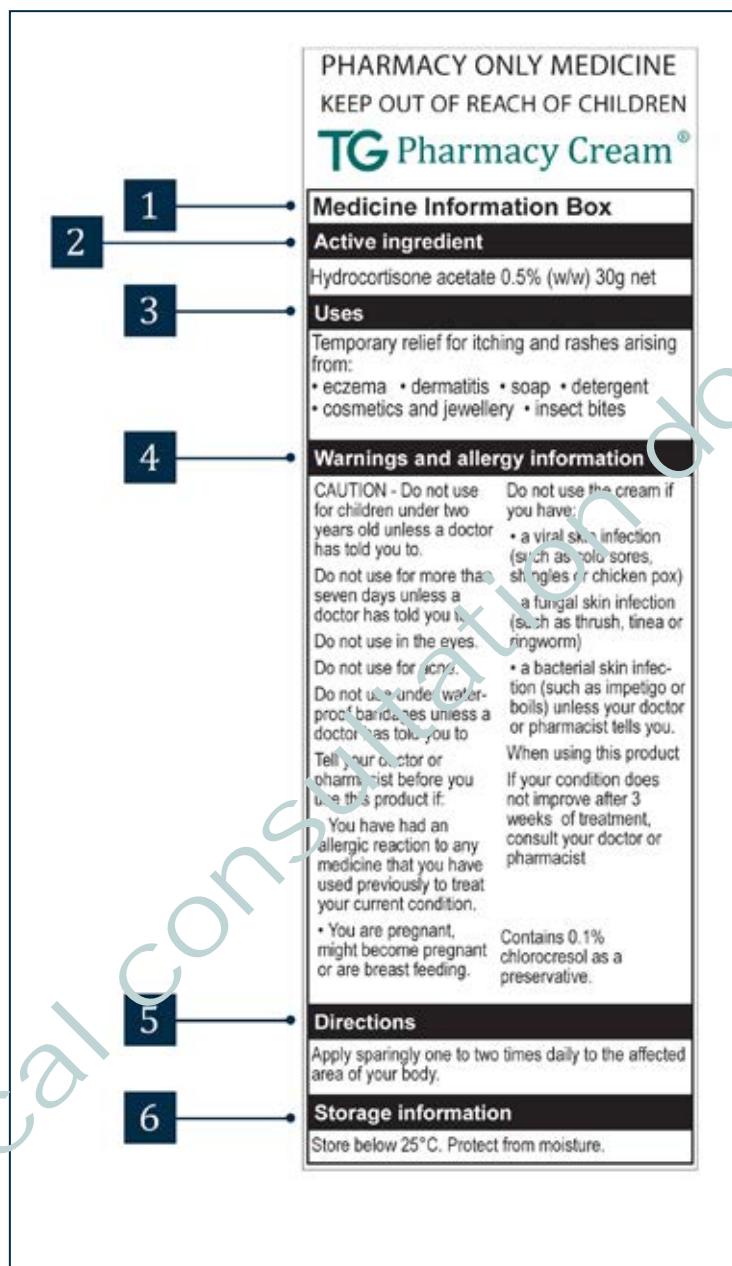
This approach also assists consumers to determine if a medicine is suitable for them as information regarding when not to take the medication and other warnings can be readily located.

Standardising information may also assist consumers to differentiate products under umbrella brands, or with names/packaging that look the same, as they will be able to easily locate the information required to identify medicines with the same active ingredients and avoid accidental overdoses.

Standardised formatting of information in this way is not intended to apply to the front of medicine packaging.

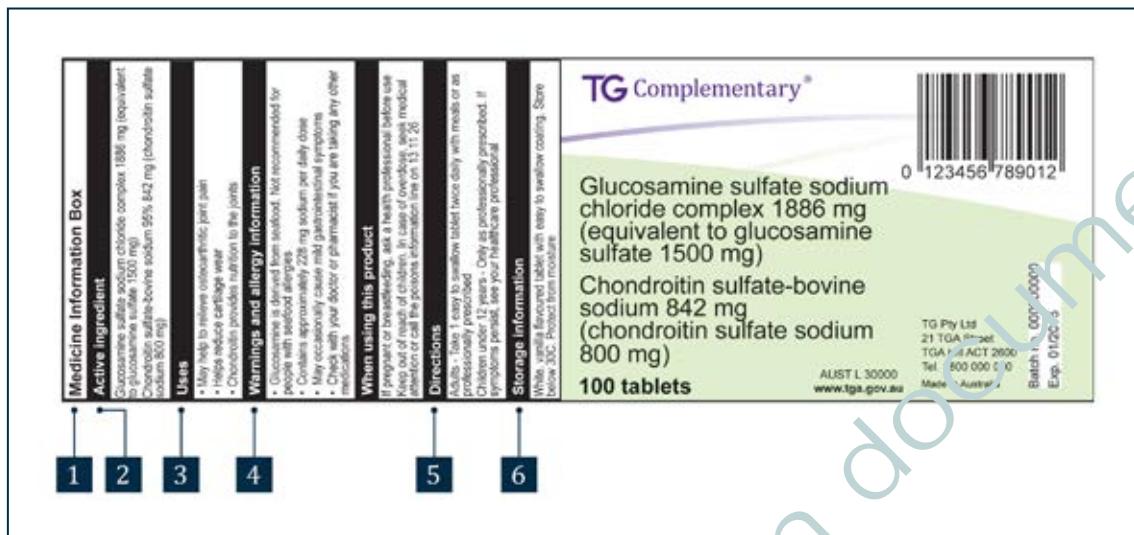
¹⁰ Shrunk, W *et al*, Effect of Content and Format of Prescription Drug Labels on Medication Use; *Ann Pharmacother* 2007;41:783-801

Figure 7: Illustration of how a medicine information box may be presented on a carton with all the required headings.



1. Standardised Medicine Information Box
2. Mandatory heading – Active ingredient
3. Mandatory heading – Uses
4. Mandatory heading – Warnings and allergy information
5. Mandatory heading - Directions
6. Mandatory heading – Storage information

Figure 8: Illustration of how a medicine information box may be presented on a bottle.



1. Standardised Medicine Information Box
2. Mandatory heading – Active ingredient
3. Mandatory heading – Uses
4. Mandatory heading – Warnings and allergy information
5. Mandatory heading - Directions
6. Mandatory heading – Storage information

Proposed regulatory changes

- 4.1 Mandated information on labels and packaging of non-prescription medicines and complementary medicines is presented in a standardised Medicine Information box, based on the US FDA Drug Facts box. The mandatory headings are:
 - Active ingredient, including the amount in each dosage unit
 - Uses (indications)
 - Warnings and Allergy Information (including when the product should not be used and when to consult with a doctor or pharmacist. This section also includes information about possible side effects and substances or activities to avoid. The final lines of this section should include information about preservatives in the product.)
 - Directions/Dosage instructions
 - Storage information.
- 4.2 The font height for information must be no smaller than 1.5mm, with heading height at least 2mm.
- 4.3 The Medicine Information Box must have a white background with black text. Headings must be highlighted or bolded so they are sufficiently emphasised.

- 4.4 Where there is insufficient room on a single face of a package, the box may be split over more than one face. However, the overall format of the information is to remain the same. In these instances a pack insert may also be included containing the Medicine Information Box as a continuous table.
- 4.5 Information about the presence in the medicine of an allergen listed in Schedule 1 of TGO 69, which may be amended, must be included under the heading Warnings and Allergy Information.
- 4.6 For products containing more than 3 active ingredients, or products in small containers, there may be insufficient space on the medicine container or primary packaging for a complete Medicine Information Box. In these cases a complete Medicine Information Box should be included as a pack insert. The minimum information to be included on the label will include information under the following headings:
 - Directions
 - Warnings and Allergy Information.

Where space restrictions do not allow for the required information to be provided in the Medicine Information Box, an alternative arrangement or formatting of information should be provided to the TGA for assessment and approval, together with a justification for non-standardised presentation. This may include breaking the information over more than one panel, or reduction in font size.

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

To what extent do you think a standardised format for information on the labels of over-the-counter and complementary medicines will improve access to information for these medicines?

Are there other ways that the presentation of information could be improved?

Do you think the proposed requirements for products with more than three active ingredients (directions and warnings and allergy information), is sufficient for these products? Please propose an alternative if you don't agree with current recommendation.

Dispensing label space

What is a dispensing label?

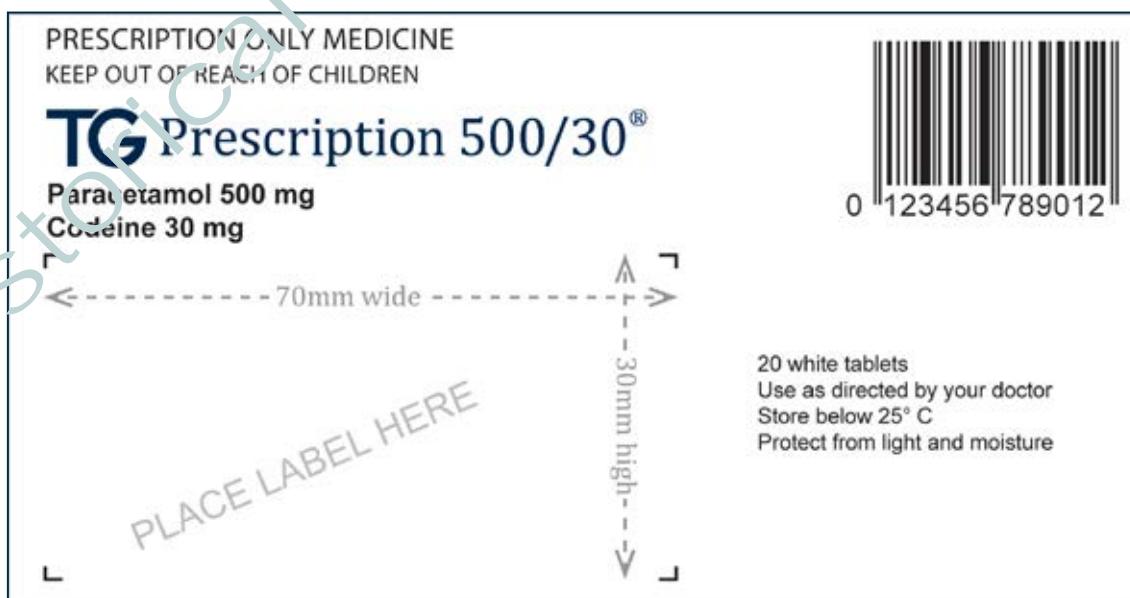
The dispensing label is the label that the pharmacist attaches to a prescription medicine. The information contained on dispensing labels or how it is presented is not regulated by the TGA. Some of these requirements are specified in the Poisons Standard and made mandatory by State and Territory legislation.

The standard size of the label used in Australia is 80 x 40 mm. Generally, information provided on the dispensing label includes the name of the patient and prescribing health care practitioner, medicine brand name, active ingredient and strength (amount of active ingredient in each dose), instructions from the doctor, the pharmacist's details and other information relating to the prescription.

What are the consumer health risks associated with not providing sufficient space on medicine packaging for dispensing labels?

Some prescription medicines are provided to consumers in the primary packaging produced by the manufacturer. When a dispensing label is attached to this packaging, it is possible that important information is covered by the dispensing label, such as dosage instructions, instructions for appropriate storage or additional warnings. Without access to this information, there is a risk that the consumer may not use the medicine appropriately, which may result in an adverse event or the desired health benefit not being achieved. This risk is potentially increased when labels are applied to small containers, such as eye drops where all the information may be covered.

Figure 9: Illustration of the proposed mandatory dispensing label space.



Proposed regulatory changes

- 5.1 A designated space of 70 x 30 mm, consistent with international best practice¹¹, must be provided to accommodate the dispensing label.
- 5.2 Where a clear space is not practical due to constraints from packaging size and shape, the information should be arranged so that information that is likely to be obscured is the same as the information repeated on the label. The area for placement of the sticker should be illustrated by corner placement marks on the packaging.
- 5.3 For small containers, for example eye drops and ointments, where a designated space of 70 x 30 mm is impractical, a clear space should be provided to affix the edges of a folded dispensing label.

General question on the proposed regulatory changes for dispensing label space

Do you support a designated space for the dispensing label on prescription medicines?
Why/why not?

¹¹ Design for patient safety: A guide to the graphic design of medication packaging, 2nd Edition; National Patient Safety Agency, 2007.

Blister strip labelling

What is a blister strip?

A blister strip, or blister pack, is a sheet of plastic with pockets that contain the tablets or capsules. The blister strip is sealed with a thin sheet of aluminium foil. Blister strips are usually packed in an outer carton (primary packaging), which has more detailed labelling. For the purpose of this consultation, dose administration aids, such as Webster or calendar packs, that may be prepared for individual consumers by their health care professional are not considered blister strips.

For medicines packed in blister strips, each pocket usually contains a single tablet or capsule. Information about the medicine is usually printed on the foil backing.

What are the consumer health risks associated with insufficient information provided on the blister strip?

Often blister strips are stored away from their outer wrapping or packaging that contains the information about how to use the medicine safely. For example, it is not uncommon for people to carry a blister strip in their handbag, purse or travel bags without the primary container.

The blister strip does not always include all of the information that is provided on medicines labels to support the quality use of the medicine. Without this information there is a risk that the medicine may not be taken in accordance with the dosage instruction, or it may be taken with another medicine that contains the same active ingredient. Where a person is carrying more than one medicine in blister strips, there is the added risk of taking the wrong medicine. Issues may also arise in hospitals when a section of the blister strip is dispensed and the carer responsible for administering the medicine cannot tell what the medicine is, the strength or the expiry date.

These consumer health risks are compounded where blister strips that can be segmented do not repeat the information that they contain on each segment.

Figure 10: Illustration of how information should be presented on a blister strip under recommendation 6.1.



1. Brand name, active ingredient and amount, expiry date and batch number repeated every 2 units.
2. Segmented strips have all the critical information.

Proposed regulatory changes

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

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

- 6.2 Where strips can be segmented, the brand name, the active ingredient and amount of active ingredient, batch number and expiry date is to appear on each segment.
- 6.3 A maximum of 3 active ingredients should be listed on each segment / each 2 units of a blister strip for registered medicines.
- 6.4 Where there are more than 3 ingredients, for example multi-vitamins packaged this way, it may be sufficient to include a single list of active ingredients printed on the foil of each blister strip. Alternatively, the brand name, together with batch number and expiry date, should be repeated on the foil.

For oral contraceptives and other medicines that have a “race track” format to support their safe use, the TGA proposes the following requirement:

- 6.5 Blister strips that have a “race track format” must include the trade name, the active ingredient(s) and their amount(s), batch number and expiry date in a single location.

General question on the proposed regulatory changes for blister strip labelling

Do you think the proposed information for blister strips is sufficient?

What other changes would you like to see for this type of packaging?

Small containers

What is a small container?

Some medicines, such as those for injection, eye drops or medicines that are not to be taken for more than a few days, are supplied within small containers. This places obvious restrictions on how much information can be included on the primary packaging or medicine label. It would be impractical to request that manufacturers supply these medicines in larger packaging that would accommodate the required information.

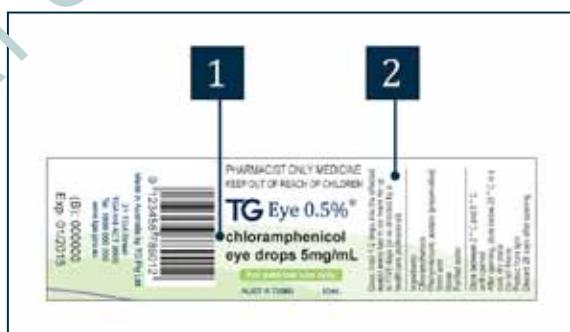
Containers that have a nominal capacity of 20 millilitres or less are considered to be small containers.

What are the consumer health risks associated with small containers?

Given the size restrictions it is not possible to provide consumers and, in the case of injectable medicines, health care practitioners, with the information they need to support the quality use of the medicine on the label or primary packaging.

Pack inserts (documents that provide more detailed information than can fit on the medicine label) and primary packaging are important additions to small containers to ensure that important information is accessible. However, this additional information is only effective if the primary packaging and package insert is not discarded and always carried with the medicine. In particular in the case of eye drops, it is common for the small container to be carried without the primary packaging or the package insert. It is therefore critical that the small container contains the most important information that a consumer or health care practitioner needs.

Figure 11: Illustration of how information might be presented on an eye drop bottle.



1. Name of the medicine and active ingredients with letter height greater than 1.5mm.
2. Alternative presentation of required presentation for a small container.

Figure 12: Illustration of how information may be presented on a small bottle of tablets.



1. This Medicine Information Box is an example of how the recommendations are applied to a small container.

Proposed regulatory changes

The following requirements are proposed for medicine containers with a nominal capacity of 20 millilitres or less:

- 7.1 These containers must be enclosed in a primary pack that fully complies with all labelling requirements and that includes a pack insert that provides detailed instructions for use.
- 7.2 The label on the container must include the following details in a letter height of not less than 1.5 millimetres:
 - The brand name of the medicine
 - The name(s) of all active ingredients in the medicine
 - For ophthalmic preparations the name of any antimicrobial preservatives in the medicine
 - Where there are more than three active ingredients, the three most abundant ingredients are to be included on the label of the container and the complete list of ingredients on the primary packaging and the pack insert
 - The batch number of the medicine
 - The expiry date of the medicine
 - If an injection, the approved route of administration
 - If an ophthalmic preparation for multidose use, a statement to the effect that the medicine should not be used later than four weeks after the container is first opened
 - If a solid ophthalmic medicine for preparing eye drops for multidose use, a statement to the effect that the medicine should not be used later than four weeks after the container is first opened

7.3 A clear space should also be provided to allow a pharmacist to affix a dispensing sticker. This space need not be the size of a standard dispensing sticker (80 x 40 mm), but should allow a folded sticker to be attached like a flag without obscuring information.

General question on the proposed regulatory changes for small container labelling

To what extent do you support the proposed changes for small container labels? Please provide details.

Do you have any further suggestions for how labelling of small containers could be improved?

Pack inserts

What is a pack insert?

A pack insert is a document that provides consumers with more detailed information about the medicine, such as more detailed directions for use than those provided on the medicine container or primary packaging. Not all medicines have a pack insert. Where a pack insert is included with the medicine, the medicine container or primary packaging notifies consumers of this.

Pack inserts are provided where the medicine is contained in a small container. Pack inserts are mandatory for injectable medicines.

What are the consumer health risks associated with pack inserts?

The key consumer health risks relate to access to information that allows them to use the medicines appropriately and safely. If pack inserts are used to compensate for information restrictions on small containers, it is important that the insert is concise and does not include extraneous information, such as advertising material.

There have been instances where the pack insert was printed on the inside of the primary packaging. The only way consumers could access this information was by cutting the primary packaging. In doing so, consumers lost access to mandatory information contained on the outside of the primary packaging.

Proposed regulatory changes

- 8.1 Advertising material will not be permitted to be included as a separate pack insert or incorporated into an approved pack insert.
- 8.2 A pack insert must be in a form separate to the packaging; i.e. it cannot be printed on the inside of a carton.

General question on the proposed regulatory changes for pack insert requirements

Do you support the proposed changes for pack inserts? Why/why not?

Do you have any further suggestions regarding pack inserts?

Labels and packaging advisory committee

The TGA proposes to establish a panel to provide advice on the acceptability of proposed names, labels and packaging, particularly for products involving potential umbrella branding or look-alike sound-alike issues.

It is important for the TGA to have access to independent expert advice on a range of matters relevant to the TGA's responsibilities as a regulator of therapeutic goods. Currently, the TGA has access to such expertise via its expert advisory committees that include subject matter experts who provide the TGA with advice on matters relating to applications for prescription medicines, non-prescription medicines, complementary medicines and medical devices, as well as post-market safety matters.

The TGA does not currently have access to specific expertise relating to the quality use of medicines for labelling and packaging. It is proposed that the panel will consist of persons who represent medicine users (including carers), community and hospital pharmacists, nurses, doctors and health care practitioners and the pharmaceutical industry.

It is proposed that this expert advisory body will provide advice to the TGA on product-specific as well as general matters relating to medicine labels and packaging.

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

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?

Appendix 1: Consolidated list of recommendations

Prominence of active ingredients on medicine labels

- 1.1 The active ingredient(s) must be listed immediately below the brand name, with the first letter of the active ingredient directly below the first letter of the brand name.
- 1.2 On the front/main panel of the label, the active ingredient must have equal prominence with the brand name.
 - 1.2.1 The intention of 'equal prominence' is for the active ingredient to be as easy to locate and identify on the label as the brand name.
 - 1.2.2 The font size of the active ingredient must be at least 100% of the font size of the medicine brand name on the main/front label.
 - 1.2.3 For improved differentiation between the brand name and the active ingredient there should be a difference in font style or letter spacing or font colour.
 - 1.2.4 The active ingredient should begin with an uppercase letter but the remainder should be in lower case.
- 1.3 Where there are more than 3 active ingredients, the most abundant ingredients must appear on the main label immediately below the brand name and the names together with the quantities of every active ingredient are to be included on a side panel/label or on a rear panel/label for the product. (This does not apply to day and night preparations.)
- 1.4 For products containing day and night preparations that have different formulations, the composition of each tablet must be provided immediately below the brand name and the font size must be no less than 2mm in height on the main/front panel.
- 1.5 The active ingredient must be included with, and of equal prominence as, the brand name on at least 3 non-opposing faces of a carton.
- 1.6 Non-prescription medicines that contain paracetamol must include the following information on the front of the packaging. The information must be presented in bold text in letters of at least 1.5mm high and on a background that contrasts with the rest of the packaging:

"Contains paracetamol. X mg. Consult your doctor or pharmacist before taking other paracetamol products."
- 1.7 Non-prescription medicines that contain ibuprofen must include the following information on the front of the packaging. The information must be presented in bold text in letters of at least 1.5mm high and on a background that contrasts with the rest of the packaging:

"Contains ibuprofen. X mg. Consult your doctor or pharmacist before taking other medicines for pain or inflammation."

Look-alike sound-alike names and look-alike packaging

- 3.1 Sponsors of new medicines will be required to submit evidence of risk assessment of the proposed labelling and packaging. The TGA will work with industry to develop guidance for this assessment, which may include consumer testing or risk assessment checklists similar to those used in other countries. The TGA is investigating methods to electronically screen proposed brand names against already existing brand names to identify potential LASA names.
- 3.2 In relation to applications to include a new medicine in the Australian Register of Therapeutic Goods (ARTG), if the proposed medicine brand name differs from another product included in the ARTG by three letters or fewer, the presentation of the proposed medicine label and packaging must use colours and designs that contrast with the medicine label and packaging of the existing product. During the implementation of this change, the TGA will work with the medicines industry to develop guidelines to provide clarity about these proposed requirements.
- 3.3 In relation to applications to change the labelling and packaging of existing medicines, if the brand name of the medicine differs from another medicine included in the ARTG by less than three letters, the proposed changes must use colours and designs that contrast with the medicine label and packaging of the other medicine.

Look-alike medicine branding

To reduce the risk of consumer confusion and medication errors caused by look-alike medicine branding, the TGA proposes the following regulatory options:

- 3.4 Products that are listed on the ARTG cannot be marketed under the same name as a registered medicine.
- 3.5 Medicines that contain the same quantity of active ingredient(s) cannot be selectively differentiated or marketed for a subset of symptoms or uses, unless the medicine has specific characteristics that make it more suitable for a particular symptom.
For example, Products cannot be marketed as “BRAND headache”, “BRAND backache”, “BRAND joint pain” if they include the same active ingredients in the same quantity.
- 3.6 The same brand name cannot be applied to products that have different active ingredients or combinations of active ingredients unless all of the following conditions are met:
 - a. The active ingredients are closely related (e.g. different salts of the same pharmaceutical chemical), and
 - b. The safety profile, efficacy and dosage regimen are similar.

Examples of the application of the above requirements include:

A brand name that has historically been strongly associated with a particular anti-histamine would not be permitted to be used for a new product with a different type of active ingredient, such as a corticosteroid or a different anti-histamine.

A well known combination product that contains paracetamol under a particular umbrella brand name would not be able to use this same umbrella brand name for another combination product that also contains ibuprofen.

Standardised Information Format: the Medicine Information Box

- 4.1 Mandated information on labels and packaging of non-prescription medicines and complementary medicines is presented in a standardised Medicine Information box, based on the US FDA Drug Facts box. The mandatory headings are:
 - Active ingredient, including the amount in each dosage unit
 - Uses (indications)
 - Warnings and Allergy Information (including when the product should not be used and when to consult with a doctor or pharmacist. This section also includes information about possible side effects and substances or activities to avoid. The final lines of this section should include information about preservatives in the product.)
 - Directions/Dosage instructions
 - Storage information.
- 4.2 The font height for information must be no smaller than 1.5mm, with heading height at least 2mm.
- 4.3 The Medicine Information Box must have a white background with black text. Headings must be highlighted or bolded so they are sufficiently emphasised.
- 4.4 Where there is insufficient room on a single face of a package, the box may be split over more than one face. However, the overall format of the information is to remain the same. In these instances a pack insert may also be included containing the Medicine Information Box as a continuous table.
- 4.5 Information about the presence in the medicine of an allergen listed in Schedule 1 of TGA 69, which may be amended, must be included under the heading Warnings and Allergy Information.
- 4.6 For products containing more than 3 active ingredients, or products in small containers, where there may be insufficient space on the medicine container or primary packaging for a complete Medicine Information Box. In these cases a complete Medicine Information Box should be included as a pack insert. The minimum information to be included on the label will include information under the following headings:
 - Directions
 - Warnings and Allergy Information.

Where space restrictions do not allow for the required information to be provided in the Medicine Information Box, an alternative arrangement or formatting of information should be provided to the TGA for assessment and approval, together with a justification for non-standardised presentation. This may include breaking the information over more than one panel, or reduction in font size.

Dispensing label space

- 5.1 A designated space of 70 x 30 mm, consistent with international best practice, must be provided to accommodate the dispensing label.
- 5.2 Where a clear space is not practical due to constraints from packaging size and shape, the information should be arranged so that information that is likely to be obscured is the same as the information repeated on the label. The area for placement of the sticker should be illustrated by corner placement marks on the packaging.
- 5.3 For small containers, for example eye drops and ointments, where a designated space of 70 x 30 mm is impractical, a clear space should be provided to affix the edges of a folded dispensing label.

Blister Strip Labelling

- 6.1 The brand name of the medicine, the active ingredient and amount of active ingredient, batch number and expiry date must be repeated at least once every two units.
- 6.2 Where strips can be segmented, the brand name, the active ingredient and amount of active ingredient, batch number and expiry date is to appear on each segment.
- 6.3 A maximum of 3 active ingredients should be listed on each segment / each 2 units of a blister strip for registered medicines.
- 6.4 Where there are more than 3 ingredients, for example multi-vitamins packaged this way, it may be sufficient to include a single list of active ingredients printed on the foil of each blister strip. Alternatively, the brand name, together with batch number and expiry date, should be repeated on the foil.

For oral contraceptives and other medicines that have a “race track” format to support their safe use, the TGA proposes the following requirement:

- 6.5 Blister strips that have a “race track format” must include the trade name, the active ingredient(s) and their amount(s), batch number and expiry date in a single location.

Small containers

The following requirements are proposed for medicine containers with a nominal capacity of 20 millilitres or less:

- 7.1 These containers must be enclosed in a primary pack that fully complies with all labelling requirements and that includes a pack insert that provides detailed instructions for use.
- 7.2 The label on the container must include the following details in a letter height of not less than 1.5 millimetres:
 - The brand name of the medicine
 - The name(s) of all active ingredients in the medicine
 - For ophthalmic preparations the name of any antimicrobial preservatives in the medicine

- Where there are more than three active ingredients, the three most abundant ingredients are to be included on the label of the container and the complete list of ingredients on the primary packaging and the pack insert
- The batch number of the medicine
- The expiry date of the medicine
- If an injection, the approved route of administration
- If an ophthalmic preparation for multidose use, a statement to the effect that the medicine should not be used later than four weeks after the container is first opened
- If a solid ophthalmic medicine for preparing eye drops for multidose use, a statement to the effect that the medicine should not be used later than four weeks after the container is first opened.

7.3 A clear space should also be provided to allow a pharmacist to affix a dispensing sticker. This space need not be the size of a standard dispensing sticker (80 x 40 mm), but should allow a folded sticker to be attached like a flag without obscuring information.

Pack inserts

- Advertising material will not be permitted to be included as a separate pack insert or incorporated into an approved pack insert.
- A pack insert must be in a form separate to the packaging; ie it cannot be printed on the inside of a carton.

Labels and Packaging Advisory Committee

- It is proposed that this expert advisory body will provide advice to the TGA on product-specific as well as general matters relating to medicine labels and packaging.

Appendix 2: Reference list

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Appendix 3: Organisations represented on the external reference group

- Australian Commission on Safety and Quality in Healthcare
- Australian Self-Medication Industry
- Complementary Healthcare Council
- Council on the Ageing
- Consumers Health Forum
- Generics Medicine Industry Australia
- Medicines Australia
- Medsafe
- National Medicine Policy
- National Prescribing Service
- NSW Clinical Excellence Centre
- Pharmaceutical Defence Limited
- Pharmaceutical Society of Australia
- Pharmacy Guild Australia
- Poisons Information Centre, NSW
- Royal Australian College of Physicians
- Smart Packs- pharmacist representative

Appendix 4: Questions & answers about the labelling and packaging review

1. Why is the TGA conducting this review?

The provision of good quality information presented on the labelling and packaging of medicines is intended to provide advice to patients and consumers on how to take their medicine safely and effectively.

This overarching principle applies whether the product is purchased from a supermarket or a pharmacy without a prescription, or following a consultation with a doctor and the pharmacist at the point of dispensing.

The TGA is aware that aspects of the current labelling and packaging requirements need to be reviewed in the context of promoting the safe and effective use of medicines. This review is being conducted in order to address issues and make recommendations on how medicine labels and packages can be presented in a way that is easy to understand by all consumers.

2. What is the primary objective of this review?

The key objective of this review is to develop changes for medicine labels to improve consumer safety when using medicines. Examples of consumer safety risks associated with medicines include accidental overdose, taking incorrect medicines for an illness or giving an incorrect medicine to a family member. Changes to medicine labels will also help consumers make informed choices about their medicines.

3. Why is information about the active ingredient important?

The active ingredient is the ingredient of the medicine that provides the health benefit to the consumer. It is common for medicines that contain the same active ingredient to be marketed by different companies. As a result, consumers have access to medicines with different labels, packaging and trade names, but with the same active ingredient.

Knowing the active ingredients of a medicine helps consumers:

- to recognise when two different brands include the same active ingredient
- to identify the differences between different medicines
- to identify any ingredients that may cause allergic reactions, or interactions with other medicines
- to identify suitable alternatives to well tolerated medicines when travelling overseas and Australian brands are not available
- avoid accidental overdose.

4. What are the risks to consumers of medicines with the same brand name?

Look-alike medicine branding can occur when two or more products are marketed under the same brand name. This may include products for treating a range of illnesses, usually of a similar type, being marketed under a single brand name, for example products for different types of coughs. This type of branding is also known as brand extension, or trade name extension.

Marketing in this way helps create brand recognition, trust and loyalty amongst medicine users, however it may also lead to confusion about the medicines which can compromise safety.

Look-alike medicine branding may result from extending an existing brand name to include a product that has been reformulated to include an active ingredient that was not previously included in the brand product range. Consumers who take the medicine based on the brand name without checking the active ingredients may suffer from adverse reactions to the newly formulated medicine. Another health risk to consumers arises when they inadvertently take more than one medicine with the same active ingredient, which may lead to an accidental overdose.

5. What are look-alike sound-alike brand names and look-alike packaging?

Look-alike, sound-alike (LASA) names are medicine names that look or sound the same as other medicine names when written or spoken. Look-alike medicine packaging refers to medicine containers or primary packaging that looks like that of another medicine, or that looks like a toy or a food.

Key risks to consumers from LASA medicine names result when they are accidentally given the wrong medicine by a pharmacist or health care professional or they select the wrong medicine themselves due to the similarity of the name or packaging of a medicine.

Look-alike medicine packaging also poses a risk to consumers from being provided a medicine that they were not prescribed by their health care practitioner. In the case where the medicine container or primary packaging looks like a toy or a food, as may be the case with some inhalers, there is a risk that children may be inadvertently exposed to the medicine.

6. What is a medicine information box?

A medicine information box is a standardised format for the information required on the labels of over-the-counter and complementary medicines. It is based on the "Drug Facts" box used by the US FDA to convey this information on over-the-counter medicines.

Information is presented in the same format and consistent location on primary packaging and medicine containers to help consumers find the information they need to make informed decisions about their medicines.

7. Why does the pharmacist sticker cover up information on the medicine box?

When a dispensing label is attached to this packaging, it is possible that important information is covered by the dispensing label, such as dosage instructions, instructions for appropriate storage or additional warnings. Without access to this information, there is a risk that the consumer may not use the medicine appropriately, which may result in an adverse event or the desired health benefit not being achieved.

8. What information is proposed to be included on a blister strip to promote safe used of the medicine?

The trade name of the medicine, the active ingredient and amount of active ingredient, batch number and expiry date must be repeated at least once every two units or each detachable segment of a blister strip.

9. What is the TGA doing to improve the labelling on small containers?

The TGA is proposing changes to the labels of containers less than 20 mL in size to improve the access to necessary information. The amount of information on the label of the container has been reviewed and requirements for primary packaging are being considered.

10. What are the recommendations for pack inserts?

Advertising material should not be included as a separate pack insert or incorporated into an approved pack insert. And, a pack insert must be in a form separate to the packaging; i.e. it cannot be printed on the inside of a carton.

11. Why is this review only focused on the way information is presented and not the content of the medicine label?

The review has focused primarily on the presentation of information on the label of medicines, with particular focus on the visual aspects that contribute to the usability of the information provided and facilitate the safe use of a medicine by consumers. Addressing the identified consumer safety issues with the proposed regulatory changes will allow improvements to be made to medicine labels in the near future. It is expected that matters regarding the content of the medicine label will be addressed over time.

12. How were the key issues identified?

These issues were determined through collation of previous consultations conducted by the TGA on labelling requirements together with feedback and reports from consumer groups, industry and consultation with key stakeholders. The proposed changes were developed in conjunction with an external reference group representing consumers, health care professionals and industry.

13. How can I have my opinion heard?

The TGA is interested in the views of all stakeholder groups—consumers, industry and health care professionals—on the proposed regulatory changes. Details of the proposed regulatory changes can be found at <<http://www.tga.gov.au>>. Alternatively, a hardcopy of the consultation can be arranged by phoning 1800 020 653.

For each of the issues, the TGA is seeking feedback for the proposed regulatory changes. Interested stakeholders are encouraged to provide a response to the general questions at the end of each section relating to the proposed regulatory changes. Stakeholders may respond to as many or as few of the questions as they wish.

Submissions to the general questions and industry specific information should be lodged electronically to <labellingreview@tga.gov.au>. Or if hardcopy is preferred please mail your submissions to TGA Labelling and Packaging Review, PO Box 100, Woden, ACT, 2606.

The closing date for submissions is close of business 24 August 2012.

14. What will the TGA do with my submission in response to this consultation?

Submissions will be published on the TGA website throughout the consultation period. At the close of the consultation period, the TGA will collate and analyse submissions on matters that are within the scope of this review. Any submissions related to other matters will be archived and may be considered at some point in the future. The TGA will make any refinements or amendments of the proposed regulatory options as appropriate.

15. I have other ideas to improve medicine labels, what should I do with these?

These should be submitted to <labellingreview@tga.gov.au>, or if hardcopy is preferred please mail your submissions to TGA Labelling and Packaging Review, PO Box 100, Woden, ACT, 2606. If they are within the scope of the review, they will be analysed and may be used to further refine and amend the proposed regulatory changes. Any submissions related to other matters will be referred on where relevant or noted and may be considered at some point in the future.

16. When will the changes come into effect? Why can't this occur sooner?

It is anticipated that the revised Therapeutic Goods Order for medicine labelling will be registered as a legislative instrument in mid-2013. This timeframe allows for the required consultation on the economic impact and the Therapeutic Goods Order to occur. From the time the new TGO is registered as a legislative instrument there will be a transition period, at this stage proposed to be three years. New medicines that are approved once the new requirements come into force will be required to comply immediately.

17. Why is the labelling of nanoparticles in medicines and sunscreens not addressed in this review?

When considering the labelling of therapeutic goods (including sunscreens regulated by the TGA), the Australian Government aims to ensure that information provided is based on medical and scientific evidence. The reason for providing information on therapeutic goods labels is to support the consumer in the appropriate and safe use of the therapeutic good. To date, the TGA has not identified any evidence that supports changing requirements to include information about particle sizes. There is currently no evidence to suggest that sunscreen products which incorporate nanotechnologies pose greater safety risks than conventional products.

18. Why are Required Advisory Statements for Medicine Labels and specific warning statements not considered as part of this review?

This review is focused on addressing issues related to consumer safety associated with the presentation of medicines information. Addressing these issues is a priority for improving consumer safety and can be achieved in a timely manner. It is envisaged that specific information included on labels will be reviewed separately when required.

19. Why are requirements for child resistant packaging not being considered as part of this review?

Child resistant packaging requirements are addressed in Therapeutic Goods Order 80, which will be subject to a separate review process in due course.

20. Why has Tall Man Lettering not been recommended for labels of medicines with identified problem names?

Tall man lettering is outside of the scope of this review because it would be of most benefit to health care professionals and in a medicines dispensing setting; not as a direct solution for consumers.

21. Why does this review not address concerns that listed medicines are not evaluated for efficacy?

Recommendations 6 and 7 of *TGA reforms: A blueprint for TGA's future* (information provided on the labels of listed medicines explaining that the efficacy of these products has not been evaluated by TGA) are being addressed as part of the reform of the complementary medicines regulatory framework that is currently underway.

Historical consultation document

Historical consultation document

Therapeutic Goods Administration

PO Box 100 Woden ACT 2606 Australia
Email: info@tga.gov.au Phone: 1800 020 653 Fax: 02 6232 8605
www.tga.gov.au
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