Australian Government

Department of Health

Therapeutic Goods Administration

Regulation impact statement

General requirements for labels for medicines

Version 1.0, August 2014

TGA Health Safety Regulation

About the Therapeutic Goods Administration (TGA)

- The Therapeutic Goods Administration (TGA) is part of the Australian Government Department of Health, and is responsible for regulating medicines and medical devices.
- The 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 <http://www.tga.gov.au>.

Version history

Version	Description of change	Author	Effective date
V1.0	Original publication	Therapeutic Goods Administration	August 2014

Contents

Introduction

There are over 32,500 medicines included in the Australian Register of Therapeutic Goods (ARTG) although many are not currently supplied. Approximately 15,760 medicines are currently marketed in Australia. Inclusion in the ARTG is a prerequisite to the medicine being permitted to be marketed in Australia.

This Regulation Impact Statement (RIS) has been prepared by the TGA. The purpose is to assist the Australian Government decision making process on how to address a number of problems that have been identified in relation to the labelling of medicines in Australia, including both prescription and non-prescription medicines (over-the-counter medicines and complementary medicines).

A number of options to address the identified issues are examined in the RIS including the risk to consumer safety if no action is taken to resolve the problems.

These options have been developed following public consultation conducted by the TGA in 2012 and further consultation in 2013 by senior TGA staff with industry peak bodies, key health professional and consumer groups including:

- Generic Medicines Industry Association
- Medicines Australia
- Australian Self Medication Industry
- Complementary Healthcare Council of Australia
- The Pharmacy Guild of Australia
- Pharmaceutical Society of Australia
- Society of Hospital Pharmacists of Australia
- Council of Australian Therapeutic Advisory Groups
- Australian Medical Association
- Royal Australasian College of Physicians (RACP)
- Consumer Health Forum of Australia (CHF)

A comparison of approaches used for medicines labelling by overseas regulators, including Health Canada, the US Food and Drug Administration (FDA), the UK Medicines and Healthcare Products Regulatory Agency, European Medicines Agency and Medsafe (the regulatory agency for therapeutic goods in New Zealand) has also been undertaken.

Background

Regulation of medicines labelling in Australia

The TGA regulates the labels of medicines and approves these as part of the assessment process prior to medicines being permitted to be sold on the Australian market. Our regulation of medicines includes setting and enforcing the requirements for the way medicines in Australia are labelled. The TGA does not regulate the dispensing labels attached to medicines after they are prescribed, as these are regulated under state and territory laws.

The current regulation includes both requirements for medicines supplied under a health practitioner's prescription and also for medicines supplied without a prescription or over the counter, such as those medicines sold directly to consumers in pharmacies, supermarkets or other retail outlets.

The Therapeutic Goods Order No. 69 – General requirements for labels for medicines (TGO 69), drafted over 14 years ago, details current mandatory labelling requirements for medicines in Australia.

In order to prevent confusion and accidents, such as overdosing, under medicating or medicating with the incorrect medicines that are associated with unclear labelling on medicines, these requirements aim to ensure that labels of medicines supplied in Australia provide healthcare professionals and consumers access to information on the medicine including active ingredient name and in the case of over-the-counter medicines proper and safe usage. In addition, clear labelling of the active ingredients in a medicine enables hospital staff and poisons centre staff to provide the most appropriate emergency advice and interventions in the event of a deliberate or accidental overdose or consumption of a product by a young child.

TGO 69 outlines the information to be included on labels and specifies where and how such information is to be presented. The requirements include:

- the name of the medicine
- strength
- storage requirements
- expiry date
- details of the medicine's sponsor
- registration number or listing number to show that the medicine has been accepted by the TGA for supply in Australia (i.e. an AUST R or AUST L number)

TGO 69 is a legislative instrument. This means it is legally enforceable by the TGA, under powers provided by the *Therapeutic Goods Act 1989* (the Act). In addition to the mandated requirements in TGO 69, best practice for a number of elements of labelling for prescription medicines are described in the TGA's best practice guideline on prescription medicine labelling and, for over-the-counter medicines, in the TGA's Australian Regulatory Guidelines for Over-The-Counter Medicines, Australian Regulatory Guidelines for Sunscreens and the Australian Regulatory Guidelines for Complementary Medicines.

These regulatory guidelines include guidance on practices that enhance the ability of healthcare professionals and consumers to select the correct medicine, use it safely, and assist to reduce medication errors. The guidelines are not enforceable by the TGA and rely on voluntary compliance and therefore the suggested practices in the guidelines are inconsistently applied.

Medicine labels may also include other information not required by TGO 69, but required by other legislative instruments (including state or territory requirements) or for commercial purposes. These include labels stating 'pharmacy medicine', 'pharmacist medicine' and 'prescription only medicine', bar codes and sponsors' logos.

The TGA must, under provisions in the Act, consult with the Therapeutic Goods Committee, an advisory committee made up of external experts, on any proposed amendments to TGO 69 or other TGOs.

Review to improve the transparency of the TGA

In 2010, the government initiated a review into the transparency of the TGA, undertaken by an expert panel representing key consumer, health practitioner and industry groups.[1] In relation to medicines labelling, the Transparency Review particularly highlighted issues relating to a need for clarification and control of the labelling requirements for therapeutic goods including consistency of the positioning and font size of important information on labels.

The review panel heard three main areas of concern with regard to labelling:

- inaccessibility of mandatory information
- inconsistency of positioning and font size for important information
- lack of information and non-active ingredients (excipients)

Stakeholders were also concerned with the lack of a requirement for compulsory disclosure of a product's complete ingredients (including non-active ingredients). This was considered to be important safety information for people with allergies and intolerances (e.g. to gluten) and for those who are concerned about the possible health risks of new ingredients or formulations.

The review recommended that the 'TGA work with stakeholders to improve labelling requirements to educate and assist consumers and health practitioners to make informed decisions about the quality use of therapeutic goods'.

TGA medicines labelling review

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

- the TGA
- medicines industry including representative organisations
- academic researchers
- safety and quality organisations

Despite these efforts, concern about the contribution of naming, labelling and packaging practices to the safety and quality of medicines continues to be voiced by both consumers and healthcare professionals.

[1] Australian Government Therapeutic Goods Administration <http://www.tga.gov.au/newsroom/review-tga-transparency-1101.htm>

In response to the issues identified in the Transparency Review, in July 2011, the TGA commenced a systematic review of the labelling regulatory framework for prescription medicines, over-the-counter medicines and complementary medicines[2].

The objective of the review of the requirements for medicine labels was 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

The TGA received 110 submissions from consumers, academics, healthcare professionals and industry. Overall there was support for the objectives of the review of labelling and packaging and the intentions of the recommendations in the consultation paper. In particular there was strong support for changes regarding active ingredient prominence, standardised medicine information presentation, and dispensing label space.

At a meeting in February 2013, the overwhelming stakeholder view was that any changes to the current labelling standard should be mandatory and incorporated into a revised TGO, rather than implemented in a voluntary and inconsistent manner.

What is the problem?

Patient risk and harm

In 2013, the Australian Commission on Safety and Quality in Health Care conducted a literature review of medication safety in Australia. This review identified that 2-3 per cent of hospital admissions in Australia are related to medication errors. It is estimated that as many as 30 per cent of unplanned admissions among geriatric patients are associated with medication problems and that medication errors resulting in hospitalisation cost $1.2 billion annually.[3,4]This figure

[2] TGA Medicines Labelling and Packaging Review 2012 <http://www.tga.gov.au/newsroom/consult-labelling-packaging-review-120524-submissions.htm>

[3] Roughhead L, Semple S, Rosenfeld E, Literature Review: Medication Safety in Australia (2013). Australian Commission on Safety and Quality in Health Care, Sydney. <http://www.safetyandquality.gov.au/wp-content/uploads/2013/08/Literature-Review-Medication-Safety-in-Australia-2013.pdf>

does not take into account the additional effect on consumers who do not attend hospital but experience pain and suffering as a result of medication errors.

While there are multiple causes of these medication errors, the evidence in the Australian Commission on Safety and Quality in Health Care review suggests that confusion or errors in reading labels could be associated with many accidents. It is not possible to estimate the proportion of the costs attributable to label issues because of the limitation of the data however the evidence would suggest that it is significant.

Additionally, there are numerous reports in the literature that labelling issues are a significant contributor to medicine errors and the source of error themselves in other instances.[5,6,7,8]

Poor labelling may also affect patient safety and the ability of patients to follow instructions regarding the proper use of medicines, by increasing the difficulty of finding and understanding of information.[9,10]

Consumers report confusion with their prescription medicines, due to the increasing numbers of generic medicines (medicines with the same active ingredient as the medicine that was marketed first). Consumers are often not aware that a different brand of medicine they have been dispensed contains the same active ingredient as the medicine they are currently taking. The greatest risk associated with confusion of this type is overdose. While much of the work in this area refers to confusion associated with prescription medicines, awareness of the active ingredient affects the quality use of medicine and safety of consumers of all classes of medicines[11]. Improvements to labelling, such as increased prominence of the active ingredient on both prescription and non-prescription medicines, has been identified as a factor leading to improved safety and quality use of medicines[12].

Prescription medicines are prescribed by a doctor and dispensed by a pharmacist. The consumer receives counselling about their medication and Consumer Medicine Information (CMI). Despite this, errors still occur and may lead to adverse outcomes. However, consumers self-select over-the counter medicines (OTC) and therefore many patients receive no information from a health care provider except the instructions on the label[13,14]. This can cause drug misuse, overdose, and abuse leading to hospitalisations, morbidity and even mortality[15]. This highlights the importance of the medication label. Therefore, whilst non-prescription medicines may be

[4] Runciman WB, Roughead EE, Semple SJ & Adams RJ, Adverse drug events and medication errors in Australia. International Journal for Quality in Health Care, 2003; 15 (supp 1):i49-i59.
[5] Cohen MR, Drug product characteristics that foster drug-use system-errors. *Am J Health-Sys Pharm*, 1995;52:395-399.
[6] Jensen LS, Metty AF, Webster CS et al, Evidence-based strategies for preventing drug administration errors during anaesthesia. *Anaesthesia*, 2004;59:493-504.
[7] Hellier E, Edworthy J, Derbyshire N & Costello A, Considering the impact of medicine label design characteristics on patient safety. *Ergonomics*, 2006;49:617-630.
[8] Gernerin P, Perneger T, Chopard P et al, Drug Selection errors in relation to medication labels: a simulation study. Anaesthesia, 2007;62:1090-1094.
[9] De Somer E & Trofimov I, Medicine Partnership of Australia – Packaging and labelling of pharmaceuticals and consumer safety - A survey of the literature, 2011.
[10] Shrank W, Avorn J, Rolon C & Shekelle P, Effect of content and format of prescription drug labels on readability, understanding and medication use: a systematic review. Ann Pharmacother, 2007a;41:783-801.
[11] Lalor D, Medicines Labelling. Australian Prescriber, 2011;34:136-138.
[12] Consumers Health Forum of Australia, Equal prominence of active ingredient and proprietary names on labels for prescription medicines. Consumers Health Forum of Australia, Canberra, 2009.
[13] Holt GA, Dorcheus L, Hall EL, et al, Patient Interpretation of Label Instructions. American Pharmacy, 1993;NS32:58-62.
[14] Shrank WH, Agnew-Blais J, Choudhry NK et al, The variability and quality of medication container labels. Arch Intern Med, 2007b;167:1760-1765.
[15] Pawaskar MD & Sansgiry SS, Over-the-counter medication labels: problems and needs of the elderly population. JAGS, 2006;54:1955-1956.

considered to be lower risk in terms of adverse events than prescription medicines, there are still significant risks to consumers due to self-selection errors.

The language used to convey that information can also be a significant factor in medicines safety and quality use of medicine[16]. Poor understanding of medication labelling or failure to recognise the consequences if exceeding a maximum recommended dosage may lead to unintentional overdoses. In a study of paracetamol in 2011, it was found that consumers had poor recognition of which products contained paracetamol.

The NSW Poisons Information Centre has also reported errors that may occur because of inadequate labelling of medicines. It receives over 4000 calls regarding problems with paracetamol dosing, including deliberate self-poisoning, paediatric accidental ingestions and therapeutic errors in both adults and children. Approximately 20 per cent of therapeutic errors reported involve the use of more than one paracetamol products at the same time. A factor that contributes to this error is the fact that the active ingredients in medicines cannot be easily identified by the consumer.

Consumers also report having trouble identifying the active ingredient in compound medicines, such as cold and flu preparations. As these preparations could contain paracetamol or aspirin, negative health consequences are possible for some people if accidently (or purposely) taken in quantities above that recommended. Improved active ingredient prominence would enable consumers to identify which medicines contain the same ingredients and help prevent unintentional overdose.

A study in 2009 investigated factors associated with the understanding by caregivers of the importance of age of the child and dosing instructions on labels for paediatric OTC cough and cold medication. It was found that label language and graphics can lead to inappropriate interpretation of the appropriate dose[17].

There are also issues with the readability of OTC labels for the elderly population. As OTC labels are the primary source of information for consumers, older people need medication information in large font and easy-to-understand language so that they can use the medications independently. Lack of adequate information and knowledge about OTC medications can cause drug misuse, overdose, and abuse leading to hospitalisations, morbidity and even mortality[18].

International experience has also identified labelling of medicines as a source of public risk - for example, a Health Canada report recently estimated that the annual cost of medication error to their health care system is $1.8 billion[19], with labelling being a contributing factor. Further, poorly designed prescription medicine labels are reported to account for approximately one-third of medication errors investigated by the United States of America's Pharmacopoeial Convention (the body that sets standards for medicines in the United States). These errors have been found to be due, at least in part, from confusion caused by labels[20].

Therefore, the evidence suggests that poorly designed labels are a significant contributing factor to medication errors.

[16] King JP, Davis TC, Bailey SC et al, Developing consumer-centered, non-prescription drug labelling, a study in acetaminophen. Am J Prev Med, 2011;40:593-598.
[17] Lokker N, Sanders L, Perrin EM, et al, Parental Misinterpretation of Over-the-Counter Cough and Cold Medication Labels. Pediatrics, 2009;123:1464-1471.
[18] Pawaskar MD & Sansgiry SS, Over-the-counter medication labels: problems and needs of the elderly population. JAGS, 2006;54:1955-1956.
[19] Amendments to the *Food and Drug Regulations* (Labelling, Packaging and Brand Names) Cost-Benefit Analysis, Health Canada April 18 2013.
[20] Holt GA, Dorcheus L, Hall EL, *et al*, Patient Interpretation of Label Instructions. *American Pharmacy*, 1993;NS32:58-62.

In January 2013, the TGA published 'Labelling and packaging practices: A summary of some of the evidence (January 2013)'[21], which summarises evidence from the published literature about the problems associated with the labelling of medicines and the subsequent health risk and harm to consumers. Some of the issues identified include:

- **Lack of prominence of the active ingredient** - leading to unintentional overdoses where a patient self-medicates with two products not realising they contain the same active ingredient[22, 23, 24, 25]This is a particular risk with active ingredients like paracetamol that can be found in a wide range of over-the-counter medicines and for which the difference between a therapeutically-effective dose (e.g. for osteoarthritis) and a dose which is potentially toxic to the liver is relatively small.

- **Lack of standardisation of the Medicine Information Panel for non-prescription medicines** - leading to a lack of adherence to directions and inadequate dosing, both with self-administered or hospital/clinic administered medications, leading to poor treatment outcomes.[26]

- **Lack of comprehension of the language used on labels and poor readability of labels** - leading to medication errors[27, 28].

- **Poor outcomes associated with taking a medicine, including complementary medicines, when they are contra-indicated in combination with other medicines** or for some conditions. For example St John's Wort should not be used with certain other medicines. This should be clearly indicated on the label to inform the consumer[29].

- **Administration of the wrong medicine** (particularly in hospital settings where staff are often fatigued and under pressure) because of difficulty in reading the labels, leading either to ineffective treatment or potentially the administration of dangerous medications not indicated for the circumstances[30, 31, 32].

Many overseas jurisdictions have legislative requirements as well as Guidelines that require the active ingredient of a medicine to be prominent and establish a hierarchy of order for information presented on labels of medicine to help with consistency of presentation, which will help with consumer compliance.

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[21] Australian Government Therapeutic Goods Administration - Labelling and packaging practices: A summary of some of the evidence (January 2013) <http://www.tga.gov.au/newsroom/consult-labelling-packaging-review-120524-analysis-evidence.htm>

[22] Sorensen L, Stokes JA, Purdie DM, et al, Medication management at home: medication-related risk factors associated with poor health outcomes. Age and Ageing, 2005;34:626-632.

[23] Graudins LV & Dooley MJ, Generic medicines literacy – minimising the potential for patient confusion. MJA, 2010;193:427.

[24] Carney SL, Gazarian M, Denholm JT et al, What's in a name? Brand name confusion and generic medicines. MJA, 2011;195:650-651.

[25] Lalor D, Medicines Labelling. Australian Prescriber, 2011;34:136-138.

[26] Wogalter MS & Vigilante WJ, Effects of label format on knowledge acquisition and perceived readability by younger and older adults. Ergonomics, 2003;46:327-344.

[27] De Somer E & Trofimov I, Medicine Partnership of Australia – Packaging and labelling of pharmaceuticals and consumer safety - A survey of the literature, 2011.

[28] Shrank W, Avorn J, Rolon C & Shekelle P, Effect of content and format of prescription drug labels on readability, understanding and medication use: a systematic review. Ann Pharmacother, 2007a;41:783-801.

[29] Lalor D, Medicines Labelling. Australian Prescriber, 2011;34:136-138.

[30] Weingart SN, Wilson R, Gibberd RW & Harrison B, Epidemiology of medical error. BMJ 2000;320:774-7.

[31] Morrow DG, Leirer VO, Andrassy JM, Hier CM and Menard WE, The influence of list format and category headers on age differences in understanding medication instructions. Experimental Ageing Research, 1998;24:231-256.

[32] Shrank W, Avorn J, Rolon C & Shekelle P, Effect of content and format of prescription drug labels on readability, understanding and medication use: a systematic review. Ann Pharmacother, 2007;41:783-801.

A number of overseas jurisdictions, such as the United States of America, the United Kingdom, the European Union and New Zealand, have also updated their standards for medicines labelling and packaging to keep pace with developments such as an increasingly ageing population (who are likely to be on several prescription medicines simultaneously and suffer from failing eyesight), increasing demands from consumers for information about the medicines they take, emerging safety issues and the emergence of new types of more complex medicines.

While the European Union does not mandate the font size of the active ingredient[33], it does legislate that the active ingredient must be prominently displayed as well as specifying a hierarchy for the order of information on the medicine label. This is supported with Guidelines for the labelling of medicines[34].

In 1999, the FDA introduced a standardised format and content requirements for the labelling of over-the-counter medicines (OTC)[35]. This was intended to assist consumers in reading and understanding OTC medicines labelling so that consumers could use these products safely and effectively. The TGA proposes to introduce a similar requirement for a standardised medicine information panel for non-prescription medicines in the revised TGO.

A study in 2007[36] evaluated the effectiveness of the 1999 FDA-mandated standardised format called 'Drug Facts' for the labelling of over-the-counter-medicines and compared three labelling formats, the old, new and simulated. They found that consumers preferred the label format with a larger font size over those currently available. In addition, it was noted that the new OTC drug labels may not be easy for some consumers to use and understand, although they are an improvement over old unstandardised labels. It was concluded that manufacturers should look beyond the mandatory minimum font size (FDA 6 point) and develop strategies to improve comprehension of information on OTC medication labels.

In April 2014, Health Canada launched its Plain Language Labelling Initiative[37]. This initiative aims to improve the safe use of medicines by making medicine labels and packaging information easier to read and understand and will be achieved through regulatory and guidance updates. Changes that improve labelling include:

- greater active ingredient prominence
- standardised medicine information presentation
- dispensing label space
- harmonisation of labelling plans with other jurisdictions where possible

Similar to the Canadian proposal, the TGA proposes to mandate in the revised TGO active ingredient font size to improve prominence, a standardised medicine information panel for non-prescription medicines as well as space for a pharmacy dispensing label for prescription medicines.

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[33] Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community Code Relating to Medicinal Products for Human Use.
<http://www.edctp.org/fileadmin/documents/ethics/DIRECTIVE_200183EC_OF_THE_EUROPEAN_PARLIAMENT.pdf>

[34] Best Practice Guidance on the Labelling and Packaging of Medicines, Medicines and Healthcare products Regulatory Agency, May 2012.
<http://www.mhra.gov.uk/Howweregulate/Medicines/Labelspatientinformationleafletsandpackaging/Overviewoflabelspatientinformationleafletsandpackagingformedicines/index.htm>

[35] Federal Register/ Volume 64, No. 51/Wednesday, March 17, 199/Rules and Regulations.

[36] Murty S & Sansgiry S, Consumer comprehension of OTC Medication Labels and the scope for improvement in font size. J Pharm Technol, 2007; 23:207-213.

[37] Health Canada; Final Release: Plain Language Revisions to Part III: Patient Medication Information and Associated Templates of the *Guidance Document - Product Monograph*, 4 April 2014.

What policy options are being considered?

There are three policy options put forward in this RIS. Removing some or all of the current regulatory requirements is not considered to be a viable option as there would be considerable problems and risks to public health safety (including the additional burden that would be placed on the healthcare system) if the current requirements for labelling of medicines were removed.

The three proposed options are:

Option 1: No change

This option would require no change to current arrangements. TGO 69 would be retained and supported by the current voluntary guidelines:

- *Best practice guidelines on prescription medicine labelling*
- *Australian regulatory guidelines for over –the – counter medicines (ARGOM)*
- *Australian regulatory guidelines for complementary medicines (ARGCM)*
- *Australian regulatory guidelines for sunscreens (ARGS)*

This option clearly has limitations given the risks identified, including the difficulties for patients and health professionals to consistently locate information on product labels and the argument for improved minimum standards to be applied to all products.

Option 2: Provide best practice guidelines in line with most current evidence

This option proposes that the guidance for industry is updated with best practice:

- *Best practice guidelines on prescription medicine labelling*
- *Australian regulatory guidelines for over – the – counter medicines*
- *Australian regulatory guidelines for complementary medicines (ARGCM)*

The updated guidelines could include labelling elements described in Option 3 such as the recommendation that the minimum text size be increased from the prescribed minimum in TGO 69 to approximately 4 mm (or 15 point Arial) and that a transdermal patch, when affixed to the skin, be labelled with the name of the medicine.

To be successful, this option would rely on universal, voluntary application of the best practice guidelines, which in TGA's experience would be unlikely. Moreover, it does not provide clear direction to industry on which standards should apply to all sponsors in the Australian market.

This option is not considered 'up-regulation' or 'additional regulation' as there would be no mandatory expectation of compliance.

The draft Best Practice Guidelines attached to this RIS are not the guidelines that would be published under this option – they are an adjunct to Option 3. If this option was selected, these guidelines would need to be drafted, taking into account the new elements contained in Option 3.

Option 3: Introduction of a new Therapeutic Goods Order (TGO 79)

This option involves making a new legislative instrument (TGO 79) to mandate new requirements for the labelling of medicines supplied in Australia, supported by updating of the guidance for medicines labelling to reflect the new arrangements.

Within the new Order there is allowance for different requirements for prescription and non-prescription medicines. For example, the requirement for a medicine information panel applies only to non-prescription registered medicines whereas the space for a pharmacy dispensing label only applies to prescription medicines. The proposed changes to the Order address concerns expressed in the initial consultation undertaken by the TGA regarding medicine labelling in 2012.

The proposed changes to the requirements for labelling include:

- introduction of a new requirement that the name(s) of active ingredient(s) be a minimum text size equivalent to 15 point Arial on the front panel for registered medicines directly under the trade name, or for a registered medicine containing four or more active ingredients, in a text size of 12 point Arial, so that the active ingredient is prominent and consistently appearing in the same place compared to other information on a label
- introduction of a new requirement for registered non-prescription medicines to provide information in a consistent order and manner in a Medicine Information Panel
- change the font size requirements of text documenting active ingredients on labels of small containers (for container capacities of greater than 2.5 millilitres to 25 millilitres, including for injectable medicines) from 1.5 millimetres (equivalent to a font size of 6 point Arial) to 2 millimetres (equivalent to a font size of 8 point Arial)
- introduction of a new requirement for a defined or specific space to be made for dispensing labelling on packaging for prescription medicines
- introduction of a new requirement for medicines packed in strips or blister packs that the name (and the active ingredient(s) and strength) of a medicine must appear at least once across every two dosage units enclosed in the strip or blister, regardless of whether the strip or blister may be readily detached
- new requirements for declaration of certain excipients
- introduction of a new requirement to mandate the inclusion of warning on labels related to the use of medicines by those who are, or may be, pregnant
- introduction of new labelling requirements for registered medicines with four or more active ingredients
- introduction of new requirements for labelling for opaque intermediate packaging and for labelling of containers of medicines which are fully enclosed in drug delivery devices

What is the likely benefit of each option?

This section analyses the impacts of the options in relation to the following:

- **Public health and safety:** changes to the risks and benefits of using medicines
- **Costs:** financial impacts likely to be experienced, whether direct (fees and charges, etc.) or indirect (relating to implementation or compliance)
- **Access:** impacts on the availability of medicines in Australia

Option 1: No change

This option would involve no change to current arrangements. TGO 69 would continue in its current form, supported by voluntary guidelines:

- *Best practice guidelines on prescription medicine labelling*
- *Australian regulatory guidelines for over –the – counter medicines*
- *Australian regulatory guidelines for complementary medicines (ARGCM)*

From the extensive consultations to date, stakeholder groups, including industry, consumer and health professional groups, consider that this option fails to tackle the fundamental concerns that have been identified with the current arrangements for labelling.

Maintaining the status quo is also not supported by the evidence published by the TGA and other major international regulators[38].

The costs to the healthcare system over time will increase and health outcomes will decrease as an ageing population finds it more difficult to read and interpret medicine labels.

Benefits and costs to consumers

This option would provide the lowest net benefit as there is no reduction in the risk to consumers and associated costs to the healthcare system are anticipated to increase.

Direct costs

Under this option the TGA would continue with its current system for labelling approvals in the pre-market approval stages. There are costs for industry involved in this approach.

The current fee schedule includes the direct costs to have a variation to a medicine label approved. Variations to medicines in the ARTG requiring changes to labels are considered to be about 30 percent of the total applications.

[38] Australian Government Therapeutic Goods Administration - Labelling and packaging practices: A summary of some of the evidence (January 2013) <http://www.tga.gov.au/newsroom/consult-labelling-packaging-review-120524-analysis-evidence.htm>

Table 1: Annual number of medicines for which an application is made to vary an existing ARTG entry

Variations	2009	2010	2011	2012	2013
Prescription medicines	13789	9946	14381	15492	17418
Over the counter medicines	320	405	326	415	305
Registered complementary medicines	5	24	17	20	19
Listed medicines	331	333	453	549	366
Yearly total	**14445**	**10708**	**15177**	**16476**	**18108**

Indirect costs

Each time a new label for a product is created, there are costs involved in preparing the application for variation to the ARTG.

Assumptions:

- The average annual total number of applications to vary an entry on the ARTG is 14980 for medicines to be marketed in Australia, based on average figures over the sampled period
- Of these applications, 30 percent involve a change to a product label. This equates to 4495 variations that involve label changes
- Variations that include label changes always involve other changes to the entry that are not related to the label
- The labour burden for businesses who need to change a label would be approximately 20 hours (includes reading the current guidance and applying it to their design work and the small amount of labour involved in providing new label information as part of the application to vary the entry) at a labour rate of $42 per hour
- The labour involved in the second and subsequent products in a product line would equate to an extra 2 hours per additional product
- There are 2470 products (or 55 percent) that are either a single product or the first product in a range of products with the same brand and active ingredient but differing in strength and 2025 products are the second and subsequent strengths in the brand with the same active ingredient
- Pre-production costs for a ‘medium’ level label change, including a number of changes to existing text and adding new text requiring the logo to be moved around (e.g. artwork, redesign) are estimated at $1937 per product
- Pre-production costs for a minor label change to a second or subsequent product in a product range (e.g. artwork, redesign) are $1280 per product
- Production costs for a medium label change (described above) for a single product (e.g. new plate(s)) are $1290
- Production costs for a minor label change to a single product (e.g. new plate(s)) are $900

- Based on these assumptions, the cost to business to comply with the current arrangements total $14.6 million per annum.

Option 2: Update the guidance on best practice for medicines labelling in Australia

Given the voluntary nature of compliance with new arrangements under Option 2, there is stakeholder concern that there would be some within the industry who would follow best practice while others would not, given that the changes would not be mandated on industry. They consider that those within the industry who choose to follow the guidance on best practice for medicines labelling in Australia would be disadvantaged in comparison with their non-compliant counterparts.

There was a perception expressed by some companies that use of the current labelling requirements could offer a market advantage over adopting best practice guidelines. However, current evidence shows consumers and healthcare professionals favour the changes that are included in Option 3 (for example, because labels would be more readable and consistent) and there could, therefore, be a market advantage afforded to any company that improved their current labels.

Net benefit

If only a small percentage of products choose to follow best practice, then the resulting benefits will be reduced proportionately. When considering the benefits of introducing better labelling practices, option 3 captures a greater net benefit and reduction in costs to the healthcare system and also to health outcomes for individuals.

Direct costs

It is anticipated that businesses would not seek to change the labels for their products unless if they were also applying to vary their entry for normal business reasons (e.g. a change in business address, a change in labels for marketing reasons), for which they are already required to pay a fee. There would be no additional direct costs to industry as any fee costs are already attached to other business decisions.

Indirect costs

There is no expectation of compliance with these guidelines and businesses will only apply the best practice recommendations if they choose. As businesses are not currently applying the guidelines well or consistently yet they have been well exposed to the concepts over the past 3 years, it is assumed that there would be a very low compliance with the recommendations going forward. If businesses do choose to adopt the guidelines, it is expected they would do so in line with other changes and therefore costs would be negligible.

If only 10 per cent of manufacturers and sponsors choose to observe (or follow best practice) then the net benefits will be reduced accordingly. It is assumed that of the companies that would ordinarily update labels, some would choose to adopt some aspects of the new best practice guidelines if they are not legislated.

Assumptions:

- 10 per cent of products on the Australian market (1580 products) will apply some of the best practice guide to their labels and businesses will only apply a non-mandated change to a label if they are already making a change for some other business purpose

- Preproduction costs for following some of the principles in the best practice guidance will constitute $640 in additional work, which is half of the total preproduction cost for changes that would have been implemented as part of usual business
- The labour burden for businesses (who apply some of the changes outlined in best practice guidance) would be approximately 20 hours (includes reading the guidance and applying it to their design work and the small amount of additional labour involved in making the application to vary the entry) at a labour rate of $42 per hour
- Most of the application to vary the entry would be performed as part of normal business
- Post production costs will not increase as businesses would have incurred this cost in any case.

Benefits and risks to other stakeholders

The risk to consumer health and safety would lie with the inconsistency of label presentations under this approach. This inconsistency would be across and within groups of medicines. There may be some improvement to medicine labels that address some of the limitations that pose a risk to consumer safety but this would take place in a limited and inconsistent way. This in turn leads to only a minimal reduction in patient health outcomes, placing additional burden on health care providers and hospitals.

Consumer expectations and safety

This option will most likely not address many of the consumer concerns relating to readability and placement of active ingredient information because it is dependent on cooperation with best practice guidelines by all of industry. It is expected there may be minimal compliance with guidelines under option 2.

Option 3: Introduction of a new Therapeutic Goods Order (TGO 79)

This option is considered by many stakeholders as providing a balanced approach to addressing potential risks to consumer safety related to the labelling of medicines with the regulatory cost to industry to provide the greatest net benefit.

Compliance with the new labelling order may involve a one-off cost for some businesses that are not changing their labels during the transition period[39] in the natural course of their business, but after that, the costs would revert back to the status quo levels. This is because once the changes are made, the business returns to normal business practices and the new labelling order would not impose any additional regulatory burden to that of the current order.

An extensive survey of industry, using contact companies provided by the relevant industry associations for innovator and generic prescription medicines, over the counter medicines and complementary medicines was conducted in early 2014 and revealed that companies regularly change labels for commercial advantage (on average every 2.9 years) as part of normal business practice. Most costs to industry would be associated with the time to familiarise themselves with the new requirements and the subsequent change to labels, which in many cases would be incorporated with other label changes.

[39] Depending on the transition period chosen (2, 3 or 4 years) the transition period is the period of time in which phase in of new labels occurs.

We have provided 2, 3 and 4 year transition period for public consultation under options 3a, 3b, and 3c, respectively. The longer the transition time, the less cost that industry would incur independent of any other label changes undertaken as part of normal business, but also the benefit to public health by reducing risk would be delayed.

Improving the risk to consumers

As provided earlier, the evidence indicates the risk to consumers from incorrectly taking medicines has emerged due to the poor readability and inconsistent placement of the names of the active ingredients. Government policy encourages the increased use of generic medicines and pharmacies encourage the use of the generic medicines, as they provide a reduced cost to consumer, pharmacy and Government. Patients are often confused when they move from a trade-branded medicine to a generic brand as the packaging may be different in colour and shape, the trade name differs and they do not identify that the active ingredient is the same. The new TGO would ensure that the active ingredient(s) is readily identifiable and readable so that patients will understand that the branded medicine and the generic form are essentially the same.

There may be some remaining concerns about the changes, including whether the proposed changes to active ingredient(s) prominence and other labelling issues are sufficient to address consumer and health professionals' viewpoint as set out in previous consultations.

Risks associated with medicines differ depending on the level of consumer access and health care professional interaction associated with the class of medicine, for example a prescription only medicine or a product for self-selection in a pharmacy or supermarket. The new TGO recognises that there are different information needs for consumers and healthcare professionals in these circumstances and for example, a medicines information panel (or similar information) is proposed for self-selected medicines such as registered complementary medicines and over the counter medicines.

The risks associated with medication errors, which can in part be ameliorated through labelling, are not simply correlated with the risk of the medicine itself that is reflected in scheduling and its status as a prescription medicine, over-the-counter medicine or complementary medicine.

For example, with over-the-counter medicines, there is a high risk of overdosing with an ingredient where it is used in combination in multiple products, taken for different purposes. For example, with paracetamol it is quite easy for someone taking two products each containing 500-1350 mg paracetamol three times a day, one for 'pain (in particular osteoarthritis pain)' and the other for 'cold and flu', to inadvertently exceed 4000 mg in a single day the dose above which toxicity can occur with an associated risk to liver function. In people with compromised liver function (including that associated with chronic excessive alcohol intake), this upper threshold is much lower.

Paracetamol toxicity is the most common cause of acute liver failure. A recent study published in the Medical Journal of Australia found that 150 Australians are week are being admitted to hospital with paracetamol poisoning, equating to 8000 poisonings a year.

While there are other controls in place to avoid this problem, such as the restriction on the number of paracetamol tablets available in non-pharmacy settings such as supermarkets in a single pack (no more than 20), paracetamol toxicity frequently occurs when the patient was unaware that they were taking more than one product containing the ingredient. This can be addressed through clearer identification of the active ingredient(s) and consistent placement on product labels.

Similarly, some complementary medicines, while generally regarded as low risk, contain ingredients that can interfere with the action of other pharmaceuticals. For example, there are

products containing St John's Wort, used in complementary medicines to control mood swings and depression, where it is not immediately evident that this ingredient is present. The patient simply knows they are for 'low mood and despondency' and 'feelings of sadness and/or tearfulness'.

However, St John's Wort is known to interfere with the action of oral contraceptives and heart medications, such as warfarin and digoxin. Improved labelling will help patients who are taking combination products containing St John's Wort and products containing affected ingredients to avoid these interactions and seek appropriate medical advice; or assist medical personnel to identify the possibility for these interactions.

Flexibility for small containers and products with a large number of ingredients, such as some complementary medicines, has been incorporated into the new TGO rather than adding complexity with a separate TGO.

Benefits to the health system

It is expected that there will be a reduction in costs to the public health system related to less incorrect and inappropriate use of medicines as a result of improvement to medicine labels. It has been estimated conservatively that this cost is approximately 2.5 per cent of the total costs from incorrect medicine use or $30 million per annum, of hospital admission attributed to medication errors. This is a conservative estimate as it also does not consider reductions in visits to general practitioners and other healthcare providers.

Costs to industry

Direct regulatory costs

Under this option the new Therapeutic Goods Order would require all businesses to update their medicine labels to match the requirements of the new legislation.

Many organisations would be updating labels as a matter of normal business practice. The costs calculated here indicate the additional costs to industry as a result of the changes being made.

Indirect regulatory costs

The indirect costs to industry include the labour involved in preparing a variation to the ARTG entry and also the costs to produce a new label.

Regulatory burden estimates

Regular changes to medicine labels are part of normal business practice. From an industry survey, it is estimated that more than half of medicine labels for products marketed in Australia are changed every three years. When proposing options for the length of the transition time to the proposed amendments, the TGA considered the need to ensure that the burden placed on industry is minimised. By doing so, the TGA proposes that label changes could occur as part of business as usual activities as opposed to being triggered by the need to meet regulatory requirements.

Furthermore, it is noted that some labels, including those of some larger generic medicine manufacturers, are already compliant with the proposed draft requirements of TGO 79. There has been no discounting for this in the costings therefore the figures outlined in this document are conservative.

The following assumptions have been made when quantifying the regulatory burden for this option:

- it takes 20 hours to prepare an application for variation for the first product strength on the ARTG. This time would include updating procedures, policies and the time taken to assemble the necessary information and fill in the form to apply to vary the application. Wage rates for the preparation of the application are $42 per hour.
- there are a total of 15,800 medicines that would require label changes. Of the 32,500 medicines included in the ARTG, 14,080 have a zero dollar turnover, indicating that they are not currently being sold in Australia. A further 2,660 medicines are for export only and would not be subject to compulsory label changes.
- currently marketed products change their labels as a matter of normal business, on average, every 2.9 years (rounded to 3 years).
- pre-production costs for a 'medium' level label change, including a number of changes to existing text and adding new text requiring the logo to be moved around (e.g. artwork, redesign) are estimated at $1937 per product. This is based on the average figure provided by an independent survey in 2014 of 9 companies covering prescription, OTC and complementary medicines.
- pre-production costs for a minor label change (e.g. artwork, redesign) are $1280 per product. This is based on the average figure provided by an independent survey in 2014 of 9 companies covering prescription, OTC and complementary medicines.
- production costs for a medium label change (described above) for a single product (e.g. new plate(s)) are $1290 . This is based on the average figure provided by an independent survey in 2014 of 9 companies covering prescription, OTC and complementary medicines.
- production costs for a minor label change to a single product (e.g. new plate(s)) are $900 . This is based on the average figure provided by an independent survey in 2014 of 9 companies covering prescription, OTC and complementary medicines.
- paper and ink for print is a business as usual cost.
- if products have different strength of the same active ingredient, the first label would constitute an 'average' change whereas the second and subsequent strengths of a product would have a 'minor' change.
- there are 8690 products that are either a single product or the first product in a range of products with the same brand and active ingredient but differing in strength and 7110 products that are second and subsequent strengths.
- extra time to prepare an application for variation for an ARTG entry where there are two or more products with the same active ingredient and different strengths is 2 hours for the second and each subsequent product
- A 6 per cent discount rate (per annum) has been applied to products that would need to change labels earlier than would be required as part of ordinary business.

Option 3a – Two year transition period

- The following assumptions are specific to this option with a two year transition period:
- There are four categories of label changes:
  - Category 1: Those that will change within the two year transition period as part of normal business. It is assumed that this is approximately 3 per cent (474) of the 15800 labels that need changes (as per a normal skewed right distribution curve).
  - Category 2: Those that would normally change in a three year cycle, but are being forced to change 1 year earlier. It is assumed that this is approximately 47 per cent (7426).
  - Category 3: Those that would normally change in a four year cycle, but are being forced to change 2 years earlier. It is assumed that this is approximately 25 per cent (3950).
  - Category 4: Those that would normally change in a five year cycle, but are being forced to change 3 years earlier. It is assumed that this is approximately 15 per cent (2370)
  - Category 5: Those that would never normally change. It is assuming this is the remaining 10 per cent (1580).
- For Category 1, it is assumed that the regulatory changes will be made in the context of the other business driven changes.
  - For Category 2, this means 4084 with medium costs; 3342 with minor costs
  - For Category 3, this means 2173 with medium costs; 1777 with minor costs
  - For Category 4, this means 1304 with medium costs; 1066 with minor costs
  - For Category 5, this means 869 with medium costs; 711 with minor costs
- For Category 2, 3 and 4 labels, it is assumed planned changes for business reasons are brought forward to avoid having to pay twice for label changes (once for the regulatory changes, once for the business need). However, there is an opportunity cost to this (other business initiatives foregone because of the cost of making the changes earlier than planned) and so costs have been increased by six per cent per year.
- For Category 2, 3 and 4 labels, it is assumed that fifty per cent of the costs are attributable to business needs and fifty per cent to the required regulatory changes, with an additional 2 hours labour.
- For Category 5 labels, it is assumed that 100 per cent of the costs are attributable to the required regulatory changes, with 20 hours labour for the medium changes and 2 hours labour for the minor changes
- For Category 2, the annual costs over ten years are $0.13 million per annum
- For Category 3, the annual costs over ten years are $0.74 million per annum.
- For Category 4, the annual costs over ten years are $0.46 million per annum.
- For Category 5, the annual costs over ten years are $0.51 million per annum.
- This gives a total cost of the change per annum over ten years as $3 million per annum.

Option 3b – Three year transition period

The following assumptions are specific to this option with a three year transition period:

- There are four categories of label changes:
  - Category 1: Those that will change within the three year transition period as part of normal business. It is assumed that this is approximately 50 per cent (7900) of the 15800 labels that need changes.
  - Category 2: Those that would normally change in a four year cycle, but are being forced to change 1 year earlier. It is assumed that this is approximately 25 per cent (3950).
  - Category 3: Those that would normally change in a five year cycle, but are being forced to change 2 years earlier. It is assumed that this is approximately 15 per cent (2370)
  - Category 4: Those that would never normally change. It is assuming this is the remaining 10 per cent (1580).
- For Category 1, it is assumed that the regulatory changes will be made in the context of the other business driven changes.
  - For Category 2, this means 2173 with medium costs; 1777 with minor costs
  - For Category 3, this means 1304 with medium costs; 1066 with minor costs
  - For Category 4, this means 869 with medium costs; 711 with minor costs
- For Category 2 and 3 labels, it is assumed planned changes for business reasons are brought forward to avoid having to pay twice for label changes (once for the regulatory changes, once for the business need). However, there is an opportunity cost to this (other business initiatives foregone because of the cost of making the changes earlier than planned) and so costs have been increased by six per cent per year.
- For Category 2 and 3 labels, it is assumed that fifty per cent of the costs are attributable to business needs and fifty per cent to the required regulatory changes, with an additional 2 hours labour.
- For Category 4 labels, it is assumed that 100 per cent of the costs are attributable to the required regulatory changes, with 20 hours labour for the medium changes and 2 hours labour for the minor changes.
- For Category 2, the annual costs over ten years are $0.70 million per annum.
- For Category 3, the annual costs over ten years are $0.44 million per annum.
- For Category 4, the annual costs over ten years are $0.51 million per annum.
- This gives a total cost of the change per annum over ten years as $1.7 million per annum.

Option 3c – Four year transition period

The following assumptions are specific to this option when considering a four year transition period:

- This is as for Option 3b, except there are only three categories:
  - Category 1: those that would make a normal business change in the four years, 75 per cent of 15800 labels

  - Category 2: those that would make a normal business change in the fifth year, but bring forward that change to comply with the four year transition, 15 per cent of 15800
  - Category 3: those that would not make a change, the remaining 10 per cent.

- Category 2 annual costs over 10 years are $0.42 million per annum.
- Category 3 annual costs over 10 years are $0.28 million per annum.
- Total costs per year over 10 years for this option are $0.7 million per annum.

The costs to make changes to a label with regard to pre-production and post-production costs has been provided through industry consultation and reflect an average of costs provided to an independent reviewer from 9 prescription, OTC and complementary medicines sponsors.

Regulatory Burden and Cost Offset Estimate Table

Average Annual Regulatory Costs (from Business as usual)				
Change in costs ($million)	Business	Community Organisations	Individuals	Total change in cost
Option 2	$0.2			$0.2
Option 3 (a)	$3			$3
Option 3 (b)	$1.7			$1.7
Option 3 (c)	$0.7			$0.7
Total by Sector	$	$	$	$
Cost offset ($million)	Business	Community Organisations	Individuals	Total by Source
Electronic Submission of Data Dossiers OBPR ref: 14783	$-3	$	$	$-3
Are all new costs offset? ✓ yes, costs are offset □ no, costs are not offset □ deregulatory, no offsets required				
Total (Change in costs - Cost offset) ($million) $0				

Who was consulted about the options and how?

A plan for future consultation has been attached to this RIS. This will follow and build on previous consultations which are summarised below.

Over the last 10 years, many stakeholders have made the TGA aware that they are concerned about medicines labelling and packaging in the context of it not keeping pace with reforms internationally, and the TGA has conducted a number of consultation processes that have been either partially or solely focussed on their concerns. Most recently the transparency review, the labelling and packaging of medicines review and the round table on safer naming, labelling and packaging of medicines have all fed into the consultative process.

The National Round Table on Safer Naming, Labelling and Packaging of Medicines, was jointly hosted by the TGA and the Australian Commission on Safety and Quality in Health Care in May 2011. The round table, with members from the medicines industry, health professionals, governments and consumer groups, made a number of recommendations for improvements to the current regulatory framework to reduce the risk of confusion of medicines names and labels which contribute to patient harm[40]. The TGA and the Commission undertook to review the recommendations and develop a national approach to reducing the risk of confusing naming and labelling contributing to patient harm.

In July 2011 the TGA commenced a systematic review of the labelling and packaging regulatory framework for prescription medicines, over the counter medicines and complementary medicines[41]. An internal working group was established to develop options for the key problems that had been identified with current labelling requirements. These options were then discussed and further refined by an invited stakeholder group comprising health care professionals, industry representatives and consumers. This group met in February 2012.

A consultation paper - TGA medicine labelling and packaging review - was subsequently released by the TGA on 24 May 2012, which was a culmination of the input of the internal working group and key stakeholder groups[42]. The paper outlined a number of proposals to address the identified problems by changing the requirements for labelling of medicines. The consultation on the paper closed on 24 August 2012. In response to the consultation, 110 submissions were received from consumers, academics, healthcare professionals and industry. Overall, there was support for the objectives of the review of labelling and the intentions of the recommendations in the consultation paper.

Following further individual discussions with stakeholders, the TGA hosted a major stakeholder meeting in February 2013 to further discuss the proposed changes that would be required to improve medicines labelling. This was followed up (March - June 2013) with senior TGA staff holding bilateral consultations with industry groups (Medicines Australia, Generic Medicines Industry Association, Australian Self Medication Industry and the Complementary Healthcare Council) as well as health professional stakeholder groups including the Pharmacy Guild, the Pharmaceutical Society of Australia, the Society of Hospital Pharmacists of Australia, Council of Australian Therapeutic Advisory Groups, the Royal Australian College of Physicians and the Australian Medical Association. The Consumer Health Forum was also consulted.

A first draft of a revised TGO (79) encompassing proposed changes was provide to industry peak bodies in June 2013.

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[40] Australian Commission on Safety and Quality in Healthcare <http://www.safetyandquality.gov.au/publications/national-round-table-on-safer-naming-labelling-and-packaging-of-medicines-report/>

[41] TGA Medicines Labelling and Packaging Review 2012 <http://www.tga.gov.au/newsroom/consult-labelling-packaging-review-120524-submissions.htm>

[42] Australian Government Therapeutic Goods Administration <http://www.tga.gov.au/newsroom/consult-labelling-packaging-review-120524.htm>

Consultation also occurred directly with members of the Therapeutic Goods Committee, with the draft Order and accompanying materials being discussed at their August 2013 and June 2014 meetings. The Committee consists of up to 12 members, who are appointed by the Minister for Health, and have expertise in their relevant fields, or are nominees of organisations that represent the interests of the main sectors of the therapeutic goods industry as well as consumers of health services. Members have been appointed on the basis of their individual skills, knowledge and expertise. The *Therapeutic Goods Act 1989* requires that the Committee be consulted on all proposed amendments to therapeutic goods orders.

Next steps

Making submissions

Content of submissions

Submissions may address any, or all, of the options to amend the general requirements for labels for medicines.

In addition, submissions might include:

- suggested improvements or alternatives to the options;
- whether or not you support the specific or parts of options or a combination of options. If you do not support the options you may make suggestions for an alternative that is acceptable to you;
- the extent to which you are already complying with the current voluntary guidelines or the proposed TGO79;
- an assessment of how the proposed options will impact on you. This is, what do you see as the likely benefits or costs to you (these may be financial or non-financial). If possible, please attempt to quantify the direct and indirect costs and benefits; and
- your views in relation to other benefits and costs that you consider relevant.

Any submissions will inform the final RIS and the CRIS that will be developed by the TGA.

What will happen?

Submissions will be reviewed and considered by the TGA and any updates on proposed actions will be made available on the TGA's Internet site.

Enquiries

Questions relating to the submission should be directed to the Head, Office of Scientific Evaluation, Mr Bill Turner by email to labellingreview@tga.gov.au or by telephone to 02 6232 8704.

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Reference/Publication #