Australian Government
Department of Health
Therapeutic Goods Administration

Regulation Impact Statement

General requirements for labels for medicines

Version 3.0, July 2016

TGA Health Safety Regulation

Contents

Introduction 6

Background 7

Regulation of medicine labelling in Australia 7

Current labelling requirements – TGO 69 and best practice guidelines 7

TGA medicines labelling review 8

What is the problem? 11

Introduction 11

Problems are applicable to prescription and non-prescription medicines 11

Consumer dissatisfaction 12

Testimonials from consumers and healthcare professionals 12

Testimonials from consumer and healthcare professionals 13

Current requirements fall short of international best practice 13

Patient risk and harm 13

International practices 17

The International Medication Safety Network 17

European Union 18

United States 18

Canada 19

Broader medicine label requirements 19

Concluding remarks 20

What policy options are being considered? 21

Option 1: No change 21

Option 2: Best practice guidelines in line with most current evidence 22

Option 3: Introduction of new Therapeutic Goods Orders (TGOs 91 and 92) 22

What is the likely benefit of each option? 24

Option 1: No change 24

Net benefit 24

Direct costs 24

Indirect costs 24

Option 2: Update the guidance on best practice for medicines labelling in Australia 25
Net benefit 25
Direct costs 25
Indirect costs 26
Regulatory burden estimates 26
Benefits to other stakeholders 26
Risks to other stakeholders 27
Consumer expectations and safety 27
Option 3: Introduction of new Therapeutic Goods Orders (TGOs 91 and 92) 27
Net benefit 27
Direct costs 27
Indirect costs 28
Benefits to other stakeholders 28
Risks to other stakeholders 29
Consumer expectations and safety 29
Regulatory burden estimates 30
Option 3a - Two year transition period 32
Option 3b – Three year transition period 33
Option 3c – Four year transition period 33
Consultation 35
Preliminary consultation 35
Subsequent consultation(s) 35
2014 public consultation 36
2015 targeted consultation 47
Other avenues of consultation: Therapeutic Goods Committee 52
Conclusion and recommended option 53
Implementation and review 55
Risks 55
Review and post-implementation activities 56
Communication and education 56
Targeted communication 56
Appendix A: List of submissions received in response to 2014 public consultation 57

Appendix B: Summary of major amended requirements made in TGO 91/92 as a result of 2014 public consultation 60

Appendix C: List of submissions received in response to 2015 targeted consultation 68

Appendix D: Summary of major amended requirements made in TGO 91/92 as a result of 2015 targeted consultation 70

Introduction

The purpose of this Regulation Impact Statement (RIS) is to assist the Australian Government decision making process on how to address problems that have been identified in relation to the labelling of medicines in Australia.

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.

These options have been developed following consultation conducted by the Therapeutic Goods Administration (TGA) in 2012, 2014 and 2015. Stakeholders participating in these consultations were industry peak bodies and key health professional and consumer groups including:

- Generic Medicines Industry Association (now the Generic and Biosimilar Medicines Association)
- Medicines Australia
- Australian Self Medication Industry
- Complementary Healthcare Council of Australia (now Complementary Medicines 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
- Consumer Health Forum of Australia

A comparison of medicine labelling requirements applied by overseas regulators has also been undertaken. These agencies include Health Canada, the US Food and Drug Administration (FDA), UK Medicines and Healthcare Products Regulatory Agency, European Medicines Agency and New Zealand Medicines and Medical Devices Safety Authority (Medsafe).

Background

Regulation of medicine labelling in Australia

As part of the Department of Health, the TGA is responsible for regulating the supply, import, export, manufacturing and advertising of therapeutic goods.

Under the powers of the *Therapeutic Goods Act 1989* (the Act), the TGA is responsible for establishing and enforcing requirements for the way medicines are labelled for commercial supply in Australia. Under the provisions of the Act, a number of standards have been created to assist in this regulatory function. These standards known, as Therapeutic Goods Orders, are registered on the Federal Register of Legislation and several are applicable to the labelling and packaging of medicines.[1] Proposed changes to a current Order, the Therapeutic Goods Order No. 69 - General requirements for labels for medicines (TGO 69) is the subject of this RIS. TGO 69 applies to both medicines supplied under a health practitioner's prescription and also those that are self-selected by consumers, without a prescription, from pharmacies, supermarkets or other retail outlets ('over-the-counter' medicines).

Current labelling requirements – TGO 69 and best practice guidelines

Medicines supplied in Australia must meet labelling requirements specified in TGO 69. Drafted over 16 years ago, TGO 69 mandates information that must be on labels and the format and placement in which it must be presented. Examples of information required by TGO 69 include the name of the medicine, the name of the active ingredient (e.g. paracetamol) and its strength or quantity, storage requirements, expiry date and the declaration of certain inert or inactive ingredients ('excipient' ingredients).

Clear and prominent labelling of active ingredients enables hospital and poisons centre staff to provide the most appropriate emergency advice and interventions in the event of an accidental or deliberate overdose, or incorrect use of a product. Declaration of active ingredients on the main labels of medicines, as required by TGO 69, seeks to minimise these incidents. However, the Order is now outdated and lags behind international labelling requirements and current labelling design research.

In some instances, Australian medicine labels must also include other information that is not required by TGO 69, such as that required under state or territory legislation or for commercial purposes. This includes label headings such as 'pharmacy medicine', 'pharmacist medicine' and 'prescription only medicine' required under the Standard for the Uniform Scheduling of Medicines and Poisons (the Poisons Standard), or bar codes and sponsors' logos. Additionally, some labels are applied after a medicine is in commercial supply; for example, dispensing labels attached to prescription medicines. TGA does not regulate the dispensing labels, nor any other user-applied labels, or implementation of the Poisons Standard as these are regulated under state and territory laws.

In addition to the mandated requirements of TGO 69, guidance documentation exists to outline best practice principles for the design of medicine labels. These guidelines aim to assist sponsors to design labels that enhance the ability of healthcare professionals and consumers to select the correct medicine, use it safely, and reduce medication errors. These include, for prescription

[1] Therapeutic Goods Administration (TGA), *Diagram of the TGA labelling and packaging framework* <https://www.tga.gov.au/tga-labelling-and-packaging-regulatory-framework#attach1>

medicines, Best practice guideline on prescription medicine labelling; and, for over-the-counter medicines, the Australian Regulatory Guidelines for Over-The-Counter Medicines, Australian Regulatory Guidelines for Sunscreens and the Australian Regulatory Guidelines for Complementary Medicines. However, recommendations in these guidance materials are not enforceable and the TGA relies on voluntary compliance. This means that best practice principles are inconsistently applied.

TGA medicines labelling review

There have been ongoing efforts by numerous organisations to improve the quality of the naming, labelling and packaging of medicines in Australia, including from:

- medicines industry, including representative organisations
- academic researchers
- safety and quality organisations
- consumer groups

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

In response to a recommendation in the 2010 Transparency Review[2] to work with stakeholders to improve labelling requirements of medicines, and in recognition of the ongoing safety concerns of medicines, in July 2011 the TGA commenced a systematic review of the regulatory framework that applied to the labelling of medicines.[3]

The objective of the review was to develop regulatory solutions that effectively addressed 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 look 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

[2] TGA reforms: A blueprint for TGA's future <https://www.tga.gov.au/publication/tga-reforms-blueprint-tgas-future>
[3] Therapeutic Goods Administration 2011, Labelling and Packaging Review

In February 2012 an External Reference Group, comprising industry, consumers, health professionals and government representatives, met to discuss labelling options. 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 through best practice guidance.

Subsequently, public consultation was held in May 2012 to seek comments on recommendations to change the presentation of information on the labels and packages of medicines.[4] The TGA received 110 submissions from consumers, academics, healthcare professionals and industry.[5] Generally, 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.

In January 2013, the TGA published 'Labelling and packaging practices: A summary of some of the evidence'[6]. This report reviewed the published literature on the problems associated with the labelling of medicines and the subsequent health risk 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[7,8,9,10] 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.[11]
- **Lack of comprehension of the language used on labels and poor readability of labels** - leading to medication errors.[12,13]

[4] Therapeutic Goods Administration 2012, TGA medicine labelling and packaging review Consultation <https://www.tga.gov.au/book/introduction-7>
[5] Therapeutic Goods Administration 2012, *TGA medicine labelling and packaging review*, <https://www.tga.gov.au/book/medicines-labelling-and-packaging-review-public-submissions>
[6] Therapeutic Goods Administration 2013, *Labelling and packaging practices: A summary of some of the evidence (January 2013)*, <https://www.tga.gov.au/labelling-and-packaging-practices-summary-some-evidence>
[7] Sorensen, L, Stokes, J, Purdie, M, et al., 2005, 'Medication management at home: medication-related risk factors associated with poor health outcomes', *Age and Ageing*, vol. 34, no. 6, pp. 626-632.
[8] Graudins, L & Dooley, M 2010, 'Generic medicines literacy – minimising the potential for patient confusion', *Medical Journal of Australia*, vol. 193, no. 7, p. 427.
[9] Carney, S, Gazarian, M, Denholm, J et al., 2011, 'What's in a name? Brand name confusion and generic medicines', *Medical Journal of Australia*, vol. 195, no 11, pp. 650-651.
[10] Lalor, D 2011, 'Medicines Labelling', *Australian Prescriber*, vol. 34, pp. 136-138.
[11] Wogalter, M & Vigilante, W 2003, 'Effects of label format on knowledge acquisition and perceived readability by younger and older adults', *Ergonomics*, vol. 46, no 4, pp. 327-344.
[12] Medicines Australia Ltd 2011, *Packaging and labelling of pharmaceuticals and consumer safety - A survey of the literature*, <http://medicinespartnership.com.au/files/2013/02/20110524-dis-Packaging-and-labelling-of-pharmaceuticals-and-consumer-safety-MA-lit-review-MPA-version.pdf>
[13] Shrank, W, Avorn, J, Rolon, C, & Shekelle, P2007, 'Effect of content and format of prescription drug labels on readability, understanding and medication use: a systematic review', *Ann Pharmacother*, vol. 41, no. 5, pp. 783-801.

- **Poor outcomes associated with taking a medicine, including complementary medicines, when they are contraindicated in combination with other medicines** or for some conditions.[14]
- **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.[15,16,17]

[14] Lalor, D 2011, 'Medicines Labelling', *Australian Prescriber*, vol. 34, pp. 136-138.
[15] Weingart, S, Wilson, R, Gibberd, R & Harrison, B 2000, 'Epidemiology of medical error', *BMJ*, vol. 320, no. 7237, pp.774-7.
[16] Morrow, D, Leirer, V, Andrassy, J, Hier, C and Menard, W, 1998, 'The influence of list format and category headers on age differences in understanding medication instructions', *Experimental Ageing Research*, vol. 24, no.3, pp 231-256.
[17] Shrank, W, Avorn, J, Rolon, C, & Shekelle, P2007, 'Effect of content and format of prescription drug labels on readability, understanding and medication use: a systematic review', *Ann Pharmacother*, vol. 41, no. 5, pp. 783-801.

What is the problem?

Summary: Medication errors are a significant contributor to healthcare costs in Australia. Many of these errors are associated with consumers or healthcare practitioners having difficulty locating and understanding critical information on medicine labels.

It has been estimated that 2-3 per cent of all hospital admissions in Australia are related to medication errors. As many as 30 per cent of unplanned admissions among patients aged 65 and over are associated with medication problems. Medication errors resulting in hospitalisation cost approximately $1.2 billion annually. Depending on the medicines involved, documented outcomes range from minor to catastrophic.

Consumers and healthcare practitioners have raised concerns about the readability of medicine labels in Australia. As the Australian medicines regulator, TGA regularly receives complaints from consumers who want labels to include more information on medicine ingredients and seek easier identification of critical information, including better legibility and consistent placement on a medicine label.

The current Australian legislation that sets a minimum standard for medicine labels is now more than 16 years old and does not reflect current best practice nor align with standards set internationally by overseas regulators.

Introduction

The design and content of medicine labels can have a significant impact on the quality and safe use of those medicines. For example, a medicine label is usually the first point of interaction between a consumer and a medicine. The selection of a specific medicine, whether by a pharmacist, nurse, doctor or consumer, requires the user to read the label, identify the medicine and (if applicable), prepare to administer the product. Therefore, labels must clearly identify a particular medicine and provide sufficient information to allow people to make safe and informed decisions about its use.

Clear and consistent placement of important information helps to ensure that, from the very point of first interaction, a medicine is selected properly and used safely.

Problems are applicable to prescription and non-prescription medicines

While there are differences in the individual requirements of labels for prescription and non-prescription medicines, many of the issues are common between the two classes.

Prescription medicines are prescribed by a doctor and dispensed by a pharmacist. The consumer receives face-to-face counselling about their medication and Consumer Medicine Information (CMI) documents are available for a patient's on-going reference. These documents provide information on how the medicine works, how and when to take the medicine, potential side effects and interactions. Despite this, errors still occur and may lead to adverse outcomes.

In the case of non-prescription medicines, consumers self-select over-the-counter (OTC) medicines and therefore may not receive any supporting information from a healthcare

provider.[18,19] Consumers rely solely on the instructions on the label. This can result in drug misuse, overdose, and abuse leading to hospitalisations, morbidity and even mortality.[20] Whilst non-prescription medicines may be considered to be lower risk than prescription medicines in terms of adverse events, there are still significant risks to consumers due to self-selection.

Therefore, the medicine label serves a crucial function for both prescription and non-prescription medicines.

Consumer dissatisfaction

One of the most common complaints received by the TGA in relation to medicine labelling is that the print on medicine labels is too small to read. This complaint was emphasised in the 1995 International Year of Older Persons Platform for Action, which recommended that manufacturers and pharmacists increase the print size on their labels.[21] Other studies have confirmed that consumers prefer labels printed with larger font size.[22]

Testimonials from consumers and healthcare professionals

'*I want the naming and packaging of drugs to be clear and identifiable easily for sick and confused patients.*

I want to change how the product is identified.

I even hope for colour coding and large type letters so it is not necessary to use a magnifying glass to read the information on the packet.'

'Why is the generic name of a drug is [sic]not required to be at least as legible as the brand name?... Generic Drug Names are small and, to vision impaired, illegible compared to the colourful brand names.'

Another common complaint is that label information is not easy to understand. The majority of people surveyed in a study commissioned by the Proprietary Medicines of Australia in 1993,[23] indicated that they were happy with the amount of information provided on medicine labels, but needed information that is more easily understood. Although the study has often been criticised for the methodology employed, and only small improvements in label useability were found, it

[18] Holt, G, Dorcheus, L, Hall, E, et al., 1993, 'Patient Interpretation of Label Instructions', *American Pharmacy*, 1993; vol. 32, no. 3, pp. 58-62.
[19] Shrank W, Agnew-Blais, J, Choudhry, K et al., 2007, 'The variability and quality of medication container labels', *Archives of Internal Medicine*, vol. 167, no. 16, pp. 1760-1765.
[20] Pawaskar, M & Sansgiry, S 2006, 'Over-the-counter medication labels: problems and needs of the elderly population', *Journal of the American Geriatrics Society*, vol. 54, no. 12, pp. 1955-1956.
[21] Therapeutic Goods Administration, *Review of the Labelling Requirements for Medicines: Consumer focused labeling- a way forward?* (March 2002) <https://www.tga.gov.au/sites/default/files/review-labelling-medicine-020417.pdf>.
[22] Vigilante, W.J. & Wogalter M.S., Over-the-counter (OTC) drug labeling: format preferences. In: Proceedings of the Human Factors and Ergonomics Society 43rd Annual Meeting. Human Factors Society, Santa Monica, CA, pp. 103-107.
[23] Russell G & and Antill J (1992), 'Making medicine labels work' 1992, Macquarie University (unreported).

provides evidence that there is increasing demand that labels should be available to assist consumers to make informed choices about the products they purchase.

Testimonials from consumer and healthcare professionals

*'Would it be feasible to suggest to all of the manufacturers to **ALWAYS** include the **pharmaceutical** name, after the trade name, on the labelling of the packages? This would make it so much easier for the patient, would save much time and phone calls to the pharmacy, or time with the GP.'*

'People with allergies need better access to all ingredients used in creating/manufacturing these medications so that they are not made more ill by medications designed to improve health.'

Current requirements fall short of international best practice

TGO 69 is out of step with current labelling design research and international labelling requirements. Specifically, current Australian labelling requirements do not address issues such as prominence of active ingredient with respect to the trade name, neither in terms of larger text size nor consistent placement. Also, there is no requirement for consistent placement of critical health information to assist consumers self-selecting non-prescription medicines.

Patient risk and harm

In 2013, the Australian Commission on Safety and Quality in Health Care (ACSQHC) conducted a literature review of medication safety in Australia.[24] The review covered medication safety literature published in Australia between 2008 and August 2003; and literature published internationally between 2002 and 2013.

The review identified that 2-3 per cent of all hospital admissions in Australia are related to medication errors.[25] Further, it has been estimated that as many as 30 per cent of unplanned admissions among patients aged 65 and over are associated with medication problems and that medication errors resulting in hospitalisation cost approximately $1.2 billion annually.[26,27,28] This figure does not account for individuals who do not attend hospital but experience pain and suffering as a result of medication errors.

[24] Australian Commission on Safety and Quality in Health Care, Sydney 2013, *Literature Review: Medication Safety in Australia*, <http://www.safetyandquality.gov.au/wp-content/uploads/2013/08/Literature-Review-Medication-Safety-in-Australia-201.pdf>
[25] Ibid p8.
[26] Ibid p25.
[27] Australian Institute of Health and Welfare. Australian hospital statistics 2011-12, Health services series no. 50. Cat. no. HSE 134. Canberra, 2013.
[28] Runciman, W, Roughead, E, Semple, S & Adams, R 2003, 'Adverse drug events and medication errors in Australia', *International Journal for Quality in Health Care*, vol. 15, supplement 1, pp. 49-59.

While there are multiple causes of these medication errors, the ACSQHC suggests that confusion or errors in reading labels could be associated with many accidents, including human error. Medication errors in hospitals, for example, may include prescribing errors, documentation errors, and misinterpretation of labels due to lack of close attention or fatigue. However, with limited data it is not possible to estimate the proportion of the costs attributable solely to labelling issues, beyond the suggestion that it is significant. Depending on the medicines involved, documented outcomes range from minor to catastrophic.[29,30]

There are numerous reports in the literature that labelling issues are both a significant contributor to medicine errors and the source of error themselves.[31,32,33,34] One study reports that confusion with medicine names accounts for 25% of reported medication errors.[35] With the increasing use of generic medicines and subsequently increased patient choice in medicine brands,[36,37] there is increased potential for patients to be confused about their therapy and inadvertently take multiple products with the same active ingredient.[38,39] This is compounded by the fact that the non-proprietary name of a medicine (i.e. the chemical name of the active ingredient e.g. paracetamol) is typically in smaller text and less prominent than the brand name of the product (e.g. Panadol®) on the medicine label. 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.[40] In many cases, essentially the same products can have dozens of different names, contributing to confusion.[41] The greatest risk associated with this is overdose. While much of the work in this area refers to confusion associated with prescription medicines, awareness of the active ingredient plays an important role in achieving quality use of all classes of medicines and ensuring safety of consumers of all classes of medicines.[42]

Improvements to labelling, such as increased prominence of the active ingredient and standardising its position on the medicine label, has been identified as a factor leading to

[29] Dunlop C (2009), Medicinal mishap, Atropt-Azopt substitution, *Australian Prescriber*, vol. 32, pp. 138-9.
[30] Phillips, M. and Williams, R. 2006, 'Improving the safety of neuromuscular blocking agents: a statement from the USP Safe Medication Use Expert Committee', *American Journal of Health-System Pharmacy*, vol. 63, no.2, pp.139-42.
[31] Cohen M 1995, 'Drug product characteristics that foster drug-use system-errors', *American Journal of Health-System Pharmacy*, vol. 52, no. 4, pp. 395-399.
[32] Jensen, L, Merry, A, Webster, C et al., 2004, 'Evidence-based strategies for preventing drug administration errors during anaesthesia', *Anaesthesia*, vol. 59, no. 4, pp. 493-504.
[33] Hellier, E, Edworthy, J, Derbyshire, N, & Costello, A 2006, 'Considering the impact of medicine label design characteristics on patient safety', *Ergonomics*, vol. 49, no. 5-6, pp. 617-630.
[34] Gernerin, P, Perneger, T, Chopard, P et al., 2007, 'Drug Selection errors in relation to medication labels: a simulation study', *Anaesthesia*, vol. 62, no. 11, pp. 1090-1094.
[35] Bermann A 2004, 'Reducing Medication Errors through Naming, Labelling and Packaging', *Journal of Medical Systems*, vol. 28, no. 1, pp. 9-29.
[36] Ortiz M, Simons LA, Calcino G,. 2010, 'Generic substitution on commonly used medications: Australia-wide experience, 2007-2008', *Medical Journal of Australia*, vol. 192, no.7, pp. 370-3.
[37] Department of Health, *Department of Health and Ageing - Medicines Australia joint monitoring report on Trends in and drivers of Pharmaceutical Benefits Scheme expenditure*, <http://www.pbs.gov.au/info/news/2013/05/report-trends-in-and-drivers-of-pbs-expenditure>, p 33.
[38] Carney, S, Gazarian, M, Denholm, J et al., 2011, 'What's in a name? Brand name confusion and generic medicines', *Medical Journal of Australia*, vol. 195, no 11, pp. 650-651.
[39] McLachlan AJ. (2010), 'Generic medicines literacy – minimising the potential for patient confusion', *Medical Journal of Australia*, vol 192, no 7; pp. 368-9.
[40] McKenzie, A. 2011, Consumer stories about labelling, *Australian Prescriber*, vol. 34, pp. 138.
[41] Australian Broadcasting Cooperation, *Rise of generic drugs increases fears of overdose*, 7 December 2011, <http://www.abc.net.au/news/2011-12-07/poor-drug-labelling-leading-to-overdose/3717198>
[42] Lalor, D 2011, 'Medicines Labelling', *Australian Prescriber*, vol. 34, pp. 136-138.

improved safety and quality use of medicines.[43,44] Consumer groups strongly advocate for greater prominence of the active ingredient on generic medicines to facilitate product identification and reduce the opportunity for error.[45,46] Poor labelling, that makes it difficult for patients to find and understand information, may affect patient safety and the ability of patients to follow instructions regarding the proper use of medicines.[47,48,49] Figures of between 12-20% of consumers experiencing difficulty reading and understanding the medicine labels have also been reported.[50,51] A 1989 review showed that only 54% of 1496 Australian adults were able to correctly identify the dose for a child from a sample medicine label (10% of participants were functionally illiterate).[52] The available data also suggest that improving label useability and consistency of information may assist consumers who have poor or developing literacy skills.

By applying sound design principles to the layout and composition of medicine labels, their usability has been documented to be considerably improved.[53] For example, the use of particular fonts,[54] colour[55] and the layout of information,[56] can be used to produce labels that allow information to be more readily located, identified, and understood. Internationally, literature has confirmed that text with a font size ranging from 9-12 point is optimal for readability of important health information such as the name of the active ingredient[57,58,59] but a larger than 12 point font size has also been suggested, particularly with respect to elderly patients.[60]

[43] Consumer Health Forum 2009, *Equal prominence of active ingredient and proprietary names on labels for prescription medicines*, Consumer Health Forum of Australia, <https://www.chf.org.au/pdfs/sub/sub-518-names-labels-prescription-meds.pdf>
[44] Lalor, D 2011, 'Medicines Labelling', *Australian Prescriber*, vol. 34, pp. 136-138.
[45] Consumer Health Forum 2009, *Equal prominence of active ingredient and proprietary names on labels for prescription medicines*, Consumer Health Forum of Australia, May 2013, <https://www.chf.org.au/pdfs/sub/sub-518-names-labels-prescription-meds.pdf>
[46] Consumers' Health Forum, *Achieving Best Practice in the Packaging and Labelling of Medicines: Report from National Consumer Workshop*, January 2011, < https://www.chf.org.au/pdfs/rep/rep-689-PackagingandLabellingReport-Jan11.pdf>.
[47] ibid.
[48] Shrank, W, Avorn, J, Rolon, C, & Shekelle, P2007, 'Effect of content and format of prescription drug labels on readability, understanding and medication use: a systematic review', *Ann Pharmacother*, vol. 41, no. 5, pp. 783-801.
[49] O'Hare F, Jeganathan VSE, Rokahr CG, Rogers SL, Crowston JG (2009), 'Readability of prescription labels and medication recall in a population of tertiary referral glaucoma patients', *Clinical and Experimental Ophthalmology* vol. 37, no.9, pp. 849-54.
[50] Sweet G, Wilson S, The 3D label project, Dandenong: Dandenong District Division of General Practice, 2006.
[51] O'Hare F, Jeganathan VSE, Rokahr CG, Rogers SL, Crowston JG (2009), 'Readability of prescription labels and medication recall in a population of tertiary referral glaucoma patients', *Clinical and Experimental Ophthalmology*, vol. 37, no.9, pp. 849-54.
[52] Wickert R., 1992, 'No single measure: summary report' (1992), *Australian Journal of Education*, v.36, no.1, p.105-107.
[53] Tyers, A 2008, 'Performance based design', *Information Design Journal*, vol. 16, no. 3, pp. 202-215.
[54] Shrank, W, Avorn, J, Rolon, C, & Shekelle, P2007, 'Effect of content and format of prescription drug labels on readability, understanding and medication use: a systematic review', *Ann Pharmacother*, vol. 41, no. 5, pp. 783-801.
[55] Hellier E, Tucker M, Kenny N, Rowntree A and Edworthy J 2010, 'Merits of using color and shape differentiation to improve the speed and accuracy of drug strength identification on over-the-counter medicines by laypeople', *Journal of Patient Safety*, vol. 6, pp. 158-64.
[56] Garnerin P, Perneger T, Chopard P, Ares, M, Baalbaki R, Bonnabry P, et al. 2007, Drug selection errors in relation to labels: a simulation study, *Anaesthesia*, vol. 62, pp.1090-4.
[57] Carter R, Day B, Megs P. Typographic design: Form and communication, Fifth Edition, 685 Hoboken (NJ): John Wiley & Sons, Inc.; 2012.
[58] Sheedy JE, Subbaram MV, Zimmerman, AB, Hayes, JR (2005), Text Legibility and the Letter Superiority Effect, *Human Factors*, vol. 47, no. 4, pp 797-815.

Evidence in the literature has also identified that a patient's inability to identify the active ingredients in both prescription and OTC medicines can lead to unintentional adverse effects.[61,62] A 2015 study reported that participants with arthritis who have low health literacy scores do not always recognise paracetamol as an active ingredient when it is present in multi-active products. This places them at risk of potential paracetamol-related adverse events.[63] Further, in a NSW study comprising 849 participants aged 65 years and older, 9% of participants reported problems reading labels while 6% had trouble understanding the label.[64] For the elderly, in particular, lack of adequate information and knowledge about OTC medications can cause drug misuse, overdose, and abuse leading to hospitalisations, morbidity and even mortality.[65]

The language used on a label can also be a significant factor in medicine safety and quality use of medicines.[66] Poor recognition or understanding of medication labelling or failure to recognise the consequences of exceeding a maximum recommended dosage may lead to unintentional overdoses. In a 2011 qualitative study, it was found that consumers had poor recognition of products containing paracetamol, e.g. only 31% of subjects knew acetaminophen (paracetamol) was in Tylenol®.[67]

The NSW Poisons Information Centre (NSW PIC) is the largest Poisons Information Centre in Australia and provides a 24-hour service to manage suspected and known poisonings and an after-hours drug information service. Some research has recently been conducted by Australian PICs on medication errors and adverse events, based on calls received by the centre.[68] In 2013, NSW PIC confirmed that it had received 13, 542 calls relating to medication errors (12% in or referred to hospital and 3% at or referred to GPs) and 11,696 requests for drug information. NSW PIC has also confirmed that many of these calls originate from confusion in the packaging and labelling of products, particularly consumer product misidentification and errors reading the dosage. Paracetamol is the most common product involved in calls to the centre, with 7243 calls received in 2013. It should be noted that these figures only account for a proportion of the true picture in Australia as NSW PIC is one of four PICs.

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

[59] Hellier, E, Edworthy, J, Derbyshire, N, & Costello, A 2006, 'Considering the impact of medicine label design characteristics on patient safety', *Ergonomics*, vol. 49, no. 5-6, pp. 617-630.
[60] Shrank, W, Avorn, J, Rolon, C, & Shekelle (2007) 'Effect of content and format of prescription drug labels on readability, understanding and medication use: a systematic review', *Ann Pharmacother*, vol. 41, no. 5, pp. 783-801.
[61] Kripalani, S, Henderson, L et al. 2006, 'Predictors of medication self-management skill in a low-literacy population', *Journal of General Internal Medicine*, vol. 21, no. 8, pp. 852-6.
[62] Wolf, M, King, J, et al. 2012, 'Risk of unintentional overdose with non-prescription acetaminophen products', *Journal of General Internal Medicine*, vol. 27, no 12, pp 1587-93.
[63] Ellis, J, Mullan, J, Weston, K et al., 2015, 'Prescription and over-the-counter pain medication in arthritis: awareness of active ingredients and attitudes to medication borrowing and sharing', *Journal of Pharmacy Practice and Research*, vol. 45, no. 1, pp 10-17.
[64] Pit SW, Byles JE, Cockburn J (2008), 'Prevalence of self-reported risk factors for medication misadventure among older people in general practice', *Journal of Evaluation in Clinical Practice*, vol. 14, no. 2, pp 203-8.
[65] Pawaskar, M & Sansgiry, S 2006, 'Over-the-counter medication labels: problems and needs of the elderly population', *Journal of the American Geriatrics Society*, vol. 54, no. 12, pp. 1955-1956.
[66] King, J, Davis, T, Bailey, S et al., 2011, 'Developing consumer-centered, non-prescription drug labelling, a study in acetaminophen', *American Journal of Preventative Medicine*, vol. 40, no. 6, pp. 593-598.
[67] ibid.
[68] Therapeutic Goods Administration, *Submissions received: medicine labelling (2015)*, NSW Poison Information Centre, <https://www.tga.gov.au/sites/default/files/consult-labelling-medicines-140822-submission-nsw-pic.pdf>

quantities above those recommended. Given the ease of access and high volumes associated with over the counter medicine use, the risks are high.[69] Improved active ingredient prominence would assist consumers to identify which medicines contain the same ingredients and help prevent unintentional overdose.

Clear dosage instructions are also critical for the safe use of self-selected medicines. A 2009 study investigated factors associated with caregivers' understanding of the importance of age of the child in determining the dosage of paediatric cough and cold medication. It was found that language and graphics used for dosage instructions on a medicine label can lead to incorrect interpretation of the appropriate dose.[70]

International experience has also identified labelling of medicines as a potential safety 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[71], with labelling being a contributing factor. Further, poorly designed prescription medicine labels are reported to account for, or contribute to, approximately one-third of medication errors investigated by the United States of America's Pharmacopeial Convention (the body that sets standards for medicines in the United States).[72]

International practices

A number of comparable overseas regulators have, during the time of the Australian review of medicine labelling, updated their equivalent standards. Updates have been made 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.

A key part of these updates relate to promotion of active ingredient prominence and a hierarchy of information on medicine labels. Changes have been implemented in both new legislation and also guidance materials.

Other significant technological advances are also being implemented in a number of overseas jurisdictions. This includes mandating the inclusion of electronic data on medicine labels to discourage the introduction and distribution of counterfeit drugs.

The International Medication Safety Network

The International Medication Safety Network (IMSN), of which Australia is a member, is an international network of established safe medication practice centres. These operate medication error reporting programs and produce guidance to minimise preventable harms from medicine use in practice.[73] It is recognised that safe design in healthcare products and systems is a key for reducing some preventable deaths and harm. The IMSN has identified that unclear, ambiguous or incomplete label information, similarities in packaging and labelling appearance and sound-alike and look-alike medicine names can lead to confusion contributing to these preventable deaths.

[69] Wolf M, King, J et al., 2012, 'Risk of unintentional overdose with non-prescription acetaminophen products', *Journal of General Internal Medicine*, vol. 27, no. 12. pp. 1587-93.
[70] Lokker, N, Sanders, L, Perrin, E, et al., 2009, 'Parental Misinterpretation of Over-the-Counter Cough and Cold Medication Labels', *Pediatrics*, vol. 123, no. 6, pp. 1464-1471.
[71] Health Canada 2012, *Cost-Benefit Analysis: Regulations Amending the Food and Drug Regulations - Good Manufacturing Practices for Active Ingredients Amendments to the Food and Drug Regulations (Labelling, Packaging and Brand Names)*
[72] Holt, G, Dorcheus, L, Hall, E, et al., 1993, 'Patient Interpretation of Label Instructions', *American Pharmacy*, 1993; vol. 32, no. 3, pp. 58-62.
[73] *International Medication Safety Network*, <http://www.intmedsafe.net/>

In October 2013, the IMSN published a position statement along with some key elements of guidance for the labelling and packaging of medicines. These highlighted the need to clearly and prominently present the following information on the outer packaging[74]:

- Proprietary name of medicine (brand)
- International non-proprietary (generic) names of active pharmaceutical substances (with emphasis on the generic name/active ingredients)
- Dose strength/concentration
- Method(s) of administration
- Dosing instructions
- Specific warnings

The IMSN also identified the use of use larger fonts for better readability.

The position statement recommends that, in all countries, regulations be strengthened for medicine naming, labelling and packaging to:

a. *require better design and field testing of medicines naming, labelling and packaging before release for use*

b. *incorporate human factors theory*

c. *promote safer use in practice.*[75]

European Union

While the European Union does not mandate the font size of the active ingredient it does legislate that the active ingredient must be prominently displayed, as well as mandating a hierarchy for the order of information on the medicine label.[76] Further information on prominence is provided in guidelines, including an active ingredient font size of not less than 7 point text size.[77]

United States

In 1999, the US FDA introduced a standardised format and content requirements for the labelling of over-the-counter (OTC) medicines.[78] This was intended to assist consumers in reading and understanding OTC medicine labelling so that these products are used safely and effectively.

[74] International Medication Safety Network 2013, *Position Statement: Making Medicines Naming, Labeling and Packaging Safer*, <http://www.intmedsafe.net/wp-content/uploads/2014/07/Making-Medicines-Naming-Labeling-and-Packaging-Safer-Final-A4-2013.pdf>

[75] International Medication Safety Network 2013, Position Statement: Making Medicines Naming, Labeling and Packaging Safer, <http://www.intmedsafe.net/wp-content/uploads/2014/07/Making-Medicines-Naming-Labeling-and-Packaging-Safer-Final-A4-2013.pdf>, page 2

[76] *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 Us*e, Article 59.

[77] European Commission, *Guideline on the readability of the labelling and package leaflet of medicinal products for human use*, Revision 1, 12 January 2009, <http://ec.europa.eu/health/files/eudralex/vol-2/c/2009_01_12_readability_guideline_final_en.pdf> page 12.

[78] Department of Health and Human Services, Food and Drug Administration, *Federal Register* of March 17, 1999 (64 FR 13254).

A 2007 US study evaluated the effectiveness of the 1999 FDA-mandated standardised format for the labelling of OTC medicines (called 'Drug Facts') by comparing three labelling formats amongst consumers.[79] The three formats comprised previously FDA-compliant labels, new labels (min 6 point text size) and simulated labels (similar information as the new label but a 10 point text size). The study report noted that the new OTC drug labels, with the standardised 'Drug Facts' format and a minimum 6 point font size, may not be easy for some consumers to use and understand, although they are an improvement over old unstandardised labels. The study found that consumers' product knowledge was significantly improved with the simulated label. It was concluded that manufacturers should look beyond the mandatory minimum FDA font size of 6 points and develop strategies to further improve comprehension of information on OTC medication labels.

Canada

In April 2014, Health Canada launched its Plain Language Labelling Initiative.[80] This initiative aims to improve the safe use of medicines by making medicine labels and packaging information easier to read and understand. The intention is that this will be achieved through updating both Regulations and guidance. 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

Broader medicine label requirements

In addition to information needed by health practitioners and consumers for quality use of medicines, labelling requirements are being expanded to address additional international concerns and the availability of new technology.

It is estimated that counterfeit prescription drugs have a market worth $75 billion a year worldwide.[81] In an attempt to discourage the introduction and distribution of counterfeit drugs, Europe and the US have implemented legislation to mandate serialisation – that is, to require that every product holds a unique serial number. In short, serialisation measures aim to provide visibility and full traceability within the supply chain, so that a product's lifecycle can potentially be traced from production right through to patient use.

The European Union has recently published delegated regulations detailing rules concerning serialisation and verification features. From February 2019, these features must appear on the packaging of medicines. The Commission Delegated Regulation (EU) 2016/161 under the Falsified Medicines Directive (Directive 2011/62/EU) requires a unique identifier and an anti-tampering device to allow the verification of the authenticity of medicinal products.

[79] Murty, S, & Sansgiry, S 2007, 'Consumer comprehension of OTC Medication Labels and the scope for improvement in font size', *Journal of Pharmacy Technology*, vol. 23, no 4, pp. 207-213.
[80] Health Canada 2014, *Notice - Final Release: Plain Language Revisions to Part III: Patient Medication Information and Associated Templates of the Guidance Document - Product Monograph*, < http://www.hc-sc.gc.ca/dhp-mps/prodpharma/applic-demande/guide-ld/monograph/pm_notice_avis_mp_2013-eng.php>
[81] Pharmaceutical Manufacturing, *Serialisization and the Drug Quality and Security Act*, January 2015, <http://www.pharmamanufacturing.com/articles/2015/serialization-drug-quality-security-act/?show=all>

In the US, the Drug Supply Chain Security Act commences in a staggered fashion from 2017. This legislation outlines critical steps to build an electronic system to identify and trace prescription drugs as they are distributed throughout the US. The legislation mandates unique serialisation numbers and bar codes to be used on these products.

Although the two serialisation models in the US ('transaction model') and Europe ('authentication model') are distinctly different,[82] the enactment of these laws is both jurisdictions is a major step in providing clear requirements and guidance to combat counterfeits.

Concluding remarks

We can see that internationally, overseas regulators are one step in front of Australia in regard to labelling of medicines.

In response to the recent reviews and consultations, it is proposed that Australian requirements are updated to (generally) mirror requirements from the FDA (health information back panel) and MHRA (active moiety front panel), thereby improving international harmonisation. Both regulators' updated labelling requirements are well-accepted although there are no conclusive studies that confirm that their adoption has resulted in lower rates of medication errors overseas. This is largely due to the complexity of isolating labelling from other contributing factors, for example, prescribing errors, documentation errors or fatigue.

In the absence of explicit evidence; by implementing new labelling requirements, we expect to see increased legibility of medication information, increased consumer satisfaction and potentially improved patient outcomes. Following the proposed 4 year transition period we will see the majority of medicine labels in the Australian marketplace presenting information in a consistent manner. This standardisation will, over time, increase consumer awareness and knowledge, allowing consumers to be comprehensively informed and engaged in all phases of health treatment. Where applicable, this increased awareness will also facilitate open and collaborative discussions between patients and their treating physician.

[82] Information from Pharmaceutical Manufacturing, *Serialisization and the Drug Quality and Security Act*, January 2015, <http://www.pharmamanufacturing.com/articles/2015/serialization-drug-quality-security-act/?show=all> Under the U.S. "pedigree" model, products are serialized, aggregated and authenticated when a change of custody occurs. Data is shared between trading partners along the supply chain. In Europe, the "authentication model" relies on item-level serialization, registration of product in a national or regional database, and then authentication at the point of dispensation.

What policy options are being considered?

Three policy options are put forward in this RIS.

Removing some or all of the current regulatory requirements would not be a viable option. Doing so would result in considerable problems and risks to public health and safety, including an additional burden on the healthcare system.

The three proposed options are status quo (option 1), best practice guidelines (option 2) and introduction of a new therapeutic goods order (option 3).

Option 1: No change

Under the status quo, TGO 69 would be maintained. It represents current policy and would not change regulatory arrangements.

Existing guidelines will remain available including:

- 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)

Importantly, the majority of stakeholders support the objectives of the labelling reform including the need to update TGO 69, providing justification as to why option 1 is not appropriate.[83] In recent years, Australian legislative intervention measures have also been implemented for both food[84] and tobacco[85] to assist with clearer labelling for consumers. As medicines are generally higher risk than these two types of products, it is imperative that some degree of consistent legislative intervention be applied to medicines to ensure appropriate minimum standards for their labelling.

Limitations to option 1 include:

- Usability and currency issues with TGO 69, which was drafted over 16 years ago.
- Objectives to improve labelling on medicines, as described in the problem section above, would not be realised under option 1. The current Australian requirements fall short of best practice. International literature supporting the need for consistency of information and active ingredient prominence to improve patient safety would be largely ignored by choosing to continue with current practices. Accordingly, there would be a lack of recognition of the identified public health and safety issues, including the importance of patients and health professionals being able to easily locate information on labels and the argument for improved minimum standards to be applied to all medicines.
- As described in the 'implementation and review' section, TGO 69 is due to 'sunset' on 1 October, 2017. A case must be made as to why this piece of legislation is still needed, and

[83] Out of 80 submissions received in the 2014 public consultation, half a dozen stakeholders indicated they were satisfied with current TGO legislative requirements.
[84] Department of Industry, *New country of origin food labels are coming*, <http://www.foodlabels.industry.gov.au/>.
[85] The Department of Health, *Introduction of Tobacco Plain Packaging in Australia* (27 May 2016), <http://health.gov.au/internet/main/publishing.nsf/Content/tobacco-plain>.

should therefore be re-made, and this gives extra incentive to review the current requirements.

Option 2: Best practice guidelines in line with most current evidence

Option 2 proposes that TGO 69 be retained but the current guidance for industry is updated in-line with internationally agreed best practice.

It is proposed that the updated guidelines would include labelling elements described in option 3 (see below), including prominence of active ingredients, space for a dispensing label, consistent location of medicine information and specific formatting of critical health information.

As described in the 'implementation and review' section, TGO 69 is due to 'sunset' on 1 October, 2017. At this time, under this option, consideration would have to be given as to the need for a nationally applied minimum standard for medicine labels.

Option 2 has other limitations, including:

- To be successful, this option would rely on universal, voluntary application of the best practice guidelines. From TGA's experience voluntary uptake is difficult to regulate and adoption would be uneven. There is a commercial advantage for companies not to re-label to adopt best practice principles, as costs are not incurred.
- Without any nationally-applied legislation, there is potential for wide diversity in labelling of medicines containing the same active ingredients or those intended for the same therapeutic use. This would increase confusion due to poorer recognition of critical health information by both consumers and health practitioners, resulting in risks to patient safety.
- This option does not provide clear direction to industry on which standards should apply to all sponsors in the Australian market. There is industry perception that the best practice principles adversely affect brand recognition (due to greater prominence being given to information on active ingredients) and this would result in resistance to their adoption.
- Limitations already described under option 1.

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

Option 3: Introduction of new Therapeutic Goods Orders (TGOs 91 and 92)

This option involves the making of new standards for medicine labels that would replace the existing TGO 69 after a transition period. New requirements to be included were identified in the initial consultation undertaken by the TGA in 2012. Acting in response to further stakeholder feedback during the 2014 consultation, it is proposed that two new TGOs be created: one for prescription medicines and the other for non-prescription medicines, TGO 91 and TGO 92, respectively. It is proposed that the new Orders are supported by revised best practice guidance documentation.

The division into these two classes recognises the different risks and information requirements associated with medicines prescribed by a medical practitioner, or used in a clinical setting, to those self-selected by consumers.

Key proposed changes to existing requirements that are included in TGO 91 and 92 are as follows:

Both TGO 91 and TGO 92 (*prescription and non-prescription medicines*)

- Increased prominence and consistent location of information on active ingredients (noting the minimum text height for all other information is 1.5 millimetres):
  - introduction of a new requirement that the name(s) and quantities of active ingredient(s) be a minimum text size of 3.0 millimetres on the front panel for registered medicines, placed either directly under or adjacent to the trade name; or
  - for a registered medicine containing four or more active ingredients, in a minimum text size of 2.5 millimetres on a side or rear panel; or
  - for a registered medicine supplied in a small container (i.e. containers with a capacity up to or equal to 25 millilitres but greater than 2.5 millilitres) in a minimum text size of 2.0 millimetres.
- New requirements for declarations of certain substances (e.g. crustacea, fish, eggs, soya, milk, tree nuts) on all medicine labels, not just those on non-prescription medicines. These requirements have been modified to address consumer needs. The cut off for declaring gluten has also been modified and aligns with Food Standards Australia and New Zealand.

TGO 91 (*prescription medicines*)

- Introduction of a new requirement for a defined space to be made available for a dispensing label. This is to ensure that important health information (e.g. dosage and active ingredient information) is not covered up by the dispensing label.
- Introduction of a new requirement such that Schedule 1 substances must be declared on the label or identified by a statement that directs consumers to the Consumer Medicine Information. (Note: Schedule 1 is a list of substances that, if present in a medicine, must be declared on the label as they have the potential to cause allergic reactions or other serious adverse health consequences in sensitive individuals. The current TGO 69 requirements for declaration of Schedule 1 substances do not apply to prescription medicines).
- Introduction of a new requirement for inclusion of a machine-readable code, this would not preclude future international convergence with the international requirements for serialisation of prescription medicines.

TGO 92 (*non-prescription medicines*)

- Introduction of a new requirement for higher risk non-prescription medicines to provide critical health information in a consistent order within a tabulated format. This is consistent with international requirements.
- Introduction of a new requirement to mandate the inclusion of warnings related to the use of medicines by those who are, or may be, pregnant.
- Introduction of a new requirement to permit the use of an active moiety only (not full approved name of the active ingredient) on the main label. This requirement only applies when the full approved name is included in the mandated tabulated 'critical health information' format. This requirement aligns with the UK Medicines and Healthcare Products Regulatory Agency.

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 or indirect
- **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*
- *ARGOM*
- *ARGCM*

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

Maintaining the status quo is also not supported by the evidence published by the TGA and other major international regulators.[86]

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

Net benefit

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

Direct costs

There are no direct costs associated with this approach.

Under this option the TGA would continue with its current system for reviewing proposed labels as part of the pre-market approval of registered medicines. Industry will continue to operate under a business as usual mode and will apply to vary labels as required or planned.

Indirect costs

There are no additional indirect costs associated with this option.

[86] Therapeutic Goods Administration, Labelling and packaging practices: A summary of some of the evidence (January 2013), <https://www.tga.gov.au/labelling-and-packaging-practices-summary-some-evidence>

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. 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 to 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, available 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

Under this option, a small benefit will be observed from the introduction into the marketplace of medicine with labels that are consistent with best practice. For these medicines, consumers should be able to more easily identify and read critical information.

However, if only a small percentage of companies choose to follow best practice, then the resulting benefits will be reduced proportionately. Although the TGA does not collect data on voluntary compliance with guidelines, from experience, levels vary depending on the associated perceived risk. Compliance has been high on safety related issues for prescription medicines, for example vinca alkaloid medicine labelling. Lack of adoption of other principles related to readability issues may be perceived as presenting a lower risk.

Recent studies in Canada report that only 44% of a randomly selected pool of 45 pharmacies met the minimum guideline of 12-point print size in accordance with labelling guidelines.[87] This figure highlights the potential uptake if such requirements were put into guidelines in Australia.

It is possible that, in the longer term, consumer demand for improved labels will result in better uptake of 'best practice' principles by sponsors. However, this is likely to be inconsistent as sponsors balance these benefits against brand recognition for individual products. Additionally, as noted earlier, these principles are already well known and, while adoption is not precluded by the current Australian regulations, there is little uptake in the existing marketplace.

If there is uneven adoption of guidelines intended to improve medicine labels, the intended benefits of consistent labelling for public health safety will not be realised.

Direct costs

There are no direct costs associated with this approach.

It is anticipated that businesses would not seek to change medicine labels to meet new 'best practice' unless there were other business reasons to do so (e.g. a change in business address, a change in label design for marketing reasons). As such, it is estimated that the costs to these businesses will be negligible as the timing of change will coincide with other changes in the

[87] Leat, S.J., Ahrens, K., Krishnamoorthy et al., 2014, 'The legibility of prescription medication labelling in Canada Moving from pharmacy-centred to patient-centred labels'. *Canadian Pharmacists Journal*, vol. 147, no. 3: 179–187. Ellis, J, Mullan, J, Weston, K et al., 2015, 'Prescription and over-the-counter pain medication in arthritis: awareness of active ingredients and attitudes to medication borrowing and sharing'. *Journal of Pharmacy Practice and Research*, vol. 45, no. 1, pp 10-17.

course of business as usual. This is especially the case for prescription medicines where it is reported that relabelling occurs more frequently. It is likely that some businesses will choose to adopt aspects of the new guidance (perhaps in response to consumer demand). However this would be part of their usual business practice and therefore not result in additional costs.

Indirect costs

Given the voluntary nature of adopting the guidance, businesses and sponsors are not expected to pass on any costs in the form of price increase to consumers. It is likely that they will adopt the guidance where it is beneficial to maintain or improve their market share for a product.

Regulatory burden estimates

There is no enforcement of compliance with these guidelines and businesses will only apply the best practice recommendations if and when they choose. Many businesses are not currently applying key best practice principles, such as prominence of active ingredient information, despite being exposed to the concepts over several years. Industry submissions emphasise concerns with loss of brand recognition if these requirements are adopted and, therefore it is assumed that there would be a very low compliance 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 even if they are not legislated.

Assumptions:

- There are 1,254 medicine sponsors identified in the TGA's business systems.
- 10 per cent of sponsors will comply with the guidance and apply some of the best practice guide to around 10% of their products and businesses will only apply a non-mandated change to a label if they are already making a change for some other business purpose.
- The cost applicable is the same as those applying under Option 3 but only affecting a proportion of the sponsors and products.
- Time required per sponsor to brief manufacturers and raise awareness is estimated at 3.34 hours applicable to 125 sponsors.
- Marginal costs associated with packaging changes are 5% where the average costs of packaging is estimated at $1.00 per package. It is estimated that around 1% of the volume (volume is based on PBS statistics on prescription and non-prescription medicines) or 29 million prescription medicines and close to 9 million non-prescription medicines will be affected.
- Time required per sponsor to notify retailers of changes is estimated at 4 hours each.
- Labour rate of $80.20 per hour is estimated.

Benefits to other stakeholders

Benefits to consumers that may be realised by implementation of this option are difficult to quantify. This is due to the high likelihood of an uneven uptake of best practice principles by medicine sponsors.

Consumers and healthcare practitioners will benefit when using the individual medicines whose labels have been updated in line with best practice principles. Critical information should be easier to identify and read on these labels. Over time, with increasing consumer awareness of this type of labelling, there may be increased market pressures that encourage more sponsors to adopt revised labelling.

Risks to other stakeholders

The risk to consumer health and safety would lie with the inconsistency of label presentations that would result from uneven and unpredictable uptake of best practice principles.

Inconsistencies between labels would be across and within groups of medicines. There may be some improvement to medicine labels that address some of the risks to consumer safety, but this would take place in a limited and inconsistent way. This in turn leads to only a minimal reduction in negative patient health outcomes, and has limited impact on the burden on healthcare providers and hospitals.

Consumer expectations and safety

This option will most likely not address many of the consumer and health practitioner concerns relating to readability of medicine labels 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 this option.

Option 3: Introduction of new Therapeutic Goods Orders (TGOs 91 and 92)

This option is considered by many stakeholders as providing a balanced approach between addressing potential risks to consumer safety related to medicine labels and the regulatory cost to industry and will provide the greatest net benefit.

Net benefit

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, for hospital admission attributed to medication errors. This estimate does not consider reductions in visits to general practitioners and other healthcare providers in the event of incorrect or inappropriate medication use.

Improved consumer understanding of active ingredients rather than reliance on recognition of trade names may result in a more competitive marketplace, contributing to the net benefit of this option.

Direct costs

Under this option the new Therapeutic Goods Orders, TGO 91 and TGO 92, would require the majority of businesses to update their medicine labels to comply with the requirements of the new legislation.

There are fees associated with the variation of labels and sponsors would be required to pay these fees to the TGA. Compliance with the new labelling orders would therefore likely involve a one-off cost for some businesses that are not otherwise changing their labels during the

transition period[88] in the natural course of their business. After the transition period, costs would revert back to the status quo levels. This is because once the changes are made, the business returns to normal business practices. The new TGOs will not impose any additional ongoing regulatory burden to that of the current Order.

A survey of industry conducted in early 2014, using contact companies provided by the relevant industry associations for innovator and generic prescription medicines, over the counter medicines and complementary medicines, revealed that companies regularly change labels for commercial advantage within 3 years as part of normal business practice. Further, submissions from industry during the 2014 public consultation identified that some product label changes are less frequent, especially in the non-prescription sector which could extend to around 7 years. Therefore, in costing the regulatory impact of the proposed changes, we have recognised that the primary costs to industry would be associated with the timing of the proposed changes, recognising that the changes may not be in line with the timing of the label changes under a business as usual scenario.

Transition periods of 2, 3 and 4 years were considered. The longer the transition period, the less cost that industry would incur independent of any other label changes undertaken as part of normal business. However, it is also recognised that the longer transition period means that the immediate benefit to public safety would be delayed.

Many sponsors 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 costs

Depending on the transition period chosen under this option, there may be some costs that businesses will pass on to consumers. The longer transition (Option 3C) will have the smallest cost impact and hence, least likely for flow-on costs. The risk that that the new labelling orders will lead to businesses transferring costs to consumers has been identified as part of public consultation feedback received. However, due to the volume of medicines sold, it is not expected that the unit cost transfer impact will be high.

Benefits to other stakeholders

Consumers may benefit from increased competition associated with active ingredients being more prominent on medicine labels. This improved awareness of the active ingredient and the equivalence between different brands may reduce reliance on brand recognition. For example, the cost of clotrimazole anti-fungal creams from a local Canberra pharmacy, containing the same active ingredient, can cost anywhere between $9.99 and $12.99. Likewise, there is a price range of 3 to 35 cents per paracetamol tablet (500mg) across 16 different products. An increased active ingredient text size and consistent location of this information will arguably increase competition as consumers will become better informed as to what medicine they are taking.

Under Option 3, consumers will have easier access to information on substances other than the active ingredients in a medicine. This information will now be available for prescription medicines. Its presentation in a consistent location for non-prescription medicines will reduce confusion and lessen the time taken by a consumer when self-selecting medicines in a pharmacy or shop.

For sponsors, consistency with international trends for labelling could potentially facilitate international trade.

[88] 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.

Risks to other stakeholders

Due to the long transition period, there will be a number of years where labels continue to display information inconsistently, delaying the realisation of benefits. Educational activities will help to manage consumer and health professional expectations about the transition period.

Consumer expectations and safety

Consumers, through the Consumer Health Forum (CHF), advocate the importance of labelling and the need for improved labels and packaging.[89] As provided earlier, the evidence indicates the risk to consumers from incorrectly taking medicines can be linked to the poor readability and inconsistent placement of the names of the active ingredients.

Risks associated with medicines are primarily addressed by the level of consumer access and healthcare professional interaction associated with purchase and use of the goods. This is determined by the scheduling of the medicine under the Poisons Standard. The new TGOs recognise that there are different information needs for consumers self-selecting medicines rather than using medication prescribed by a practitioner and also for healthcare professionals administering medicines in a clinical setting. Appropriate labelling of the medicine is an important factor in managing on-going use of that medicine.

There are medication errors that can be reduced through labelling, such as taking multiple substances containing the same active ingredient. For example, it is quite easy for someone to inadvertently exceed 4000 mg of paracetamol in a single day by 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'. At these dosages, toxicity can occur with an associated risk to liver function; paracetamol toxicity is the most common cause of acute liver failure. A recent study found that paracetamol is responsible for one in five deliberate poisonings which present to emergency departments, Australia-wide.[90]

Paracetamol, the most common household medicine, has been found to poison around 150 Australians a week, equating to 8000 poisonings a year.[91] While there are controls in place to avoid this problem, such as the restriction on the number of paracetamol tablets available as single packs in non-pharmacy settings such as supermarkets, 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 of this critical information on medicine labels.

Similarly, active ingredient awareness is paramount for prescription medicines. Government policy encourages the use of generic medicines as they provide a reduced cost to consumer, pharmacy and Government. However, patients are often confused when they move from a trade-branded medicine to a generic brand as the packaging may be different, the trade name differs and they do not identify that the active ingredient is the same. The new TGOs would ensure that the active ingredient(s) is readily identifiable to assist patients in recognising that the branded medicine and the generic form are essentially the same.

Increased prominence of the active ingredient name also assists when patients move between different generic brands. If patients are more aware of the fact that the two brand names are

[89] Consumer Health Forum 2009, *Equal prominence of active ingredient and proprietary names on labels for prescription medicines*, Consumer Health Forum of Australia, <https://www.chf.org.au/pdfs/sub/sub-518-names-labels-prescription-meds.pdf>

[90] Graudins A, Overdose with modified-release paracetamol (Panadol Osteo®) presenting to a metropolitan emergency medicine network: A case series, *Emergency Medicine Australasia*: 2014:4:398-402.

[91] Ibid.

actually the same active ingredient, these moves are less confusing and the chance of medication errors is lessened.

Non-prescription medicines, while generally regarded as low risk, may also be dangerous in high doses, for example iron supplements. Iron is important in the transportation of oxygen around the body and individuals who are iron-deficient are often recommended to take iron supplements. However, many people are unaware that iron is also contained in other multivitamin and mineral products. If these medications are taken concurrently, this can lead to excessive iron stores which are highly dangerous and result in organ damage. In the USA, iron overdose has been documented as the leading cause of poisoning deaths in children.[92] Improved labelling including more prominent display of active ingredients will help patients who are taking specific supplements, such as iron, and combination products to avoid these interactions and seek appropriate medical advice. Similarly this will assist medical personnel in identifying the possibility of these interactions.

It may be considered that the proposed changes to medicine label requirements are not sufficient to address all the consumer and healthcare professionals' concerns raised during the extensive consultation. To achieve practical outcomes, the proposals attempt to balance these needs against factors such as the costs to industry that would be associated with re-packaging to create increased current label space.

Regulatory burden estimates

Regular changes to medicine labels are part of normal business practice. As discussed above, 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 new regulatory requirements.

Furthermore, it is noted that a small percentage of labels are already compliant with the proposed draft requirements of TGOs 91 and 92.

A number of activities associated with compliance with the new Orders have been costed, with the majority having a one-off impact on the affected sector. The following assumptions have been made when quantifying the regulatory burden for this option:

- The average cost of staff is estimated at $80.20 per hour. This is consistent with the costing undertaken for the adoption of Required Advisory Statements for Medicine Labels (RASML).[93] The cost also aligns with those identified by some sponsors in the labelling public consultation submissions;
- It is estimated that there are 25,585 affected products – this is based on the number of medicines on the ARTG (33,000 or 30,000 excluding exports) and accounting for a multiplier effect on number of products per ARTG entry, and discounting it by a low value turnover and product range (this accounts for products that will be discontinued or varied). The application of the multiplier and the discounts takes into account the number of products that will be affected.
    - The numbers of medicines on the ARTG often converts to more than one product. For example, in the case of OTCs, the number of products count includes different

[92] Poison Control National Capital Poison Centre, Iron Poisoning, <http://www.poison.org/articles/2014-jun/iron-poisoning>.
[93] Therapeutic Goods Administration, Regulatory impact statement (RIS) - update to the Required Advisory Statements for Medicine Labels (RASML), <https://www.tga.gov.au/regulatory-impact-statement-ris-update-required-advisory-statements-medicine-labels-rasml>.

packaging sizes and stock keeping units even if the medicine is the same, while it will be counted as ONE medicine on the ARTG. While situation is the same for listed medicines, the multiplier is lower than that applied to registered OTCs.

– The discount is applied as products are often removed/discontinued as part of normal business practices. The discounts were developed during the costing associated with the RASML changes. It recognises that while some products are currently available, they may not be affected by the labelling changes as they would have been discontinued or varied.

– Table 1 provides the multiplier and discount values for each class of medicine on the ARTG.

Table 1: Multiplier used for ARTG entries

	Prescription	OTC	Listed
Multiplier for number of products per ARTG	2.3	2.5	1.0
Discount for low value turnover and product range	0.38	0.64	0.65

· There are 1,254 sponsors;

· Time required per sponsor to familiarise with the new requirements is estimated at 6.25 hours each;

· Time required per sponsor to brief manufacturers and raise awareness is estimated at 3.34 hours;

· Marginal costs associated with packaging changes are 5% where the average costs of packaging is estimated at $1.00 per package. It is estimated that around 10% of the volume (volume is based on PBS statistics on prescription and non-prescription medicines) or 29 million prescription medicines and close to 9 million non-prescription medicines will be affected;

· Costs associated with the redesign of new labels are estimated at $500 per product (average and based on mid-point for re-design provided in submissions). It is also estimated that a proportion of products will require some form of re-design depending on the length of the transition period;

· Time required per sponsor to notify retailers of changes is estimated at 4 hours each;

· The estimated costs for labelling vary depending on the scope of the change required. The costs per product were based on a desktop review and stakeholder consultation and analysis. The costs are an average and are all inclusive (includes pre-production including re-design and productions costs as well as packaging costs) as provided in Table 2.

Table 2: Medicine label change estimates

Product Type	Minor Labelling change cost estimates (per product)	Medium Labelling change cost estimates (per product)	Major Labelling change cost estimates (per product)	Weighted cost for labelling change per product (based on weighting in table below)
Prescriptions	$2,979	$4,237	$9,684	$3,734
OTC	$4,171	$5,491	$12,714	$5,817
Listed	$667	$1,165	$5,052	$1,404

Table 3: Cost weighting

Product Type	% of products assumed to have minor Labelling change	% of products assumed to have medium Labelling change	% of products assumed to have major Labelling change
Prescriptions	40%	60%	0%
OTC	30%	60%	10%
Listed	30%	60%	10%

Table 4 outlines that the proportion of products estimated to be affected with the transition period proposed.

Table 4: Assumption for label redesign

Transition period	2 years	3 years	4 years
Prescription	100%	80%	60%
Non-prescription	100%	80%	60%

Option 3a - Two year transition period

- The assumptions outlined in option 3 are applicable to a 2-year transition period. The two-year transition would mean that all those identified in the labelling cycle of 3 years and above would be affected by the change.
- The additional cost to industry is related to the label redesign costs. The average redesign cost of $500 is assumed applicable to all the products.
- The estimated average annual cost (over 10 years) under the 2-year transition is $1.6m per annum.

Option 3b – Three year transition period

- The assumptions outlined in option 3 are applicable to a 3-year transition period. The three-year transition would mean that all those identified in the labelling cycle of 4 years and above would be affected by the change.
- The additional cost to industry is related to the label redesign costs. The label redesign costs are estimated at an average of $500 per product and are applied to 80% to the total products.
- The estimated average annual cost (over 10 years) under the 3-year transition is $1.4m per annum.

Option 3c – Four year transition period

- The assumptions outlined in option 3 are applicable to a 4-year transition period. The four-year transition would mean that all those identified in the labelling cycle of 5 years and above would be affected by the change.
- The cost to industry is related to the label redesign costs. The label redesign cost is estimated at an average of $500 per product and is applied to 60% to the total products.
- The estimated average annual cost (over 10 years) under the 4-year transition is $1.1m per annum.
- The timing of this option aligns to other international changes such as the EU and the US requirement for serialisation and is the most well accepted by industry. It is also the transition period allowed under the TGA Updating Medicine Names project (IHIN project) which has recently commenced.

Table 5: Summary of Regulatory Burden and Cost Offset Estimates for all options

Average Annual Regulatory Costs (from Business as usual)				
Change in costs ($million)	Business	Community Organisations	Individuals	Total change in cost
Option 2	$0.032			$0.032
Option 3 (a)	$1.6			$1.6
Option 3 (b)	$1.4			$1.4
Option 3 (c)	$1.1			$1.1
Total by Sector	$	$	$	$

Average Annual Regulatory Costs (from Business as usual)				
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? P yes, costs are offset * no, costs are not offset * deregulatory, no offsets required				

Consultation

TGOs 91 and 92 are the result of extensive consultation with stakeholder groups.

Preliminary consultation

Over the last 10 years, many stakeholders have alerted the TGA to concerns about labelling and packaging of medicines, including the contribution of naming, labelling and packaging practices to the safety and quality use of medicines. A number of consultation processes 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 contributed to the consultative process.

In May 2011, the TGA and the ACSQHC jointly hosted the National Round Table on Safer Naming, Labelling and Packaging of Medicines Report on Safety and Quality in Healthcare. The aim of the roundtable was to develop a coordinated approach to improving medicines naming, labelling and packaging in Australia by agreement and coordination amongst key stakeholders. Industry, health professionals, governments and consumer representatives participated. At the meeting the TGA confirmed that a review of medicine labelling and packaging requirements would be conducted. Members made a number of recommendations for improvements to the current regulatory framework with the aim of reducing the risk of confusion of medicines names and labels.[94] The TGA and the ACSQHC 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 comprehensive review of the labelling and packaging requirements for medicines and an internal working group was established to develop options for the key problems that had been identified with current requirements. These options were further discussed and refined by an invited external stakeholder group comprising healthcare professionals, industry representatives and consumers. This group met in February 2012, marking the start of a collaborative approach with stakeholders to addressing the issues identified with medicine labels. The outcomes of these discussions formed the basis of a consultation paper released later that year.

Subsequent consultation(s)

The TGA medicine labelling and packaging review consultation paper was released for public comment on 24 May 2012. The release of the paper marked the culmination of the previous two years of consultation with the internal working group and key stakeholder groups.[95] The paper outlined a number of proposals to address the identified problems by changing the requirements for labelling of medicines. 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.

[94] Australian Commission on Safety and Quality in Healthcare, *Report on the National Round Table on safer naming, labelling and packaging of medicines*, 24 May 2011, <http://www.safetyandquality.gov.au/publications/national-round-table-on-safer-naming-labelling-and-packaging-of-medicines-report/>, page 6-8.

[95] Australian Government Therapeutic Goods Administration < https://www.tga.gov.au/consultation/tga-medicine-labelling-and-packaging-review>

In February 2013, the TGA hosted a major stakeholder meeting to discuss proposed changes that would be required to improve medicines labelling. Stakeholders at this meeting generally agreed that any major changes to the current labelling review should be mandatory and incorporated into a revised TGO, as opposed to best practice guidance. At this time, and after the creation of a joint regulatory agency with New Zealand was abandoned, the TGA proceeded to update labelling requirements separately from the review of medicine packaging.

In March - June 2013, senior TGA staff held bilateral consultations with industry,[96] health professional[97] and consumer groups to discuss the proposed changes to labelling requirements.[98]

A first draft of a revised Order (at the time -'TGO 79') was provided to industry peak bodies in June 2013. Resultant feedback was incorporated as refinements to draft TGO 79.

Between 2013 and mid-2014, draft TGO 79 was further amended and prepared for public consultation.

2014 public consultation

A ten-week consultation took place between 22 August 2014 and 5 November 2014. The consultation package[99] released for comment comprised:

- The consultation RIS
- Draft TGO 79
- Comparison of TGO 69 and draft TGO 79
- A draft *Guideline for the labelling of medicines*.

As part of this consultation process, comment was also sought on three proposed policy options outlined in this RIS.

In total, 80 submissions were received from pharmaceutical companies, professional bodies, Government bodies, industry, consumer organisations and members of the public.[100] A list of non-confidential submitters is provided at Appendix A.

The main issues raised in the submissions have been summarised in Table 6, including responses from the TGA on these. It was not possible to individually respond to every comment received; therefore, only significant issues or issues that were raised in several submissions are included in the table.

A summary of major labelling requirements that were amended following the 2014 public consultation is provided at Appendix B.

[96] Medicines Australia, Generic Medicines Industry Association, Australian Self Medication Industry and the Complementary Healthcare Council.
[97] The Pharmacy Guild of Australia, 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.
[98] Consumer Health Forum of Australia.
[99] Therapeutic Goods Administration (2014), *Consultation: Medicine Labelling* <https://www.tga.gov.au/consultation/consultation-medicine-labelling>
[100] Therapeutic Goods Administration (2015), Submissions received: Medicine labelling, <https://www.tga.gov.au/submissions-received-medicine-labelling>

Table 6: Summary and Response to 2014 public consultation

Issue	Comment	Response from TGA
Policy options	Option 3 (regulatory option) was the predominant choice amongst stakeholders. There was a clear message that the RIS and the draft TGO 79 both required revision and then further amendment and consultation prior to any implementation. Option 2 (guidance) was not preferred on the basis of potential lack of compliance, while Option 1 (status quo) was seen as not addressing the issues which are overall well recognised and understood by stakeholders. Industry preference was for a 4-year implementation (or longer) while health professionals and consumer representation preferred the 2-year implementation option.	The RIS and draft TGO 79 have been revised. While a 2-year transition period would be optimal for objectives of the review including quick uptake and benefits to be realised, the cost to implement is too high. A 4-year transition period more closely aligns with typical business as usual activities for the therapeutic goods industry. A 4-year transition period has been chosen to minimise costs and align with IHIN transition period. During IHIN consultation, some stakeholders indicated that a shorter transition period could lead to a disruption in the supply chain for products that have a short shelf life and potentially result in medicine shortages and risks to public health. If there are specific safety issues with particular types of goods, these can be dealt with through, for example, amendments to the Required Advisory Statement for Medicine Labels for non-prescription medicines[101] or through specific conditions of registration or listing.[102]

[101] *Required Advisory Statements for Medicine Labels (RASML)*, <https://www.tga.gov.au/publication/required-advisory-statements-medicine-labels-rasml >.
[102] *Applying to registered or listed therapeutic goods under Section 28 of the Therapeutic Goods Act 1989, Standard 1995 Specific 1998* <https://www.tga.gov.au/sites/default/files/dr4-appendix-04.pdf>.

Issue	Comment	Response from TGA
RIS: costs	Industry and business provided data to support the view that the costings provided in the RIS significantly underestimated the true implementation cost to be incurred. For example, evidence included the hourly/expertise rates the time involved, the number of artwork changes per ARTG entry, the complexity of a label change (and categorisation as a 'major change'), and the frequency of labelling changes. In some cases industry provided extensive data to show that implementation costs previously accounted for in the RIS did not cover the range of business activities that would be affected, if Option 3 were implemented. Evidence was also provided that, for some products, new and larger packaging would be required. It was purported that, in the case of relatively low value products, this could affect the viability of production. Some sponsors also indicated that the costs associated with new packaging would ultimately be passed onto the consumer via an increased retail price.	The assumptions and costings detailed in submissions have been considered by the TGA. Where appropriate, the assumptions and costings have been revised and are the subject of this current RIS.

Issue	Comment	Response from TGA
RIS: evidence to support new requirements	While the RIS identified specific concerns with current labelling practices, a number of respondents from both the health professions and industry considered that it did not provide a good level of evidence that the proposed actions would deliver the overall desired level of improvement in public health and safety. Comments particularly applied to low risk, non-prescription products. The comments also drew on the lack of good base level data and the absence of an evaluation plan.	Evidence from literature has been relied upon to support objectives of the labelling review, where available. Literature in Australia on the true extent of the problem attributed solely to labelling and packaging is limited. Therefore, much of the evidence outlined in the RIS comes from overseas.
RIS: risk based approach (proportionate response)	Feedback noted that the draft TGO 79 presented a 'one size fits all' approach and did not adequately differentiate requirements on the basis of the risk. Many respondents identified problem products, such as those containing paracetamol and ibuprofen, and considered that their risks should be directly addressed, rather than imposing requirements on all medicines in a particular category.	Implementing a risk-based approach would be too difficult to define in a labelling Order. Specific issues of this nature would not be dealt with through a labelling Order update. For example, for a particular active ingredient, issues of this nature can be addressed by applying specific conditions of registration or listing to particular classes of goods.[103] Consideration is being given to issues raised on a case-by-case basis. For example the split between prescription and non-prescription medicines has led to greater differentiation between the types of goods (low risk vs higher risk registered goods). This can be seen through exemption for medicine information panel (now called the display of 'critical health information') for low risk products.

[103] *Applying to registered or listed therapeutic goods under Section 28 of the Therapeutic Goods Act 1989, Standard 1995 Specific 1998* <https://www.tga.gov.au/sites/default/files/dr4-appendix-04.pdf>

Issue	Comment	Response from TGA
User testing	There was high level support, including from industry, for the principles behind the new Order but some comment that proposed label design should be thoroughly tested prior to implementation. Conduct of such testing would assist with an underlying issue - that is the end users of prescription versus non-prescription medicines have different information needs, notwithstanding the common issues such as prominence of active ingredient, etc.	The requirements have been developed in line with existing overseas regulatory frameworks. Specifically with reference to the UK front medicine panel ('active ingredient prominence, active moiety), the USFDA 'Drug Facts' and UK 'critical health information panel'.
Active ingredient name & prominence	There was strong support for increasing the prominence of the active ingredient name. The location under the trade name was also well supported, particularly by the prescription medicine sector; however the OTC sector identified some concerns. There was strong support from healthcare professionals for the active ingredient to be as prominent (or more prominent) as the trade name, with some requests from healthcare groups that it be above the trade name. Industry raised issues with space constraints with the amount of information required on a label, and in many cases, unlikely to fit on the label.	Prominence of active ingredient retained. To deal with space constraints issues, an amendment has been made in the non-prescription medicines Order, removing the need for display the salt and quantity of the drug, providing this information is contained within the critical health information section on the rear. These requirements align with the UK.

Issue	Comment	Response from TGA
Font size	Industry stakeholders raised concerns about the proposed font sizes and the relationship to/impact on other information already on the front label, including current artwork/branding. Critical issues included strong support for the size of letters to be defined using millimetres rather than point size and also the claim that 15 point font will lower readability & clutter the existing information. There were alternative suggestions that the name of the active ingredient be proportional to the trade name (as per the Poisons Standard requirement). Some respondents maintained that it will be difficult for evaluators to assess compliance on the basis of point size and further noted that font size is not mandated in the UK, EU, and Canada.	Font size has been changed to millimetres, per current TGO 69 requirements. For medicines with fewer than 4 active ingredients, the minimum text size has been reduced from 15 point to not less than 3.0 millimetres (equivalent to 12 point font size). For medicines with 4 or more active ingredients, the minimum text size has been reduced from 12 point to not less than 2.5 millimetres (equivalent to 10 point font size).

Issue	Comment	Response from TGA
Medicine Information Panel (MIP)	Overall approach was well supported by the range of respondents. However, concern was expressed that the design had not been user tested, in contrast to the presentation used by some companies who already provide a similar panel on the back of the packaging. There was also some concern with the requirement being applied to low-risk products (hand wash, toothpaste) – and a request for consideration of exemptions. Concern was expressed over 'lack of integration' between information on the front & back panels (i.e. possible duplication of information).	Specific product exemptions have been incorporated into the non-prescription order based on the risks being deemed as low risk or being used directly by health practitioners. This includes: · medicated throat lozenges, inorganic salt-based antacids where the space available for a label on the primary pack is less than 70cm2 or; · the medicine is intended for use as a skin antiseptic by a healthcare professional as either hand-hygiene preparation or patient pre-operative preparation. Criteria for exemptions was combination of pack size (overdose risk), low risk actives and intended use (no 'course of treatment', occasional relief/symptomatic relief. Greater degree of flexibility of MIP label requirements retained, consistent with north American requirements, for better international alignment. Regarding formatting, MIP format has been removed from the schedule of Order and requirements have been moved up higher in order (i.e. no longer contained in special requirements section). Specific details are also provided in guidance (e.g. examples).

Issue	Comment	Response from TGA
Small containers	The majority of industry submissions detailed concerns about the requirements for small containers (defined as 25ml or less) relating to font sizes, existing information requirements and impact on package size especially re the proposed MIP. A number of respondents proposed a redefinition of 'small container', up to 100ml.	An exemption has been made for small containers where multiple actives can be on the same line. Also, as described above, low risk medicines with a label size of less than 70cm2 no longer require an MIP.
Readability & functionality of TGO79	A number of submissions considered the document to be difficult to read & use. Some proposals noted that TGO 79 is written in such a way that the reader needs to look through several sections of the Order to find specific labelling requirements and that this reduces the functionality of the Order. They also noted that TGO 79 as written introduces an additional level of complexity for the design function and, because of this complexity, predicted difficulty in ensuring compliance.	To improve readability (and based on the need to consider different risk levels for different products) the TGO was divided into two separate Orders for prescription and non-prescription medicines, TGO 91 and TGO 92. Changes to formatting and the arrangement of sections have been made.
Alignment with other regulators	There was a consistent theme for the need to retain alignment with requirements in New Zealand and, where possible, to harmonise with major international regulators (UK, Canada & USA).	Noted. Formal government policy requires international collaboration with major regulators to achieve greater regulatory convergence.[104]

[104] TGA international engagement strategy 2013-2015, <https://www.tga.gov.au/publication/tga-international-engagement-strategy-2013-2015-0>

Issue	Comment	Response from TGA
12-month transition period to allow update for change in sponsorship/distributor details	Some submissions maintain that this is not sufficient time, others that the proposed period is too long.	A 12-month transition period has been maintained. The definition of 'name and contact details' in section 6 has also been revised to align with the Poisons Standard, plus reference to website and email as possible additional information.
Information required to be on a label must be in a colour or colours contrasting strongly with the background.	Industry stakeholders have concerns with subjectivity of 'colour contrast' and requested an exemption to this contrast allowing expiry and batch number on blister packaging to be permitted, given the high expense of imposing this requirement and inconsistency with international practice. Health professionals strongly advocate the need for important information to be in a colour contrasting with the background.	Exemption provided for batch number and expiry date details from being in a colour or colours contrasting strongly with the background.

Issue	Comment	Response from TGA
Options for identification of declarable substances on labels of prescription and related medicines	Many industry stakeholders raised issues with the inclusion of a leaflet inserted into the primary pack to disclose schedule 1 declarable excipients, citing unacceptable costs for sponsors when the information is already included in the consumer medicine information (CMI). Some speciality health groups also provided feedback on specific schedule 1 excipients (gluten, lactose), for example, the inconsistency between schedule 1 and Australian Food Standards Code.	A full review of schedule 1 declarable excipients is beyond the scope of this labelling review. However, to align with Food Standards Australia New Zealand, a gluten declaration has been prescribed where gluten is present in a concentration of 20 parts per million or more. A number of issues have been taken into account including difficulties in including the CMI in the pack; concerns about the ability to fit all required information on medicine labels; the need for consumers to have consistent access to important safety information; the levels of risk associated with different excipients and dosage forms; the merits of determining threshold levels for excipient concentrations; and the possibility of greater harm resulting from medicines not being taken because of a perceived risk from exposure to certain excipients. Considering declarable excipients in schedule 1 may pose considerable safety risks to consumers, the prescription medicines Order has been amended to allow a *choice* of declaring the schedule 1 excipients through: · declaration [of the specific excipients] on the label; or · identified by a statement that directs consumers to the CMI. The point that identifies the declarable excipients is a 'flag' that alerts consumers and initiates a conversation with healthcare practitioners on appropriate medication. It does not necessarily preclude use of the medicine.

Issue	Comment	Response from TGA
The primary package of prescription medicines must contain a space for the dispensing label.	Health practitioner groups recommended that a dispensing label space of 80 x 40 mm be mandated, consistent with TGA's best practice guidelines on medicine labelling. Industry stakeholders maintained that a space of 70 x 30 mm should be maintained, consistent with international best practice.	A dispensing label space of 70 x 30 mm has been maintained, consistent with international best practice. An exemption has also been made for starter packs and medicines used in a clinical setting (i.e. where self-administration will not occur).
Presentation of the name of the medicine: *continuous uninterrupted manner and not be broken up by additional information or background text*	Many OTC industry stakeholders held that labelling requirements would impact on trademarks and branding for OTC medicines.	An amendment has been made to allow for a greater degree of flexibility in placement of active ingredient either immediately or adjacent to the name of medicine (if trade mark would be obscured).
For medicines packed in strips or blister packs, the name (and the names and strengths of the active ingredients) 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.	Industry concern about extent of information to be included on blister packs. Non-industry stakeholders concerned about removal of requirement for non-detachable blisters.	This requirement was introduced in TGO 79 and has now reverted to the requirement specified in TGO 69 (i.e. repetition of at least once every 2 dosage units applies only to blisters where individual dose can be readily detached).
Individually wrapped goods-requirements concerning transdermal patches (previously paragraph 10(16)(d) of TGO 79)	Healthcare professional groups advocated the need for this requirement, particularly in the emergency setting. Industry concern about cost including changes to manufacturing processes, inconsistency with overseas requirements and privacy concerns for a patient.	This requirement has been deleted due to practicalities and privacy concerns.

Issue	Comment	Response from TGA
Omissions from TGO 79	Health professionals & consumer representatives were concerned that the issue of 'look-alike, sound-alike' names was no longer included in TGO 79 (compared with preceding consultations) and that the proposal to establish an advisory committee on labelling and naming issues had also been excluded from this paper.	Look-alike, sound alike names and packaging are issues that can be addressed when either the overall presentation of goods is considered by TGA delegates when deciding to register a new medicine or when a delegate is deciding if the presentation of listed medicines is unacceptable. The TGA has access to several Committees for the provision of high-level, independent expert advice.

2015 targeted consultation

In 2015, after reviewing submissions from the 2014 consultation and in response to the feedback, draft TGO 79 was restructured into the new draft TGO 91 and draft TGO 92. Certain technical requirements were also revised in response to stakeholder concerns and these were adopted into this new structure.

In October 2015, the revised draft Orders, TGO 91 and 92 and revised guidance were released for targeted consultation. To ensure continuity of engagement, this round of consultation was conducted with the same individuals and organisations that provided comment during the 2014 consultation. Targeted consultation closed in late December 2015.

A total of 38 submissions were received from pharmaceutical companies, professional bodies, Government bodies, industry, consumer organisations and members of the public.[105] A list of non-confidential submitters is provided at Appendix C.

The main issues raised in the submissions are summarised in Table 7, including responses from the TGA on these. As mentioned in response to the 2014 public consultation, it was not possible to individually respond to every comment received; therefore, only significant issues or issues that were raised in several submissions are summarised below.

A summary of major labelling requirements that were amended following the 2015 targeted consultation is provided at Appendix D.

Many of the comments received reiterated concerns raised during the 2014 public consultation. These issues have been described in Table 6 (or Appendix B) and will not be repeated.

[105] Therapeutic Goods Administration (2015), Submissions received: Medicine labelling, <https://www.tga.gov.au/submissions-received-medicine-labelling>

Table 7: Summary and Response to 2015 targeted consultation

Issue	Comment	Response from TGA
RIS: costs	Industry held that the proposed amendments to TGOs would not significantly alter any comments previously made as part of the 2014 public consultation with respect to costings.	Due to timing and resource constraints, the RIS had not been amended prior to the targeted consultation. Since the close of targeted consultation, a consultant has revised the costings contained within the earlier RIS. These costings take into account many of the comments received as part of previous consultations, including the need to account for some label changes as 'major.' The revised costings are the subject of this current RIS.
Active ingredient name, & prominence	Industry concern that many medicines will not comply due to text size requirement. Some submissions requested an exemption from minimum text size for medicines requiring dual spelling during the IHIN implementation timeframe. This is due to space constraints for very long names. Three was also a request that listed medicines containing two or more actives be permitted to list on the side/rear and not the main label.	Proposed exemption for 'dual names' has been adopted. A reduced min. text size of 2.5mm during the IHIN transition period has been drafted. A new Schedule 2 has been added to the Orders and lists the names to which the exemption would apply. Difficulty for herbal preparations, vitamins and minerals to be included at required text size recognised. TGO 69 requirement 3(3)(b) to be reinstated such that if two or more of these, actives can be included on the side/rear label. This would apply to both registered and listed medicines.

Issue	Comment	Response from TGA
Option for use of active moiety only (not full approved name) on the main label	Concerns with lack of harmonisation with NZ. Concern with potential issue of differing requirements between products and sponsors (e.g. active moiety vs full name on main label) as potentially being confusing to a consumer.	This requirement has been retained. Clarity has been provided to ensure that the active moiety is part of the full Australian Approved Name. TGA has discussed this matter directly with the NZ regulator, Medsafe. It should be noted that the NZ Government has reviewed the Medicines Act and a Bill in the NZ parliament proposes significant changes including greater recognition of Australian and other international standards for medicines.
Definition of small container – 25mL	The majority of industry submissions detailed concerns about the requirements for small containers (defined as 25ml or less) relating to font sizes, existing information requirements and impact on package size especially re the proposed display of critical health information (CHI) (previously MIP). A number of respondents proposed a redefinition of 'small container', even up to 100ml.	A 'medium' size has been re-drafted for TGO 92 with a capacity of 25-60mL, and smaller text size requirements (2.5 mm on main label and 2.0mm on side/rear panel). Active ingredients can be presented on one line rather than on separate lines on the main label.
The primary package of prescription medicines must contain a space for the dispensing label	Health practitioner groups have recommended that a dispensing label space of 80 x 40 mm be mandated. Further healthcare groups have maintained that a dispensing label space should be required even when it is intended for use only in a clinical setting as it cannot be envisaged that a medicine will only be used in a clinical setting or remain so.	The requirement for a minimum space of 70x30 mm has been retained but a recommendation to have a larger space where possible has been included in the best practice guidance. Clarity provided on when the space should be on the container rather than an outer pack and also an exemption for medicines that are supplied to hospitals (ie. where self-administration will not occur).

Issue	Comment	Response from TGA
Labels of registered non-prescription medicines must provide information in a consistent order and manner.	Concern regarding no definition of 'MIP'. Request for clarity on the degree of flexibility allowed, especially inclusion of 'other information'.	TGO 92 has been amended to reflect a move away from prescriptive 'box/panel presentation.' Reference is now made to 'critical health information (CHI)' rather than a 'panel'. CHI has been defined in section 6.
Medicine Information Panel (MIP) requirements for non-prescription medicines *Note: now Display of critical health information*	Industry stakeholders requested further exemptions for certain lozenges, antacids, some hand sanitisers.	Extend exemptions to all hand sanitisers and also toothpastes. Requests for exemptions for anti-acne, anti-fungal, corn and callus removers not accepted (for safety reasons). Criteria for exemptions was combination of pack size (overdose risk), low risk actives and intended use (no 'course of treatment', occasional relief/symptomatic relief.
Medicine name to be on at least 3 sides of a carton	Removal of this requirement from TGO 92 has raised concerns with some non-industry stakeholders.	Maintained. Reiterating the same information on multiple sides of the carton would clutter important health information on non-prescription medicines.
Small containers	The majority of industry submissions detailed concerns about the requirements for small containers (defined as 25mL or less) relating to font sizes, existing information requirements and impact on package size especially re the proposed MIP. A number of respondents proposed a redefinition of 'small container', even up to 100mL.	Exemption for small containers has been included where multiple actives can be on the same line and smaller minimum text size used for active ingredients on labels of small containers that do not have outer packaging.

Issue	Comment	Response from TGA
Information required to be on a label must be in a colour or colours contrasting strongly with the background.	Industry stakeholders have concern with subjectivity of 'colour contrast' while some non-industry stakeholders have reiterated their concerns regarding this exemption.	The TGA has taken the opposing views into consideration and recommended, through best practice guidance, that ink be used instead of embossing or debossing. The decision aligns with guidance requirements internationally.[106,107,108] The Vision Australia colour contrast analyser has been referred to in the best practice section of the guidance to assist sponsors.
Individually wrapped goods-requirements batch and expiry date	Industry stakeholders held that certain goods will not be able to comply with the requirement for batch and expiry on individually wrapped goods. This would result in an increase in section 14 requests. (Note: Requests can be made to the TGA seeking the Secretary's consent to import or supply goods that do not comply with a standard, in this case the labelling Order. Consent is granted under the provisions of section 14 of the Act.)	TGO 69 provision in 3(12) reinstated to remove requirement for batch and expiry on unsealed individually wrapped goods.
IV bags	Stakeholders identified concerns that many aspects of existing bags would not be compliant with the new labelling Order.	Specific requirements for placement of information on flexible bags containing IV solutions have been drafted to reflect best practice use.

[106] Health Canada, *Guidance Document: Labelling of Pharmaceutical Drugs for Human Use*, 13 June 2015, section 3.6.3.
[107] Medicines and Healthcare Products Regulatory Agency, *Best practice guidance on labelling and packaging of medicines*, June 2003, section 6.4.
[108] New Zealand Medicines and Medical Devices Safety Authority, *Guideline on the Regulation of Therapeutic Products in New Zealand Part 5 Labelling of medicines and related products, Edition 1.5, October 2015*, pp 6.

Other avenues of consultation: Therapeutic Goods Committee

The Therapeutic Goods Committee (TGC) was established under Regulation 34 of the Therapeutic Goods Regulations 1990 (Regulations) to provide advice and to make recommendations to the Minister for Health on the adoption of standards for therapeutic goods and matters relating to the requirements for labelling and packaging. The current membership is available on TGA's website.[109]

In accordance with the Regulations, the TGC was consulted on the (then) draft TGO 79 and guidance in August 2013 and then again in June 2014, prior to public consultation.

Following 2014 public consultation and subsequent decision to split draft TGO 79, the TGC was consulted on the new draft TGO 91 and 92 prior to the 2015 targeted consultation.

On 13 May 2016, TGC were consulted on the amended TGO 91 and TGO 92. At this meeting, the TGC recommended the Orders were suitable for adoption.

[109] Therapeutic Goods Committee, February 2016, <https://www.tga.gov.au/committee/therapeutic-goods-committee-tgc>

Conclusion and recommended option

Option 3, the introduction of TGO 91 and 92 meets the objectives of the labelling reform, and Option 3C, introduction of TGO 91 and 92 over a 4 year transition period, is the preferred option.

Neither the status quo (option 1) nor the introduction of new best practice guidelines (option 2) would satisfy consumers who are already dissatisfied with the legibility of key medicine information.

Option 1 would continue to be out of alignment with international labelling requirements. Net benefits would be minimal and are the lowest of the three policy options put forward.

Implementation of Option 2 has the potential to create even greater inconsistency across medicine labels in the Australian marketplace. There is likely to be some benefit to consumers and healthcare practitioners when using the individual medicines whose labels have been updated in line with best practice principles - critical information should be easier to identify and read on these labels. However, education of, and improved awareness within, consumer populations will be adversely affected by uneven uptake and greater inconsistencies in medicine labels both within and across medicine classes.

Throughout the formal and informal consultations that have taken place over the last 5 years, there has been high level support for the objectives of the labelling reform from industry, healthcare groups, consumer groups and individuals. Option 3 is the only option likely to fully address the objectives of ensuring Australian medicine labels are easier to read and understand and that critical health information is easily identified. Improved medicine labels are a key component in improving quality use of medicines for both consumers of over-the-counter medicines and medical professionals administering to patients. Option 3 introduces a number of improvements to medicine labels.

Option 3 will result in increased prominence, and consistent placement, of the active ingredient. These requirements, along with consistent placement of critical health information, will assist in educating consumers about the medicines they are taking as they become familiar with where to find critical health information. By increasing consumer knowledge and awareness, Option 3 will help to minimise the chances of medication error.

Option 3 will also assist in communication of essential information in emergency situations. Due to prominence and consistency of information location, in an emergency phone call to poison information centres, a family member who has become familiar with a more standardised lay-out of medicine labels should be able to quickly identify the active ingredient consumed, or due to increased text size used for this information, be able to read this more easily. This increased knowledge will help ensure that the affected individual receives advice appropriate for that ingredient.

Option 3 draws upon medicine labelling best practice principles that have been adopted overseas. The benefits associated with improved labels in those jurisdictions are difficult to measure due to the interrelationships between confounding factors. However, the changes proposed under this option address recognised problems with readability and easy identification of critical health information using approaches that are consistent with those whose success in other countries is widely acknowledged.

Option 3C ensures that these changes can be made sustainably. A 4-year transition period will ensure that the burden placed on industry is minimised. This increases the opportunity to incorporate necessary label changes as part of business as usual activities as opposed to being triggered by the need to meet new regulatory requirements.

By reducing the burden on industry, Option 3C reduces the risk of medicine shortages that may arise as sponsors strive to meet the new requirements.

The 4-year transition period is also being aligned, as closely as possible, to the International Harmonisation of Ingredient Names (IHIN) labelling reform work.[110] The transition period for the IHIN reform commenced in April 2016. Executing both reforms in parallel will ensure that costs to industry are minimised. This aligns with feedback received from industry during recent consultation activities undertaken.

[110] *Regulation impact statement: International harmonisation of ingredient names*, November 2015, <https://www.tga.gov.au/publication/regulation-impact-statement-international-harmonisation-ingredient-names>

Implementation and review

Should the proposal to update TGO 69 be accepted, TGOs 91 and 92 will be finalised and a decision on their adoption as Ministerial Standards made by the delegate of the Minister (under the provisions of section 10 of the Act). Once the decision is made, the documents and associated Explanatory Statements will be registered on the Federal Register of Legislation (FRL). As TGO 91 and 92 are legislative instruments, they are both subject to disallowance by the Federal Parliament.

Prior to registration, key stakeholders will be notified and information made available on the TGA website. The draft guidance document that has been prepared to assist industry in applying the new requirements will also be published.

As the existing labelling Order, TGO 69, is due to 'sunset' on 1 October 2017 it will need to be re-made. Sunsetting is the process by which legislative instruments undergo automatic repeal after 10 years following their registration. Remaking TGO 69 ensures that medicine sponsors have the choice of complying with either the current requirements or TGO 91 /92 (as relevant) over the 4-year transition period.

Once the new standards are registered, a mechanism for their review and variation exists under section 10 of the Act.

Risks

Undue delay of implementation of new labelling requirements would result in a misalignment with the IHIN implementation and potential increase in label update costs. This risk has been raised as a concern by industry stakeholders.

If the draft TGOs 91 and 92 are not adopted, TGO 69 will still need to be remade as all stakeholders agree that mandatory labelling requirements are necessary for medicines supplied in Australia. However it is also widely accepted that TGO 69 does not reflect current best practice for quality use of medicines.

In addition, the lengthy consultation on revised labelling requirements has raised stakeholder expectations which would need to be managed in the event of the current requirements being maintained.

There is also the risk of implementing TGO 91 and 92 with unintended consequences, such as stakeholders finding ambiguity or contradiction within the relatively complex framework. While consideration has been given to these issues and relevant technical and legal expertise engaged in drafting the Orders, it is not until the new requirements are implemented that this can be fully identified. If these situations arise, consultation with affected stakeholders would be conducted and either the existing mechanism for review and variation to the Orders would be utilised or the guidance document updated.

It is possible that the new Orders have been drafted in ignorance of a specific stakeholder need due to lack of involvement in the consultation - that is, requirements for a particular type of medicine may not have been incorporated. This risk is slight given the extensive consultation process and in fact reflects an existing situation; that is, TGO 69 cannot be applied to some medicines already on the market. These medicines are appropriately regulated by the Secretary of the Department of Health granting consent for their supply under the provisions of sections 14 and 14A of the Act. This mechanism is still available post-implementation of the new TGOs 91 and 92 and could be utilised until the Orders were updated as needed.

There is also a risk of dissatisfaction from consumer and healthcare groups that the requirements in TGO 91 and 92 do not go far enough in meeting their objectives. The balancing of stakeholders views between improving safety outcomes on the one hand, and economic viability and international harmonisation on the other, required careful consideration. It is therefore likely that consumer and healthcare groups will be dissatisfied that many of the issues raised throughout the consultations have not been reflected adequately in legislation (e.g. active ingredient name above trade name, expiry/batch colour contrast requirements). The creation of specific best practice principles may be an appropriate way to address some of these issues once the new labelling Orders have been implemented.

Review and post-implementation activities

It is intended that TGO 91 and 92 will be reviewed on a regular basis. Many issues raised by stakeholders in previous consultations were considered out of scope for the current medicine labelling reform, but may be considered for future updates (e.g., a review of Schedule 1 substances which was raised by some consumer groups). It is envisaged that the splitting of TGO 69 into separate Orders for prescription and non-prescription medicines will help ensure that future updates are more targeted and streamlined. Each review will involve further consultation. A regular ongoing process of review will assist in maintaining currency of the Orders.

Communication and education

An education strategy for industry, healthcare professionals and consumers will help raise awareness of the key medicine labelling changes.

We will work closely with consumer, healthcare professional and industry peak bodies to develop and disseminate information about the changes. These organisations have existing resources and networks that extend beyond those currently available to TGA.

Targeted communication

TGA will work with consumer and healthcare professional organisations to develop communication and education strategies. The overall intention of the new Orders is to improve access to information for consumers and healthcare professionals; however it is anticipated that explanation on why information is now being presented a certain way, and why not all labels will be compliant immediately, will be needed. We will work closely with these stakeholders to address their communication needs.

For industry stakeholders, it is anticipated that education sessions on how to use and interpret the new Orders may be required. We will be working closely with these stakeholders to identify and respond to their needs.

A range of education materials will be developed through different media to meet the needs of different stakeholders. These may include targeted mail-outs to sponsors, information that healthcare professionals can pass on to consumers, and presentations at professional seminars or conferences. A consumer education video can also be created for GP waiting rooms.

TGA will also create a dedicated page on the TGA website that will be a central source of information on the new Orders and contain a copy of useful communication and education materials. All education materials will provide links back to this central webpage.

Appendix A: List of submissions received in response to 2014 public consultation

80 submissions were received in total, 63 non-confidential, 17 confidential.

AbbVie Pty Ltd

Accord Australasia Ltd

Allergy & Anaphylaxis Australia

Amgen Australia Pty Ltd

Australian Self Medication Industry

Australasian Society of Clinical and Experimental Pharmacologists and Toxicologists

Australian Medical Association

Bayer Australia Limited

Bayer HealthCare

BioCeuticals Ltd

Boehringer Ingelheim Pty Ltd

Clinical Excellence Commission

Coeliac Australia

Combined Pensioners & Superannuants Association

Communication Research institute

Complementary Medicines Australia

Consumers Health Forum

Council of Australia Therapeutic Advisory Groups

Department of Health and Human Services Tasmania

Ego Pharmaceuticals Pty Ltd

Generic and Biosimilar Medicines Association (at the time of submission, the Generic Medicines Industry Association)

Gillian Shenfield – Retired Professor of Clinical Pharmacology

GlaxoSmithKline

GlaxoSmithKline- Consumer Healthcare

Global Standards 1

Hodge Murray Hodge Pty Ltd

iNova Pharmaceuticals Australia Pty Ltd

Johnson & Johnson Pacific Pty Ltd

Lundbeck Pty Ltd

Medicines Australia

Medicines New Zealand

Medicines Regulation and Quality Team

National Pharmaceuticals Services Association

NEHTA - Clinical Terminology

Nestle Australia

New Zealand Self Medication Industry

Novartis Pharmaceuticals Australia Pty Ltd

Novo Nordisk Pharmaceuticals Pty Ltd

NPS Medicine Wise

NSW Poison Information Centre

NSW Therapeutic Advisory Group

Peninsula Health – Frankston Hospital

Pfizer Australia Pty Ltd

Pharmaceutical Defence Limited

Pharmaceutical Society of Australia

Pharmacy Board of Australia

Professional Pharmacists Australia

Purvis Regulatory Consulting

Quality matters Safety Matters Pty Ltd

Reckitt Benckiser

Roche Products Pty Ltd

Royal Australasian College of Physicians

Sanofi-Aventis Australia Pty Ltd

Servier Laboratories Australia Pty Ltd

Smart Prescription Packs

Society of Hospital Pharmacists of Australia

South Australian Medicines Advisory Committee

Specialist General Practitioner

The Pharmacy Guild of Australia

The Royal Australian College of General Practitioners

The Royal Australian and New Zealand College of Psychiatrists

Theo Raynor, Professor, University of Leeds, UK

Western Australia Therapeutic Advisory group

Appendix B: Summary of major amended requirements made in TGO 91/92 as a result of 2014 public consultation

Requirement	Section in TGO 91	Section in TGO 92	Changes made following 2014 consultation
Definitions (section 6)			
Definition of: · Certificate of listing (TGO 92) · Default standard (TGO 91) · Infusion (TGO 91) · Listing number (TGO 92) · Registration number · Stated volume of fill · Stated weight · Supply · Text size	Section 6	Section 6	These are new definitions that have been added to aid readability and to support re-drafted sections of the new draft Orders.

Requirement	Section in TGO 91	Section in TGO 92	Changes made following 2014 consultation
Definition of: · Biological medicine (TGO 91) · Capacity · Label · Machine Readable Code	Section 6	Section 6	These are amended definitions that have been added to aid readability. Note: the definition of a 'label' has been amended because the requirements for 'durability' have been removed.
Warning statements (non-prescription medicines)	Section 6	Section 6	Separate definitions have been given in each labelling Order reflecting the different statements that are required for prescription and non-prescription medicines.
Definition of 'distributor'	Section 6	Section 6	This definition was added to resolve confusion identified in submissions in relation to the terms 'supply, 'release for supply' and 'supplier'- which were previously undefined.
Definition of 'durable'	N/A- definition has been removed		Definition of 'durable' and subsection 7(3) has been removed. Definition of 'label' has been amended to align with TGO69. Durable has been added to paragraph 7(2)(c) in relation to the label or labels being durable and in English.
Definition of 'expiry date prefix'	Section 6	Section 6	In this definition the words 'USE BY' and 'USE BEFORE' have been re-instated.

Requirement	Section in TGO 91	Section in TGO 92	Changes made following 2014 consultation
Definition of 'name and contact details'	Section 6	Section 6	This is a revised definition to align with the Poisons Standard, plus reference to website and email as possible additional information. For clarity, the provision to allow medicines that are affected by a change to these details to be supplied for a certain period after the change is made and prior to the labels being amended, has been added here instead of inclusion in subsection 8(1).
Definition of 'machine readable code'	Section 6	Section 6	This definition has been amended to ensure that a (proprietary) non-standard bar code to encode GS1 GTINs cannot be used.
Definition of 'starter pack' (TGO 91)	Section 6 and throughout the Order	Removed from the Order as not applicable to non-prescription medicines	The definition was amended to align with the Medicines Australia Code of Conduct definition. It was identified that this definition was not required for non-prescription medicines, hence it has been removed from draft TGO 92.
Definition of 'text size'	Section 6	Section 6	This definition has been added as a result of the removal of references to '*text size equivalent to Arial font*' from the labelling Orders. The definition is the same as the 'letter height' definition in TGO 69. Text size is to be measured in millimetres and definition to refer to ascender/descender for consistency with the Poisons Standard.

Requirement	Section in TGO 91	Section in TGO 92	Changes made following 2014 consultation
Definition of 'very small container'	Section 6	Removed from TGO 92	Capacity of a 'very small container' has been increased from 2.5mL to 3.0mL. As these requirements were drafted with regard to medicines such as vaccines, they are not required in the draft TGO 92.
Section 7			
AUST L/AUST R number	Paragraph 7(2)(d)	Paragraph 7(2)(d)	For readability and completeness, the AUST R/AUST L requirement for minimum text size has been added.
Label or labels must be in a colour or colours contrasting strongly with the background	Paragraph 7(2)(e)	Paragraph 7(2)(e)	An exemption has been inserted so that this contrast requirement does not apply to the expiry date and expiry date prefix and the batch number and batch number prefix.
Section 8			
Options for identification of declarable substances on labels of prescription and related medicines	Subsection 8(1)	N/A	These requirements have been changed to allow Schedule 1 substances to be: · declared on the label; or · identified by a statement that directs consumers to the Consumer Medicine Information.

Requirement	Section in TGO 91	Section in TGO 92	Changes made following 2014 consultation
Warnings statements related to the use of medicines by those who are, or may be, pregnant.	Not applicable	Paragraph 8(1)(k)	This is a new requirement from TGO 69. An additional amendment has been made to exempt medicines containing nicotine for the purpose of smoking cessation.
Medicine name to be on at least 3 sides of a carton	Paragraph 8(1)(p)	Removed	This requirement has been removed from the non-prescription medicines order to allow for more space for Medicine Information Panel. This requirement is still contained within the prescription medicines order (paragraph 8(1)(p)).
The primary package of prescription medicines must contain a space for the dispensing label.	Subsection 8(2)	N/A	Clarity provided on when the space should be on the container rather than an outer pack. Clarity has been provided on how this space can be used for starter packs. An exemption for medicines that are supplied to hospitals (i.e. where self-administration will not occur).
Labels of registered non-prescription medicines must provide information in a consistent order and manner in a Medicine Information Panel.	Not applicable	Subsection 8(2)	Specific exemptions have been added into the non-prescription Order (subsection 8(3)). Greater degree of flexibility in the format of the Medicine Information Panel. Specific details to be provided in guidance (e.g. medicine information panel examples).

Requirement	Section in TGO 91	Section in TGO 92	Changes made following 2014 consultation
Disposable delivery device	Subsection 8(3)	Not applicable	Minor changes to subsection 8(3) in TGO 91 to reflect a common-sense approach where the pharmacist places the dispensing label on the device. The changes should apply whether single dose or multi-dose, and should apply to inhalation products where the cartridge is fully enclosed in the delivery device.
Proximity of active ingredient name in relation to the trade name and requirement for separate lines	Subsection 9(3)	Subsection 9(3)	Greater degree of flexibility in placement of active ingredient either immediately or adjacent to the name of medicine (if trademark would be obscured). Exemption for small containers where multiple actives can be on the same line. Prominence of active ingredient retained.
Use of full Australian approved name on the main label of all medicines	Not applicable	Subsection 9(7)	For medicines that have an MIP, the requirement for display of the full Australian approved name on the main label has been removed. This can only occur if a commonly understood name is used on the main label and that no statement of quantity or amount is displayed; and the full name and quantity of the active ingredient is displayed in the MIP.

Requirement	Section in TGO 91	Section in TGO 92	Changes made following 2014 consultation
The name(s) of active ingredient(s) in registered medicines with less than four active ingredients must be in a text size of not less than 3.0 millimetres on the front panel directly under the trade name. The names of active ingredients in prescription medicines with four or more active ingredients must be in a text size of not less than 2.5 millimetres.	Subsection 9(5) Subsection 9(6)	Paragraph 9(7)(a) Paragraph 9(7)(b)	Font size has been changed to millimetres. 'Text size' definition has been changed to original TGO 69 wording. For medicines with fewer than 4 active ingredients, the minimum text size has been reduced from 15 point to not less than 3.0 millimetres (equivalent to 12 point font size). For medicines with 4 or more active ingredients, the minimum text size has been reduced from 12 point to not less than 2.5 millimetres (equivalent to 10 point font size).
Section 10			
Biological medicine labelling requirements (previously subsection 10(8) of TGO 79)	Not applicable	Not applicable	Section 10(8) has been removed as information can be retained in other documentation such as the PI/CMI for the products. These requirements were felt to be unnecessary duplication. One of the requirements which are related to sensitivity/allergy issues has been placed into Schedule 1 (antibiotics).
Specific labelling required for starter packs	Subsection 10(9)	Not applicable	The requirement for a space for practitioner/patient details and the requirement for state and territory warnings have both been removed.

Requirement	Section in TGO 91	Section in TGO 92	Changes made following 2014 consultation
For medicines packed in strips or blister packs, the name (and the names and strengths of the active ingredients) 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.	Paragraph 10(13)(c)	Paragraph 10(9)(c)	This requirement was introduced in TGO 79 and has now reverted to the requirement specified in TGO 69 (i.e. repetition of at least once every 2 dosage units applies only to blisters where individual dose can be readily detached.
Individually wrapped goods-requirements concerning transdermal patches (previously paragraph 10(16)(d) of TGO 79)	Not applicable	Not applicable	Paragraph 10(16)(d) previously required that a patch on the skin is identified by a code, or the name of the medicine and strength if more than one medicine, or the name of the active ingredient and how much release in a given time. This requirement has been deleted due to practicalities and privacy concerns.
Gluten declaration cut off requirements	Schedule 1	Schedule 1	A gluten declaration has been prescribed where gluten is present in a concentration of 20 parts per million or more. This requirement is to align with Food Standards Australia and New Zealand.

Appendix C: List of submissions received in response to 2015 targeted consultation

45 submissions were received, 38 non-confidential and 7 confidential.

Accord Australasia Ltd

Allergy & Anaphylaxis Australia

Australasian Society of Clinical and Experimental Pharmacology and Toxicology

Australian Medical Association

Australian Red Cross Blood Service

Australian Self Medication Industry

Bayer Australia Ltd

Clinical Excellence Commission

Coeliac Australia

Communication Research Institute

Complementary Medicines Australia

Department of Health, Queensland

Department of Health and Human Services, Tasmania

Ego Pharmaceuticals Pty Ltd

Generic and Biosimilar Medicines Association

Global Standards 1

GlaxoSmithKline

GlaxoSmithKline- Consumer Healthcare

Human factors Specialist, Clinical Excellence Commission

Johnson & Johnson Pacific Pty Ltd

Medicines Australia

Medicines New Zealand

National Pharmaceuticals Services Association

Nestle Australia

New Zealand Self Medication Industry

NSW Therapeutic Advisory Group

Pfizer Australia Pty Ltd

Pfizer Consumer Health care

Pharmaceutical Defence Limited

Pharmacy Board Australia

Pharmaceutical Society of Australia

Reckitt Benckiser

Smart Prescription Packs

Society of Hospital Pharmacists of Australia

The Pharmacy Guild of Australia

The Royal Australian College of General Practitioners

The Royal Australian and New Zealand College of Psychiatrists

Theo Raynor, Professor, University of Leeds, UK

Appendix D: Summary of major amended requirements made in TGO 91/92 as a result of 2015 targeted consultation

Requirement	TGO 91/92 (Oct 2015 draft)	Issue	Current (Feb 2016)
Section 6			
Definition of small container – 25 mL	TGO 92: Section 6	Industry has identified containers greater than 25mL that would need text size concessions as per current 'small containers'.	A 'medium' size is currently being re-drafted for TGO 92 with a capacity of 25-60mL, and smaller text size requirements (2.5 mm on main label and 2.0mm on side/rear panel). Active ingredients can be presented on one line rather than on separate lines on the main label.
Transition period to allow update for change in sponsorship/distributor details	TGO 91 & 92: Section 6 Change to labels must be made within 12 months	Some submissions maintain that this is not sufficient time, others that the proposed period is too long.	Maintained.
Section 7			
AUST L/AUST R number in the Regulations and not duplicated in the TGOs.	TGO 91 & 92: 7(2)(d)	Some stakeholders requested that the Orders explicitly refer to the inclusion of AUST R/AUST L on the label.	Maintained.

Requirement	TGO 91/92 (Oct 2015 draft)	Issue	Current (Feb 2016)
Information required to be on a label must be in a colour or colours contrasting strongly with the background.	7(2)(e) Exemption for batch number and expiry date details.	Industry stakeholders have concern with subjectivity of 'colour contrast'. Non-industry stakeholders have reiterated their concerns regarding this exemption.	Maintained.
Section 8			
Requirement for tabulated medicine information on registered non-prescription medicines.	TGO 92: 8(3) Exemptions for certain lozenges, antacids, some hand sanitisers.	Requests for further exemptions	Extend exemptions to all hand sanitisers and also toothpastes. Requests for exemptions for anti-acne, anti-fungal, corn and callus removers not accepted (for safety reasons).
Options for identification of declarable substances on labels of prescription and related medicines	TGO 91: 8(1) Option for declaration on the label OR statement referencing CMI	Some submissions identify a concern that this requirement results in the need for a package insert.	Maintained. Additional information to be provided to confirm that there is not a new requirement for a package insert.

Requirement	TGO 91/92 (Oct 2015 draft)	Issue	Current (Feb 2016)
Medicine name to be on at least 3 sides of a carton	TGO 91: 8(1)(p)	Removal of this requirement from TGO 92 has raised concerns with some non-industry stakeholders.	Maintained.
The primary package of prescription medicines must contain a space for the dispensing label.	TGO 91: 8(2) 70 x 30 mm Exemptions for starter packs and medicines used in a clinical setting.	Health practitioner groups have recommended that a dispensing label space of 80 x 40 mm be mandated. Further healthcare groups have maintained that a dispensing label space should be required even when it is intended for use only in a clinical setting as it cannot be envisaged that a medicine will only be used in a clinical setting or remain so.	Maintained.
Labels of registered non-prescription medicines must provide information in a consistent order and manner.	TGO 92: 8(2)	Concern regarding no definition of 'MIP'. Request for clarity on the degree of flexibility allowed, especially inclusion of 'other information'.	Maintained. No definition of MIP to be included. Existing drafting to be amended to reflect move away from prescriptive 'box/panel' presentation. Reference to a 'MIP' to be replaced by recognition of 'critical health information.'

Requirement	TGO 91/92 (Oct 2015 draft)	Issue	Current (Feb 2016)
Section 9			
Presentation of the name of the medicine: continuous uninterrupted manner and not be broken up by additional information or background text	TGO 91 & 92: 9(2)-(3)	Industry have raised concerns that this section as written would impact on trademarks and branding. It has been requested that this be changed to 'best practice'.	Maintained. A document was circulated to industry peak bodies in March 2016 for comment. The document outlined TGA's rationale for this requirement and general principles for interpreting this requirement. This information will be included in the labelling guidance.
Option for use of active moiety only (not full approved name) on the main label	TGO 92: 9(7)	Concerns with lack of harmonisation with NZ. Concern with potential issue of differing requirements between products (e.g. active moiety vs full name on main label) as potentially being confusing to a consumer.	Maintained.

Requirement	TGO 91/92 (Oct 2015 draft)	Issue	Current (Feb 2016)
Text size and need for prominence of active ingredients	Less than four active ingredients: · TGO 91: 9(5)(a) · TGO 92: 9(5)(a) Four or more active ingredients: · TGO 92: 9(6)	Industry have raised concerns of lack of available space on the main label with proposed text size, and issues around long active ingredient names. Non-industry stakeholders have maintained the need for prominence of active ingredients compared to the medicine name to help consumers distinguish the active ingredient from brand name.	Maintained.
The name(s) of active ingredient(s) in registered medicines with less than four active ingredients must be in a text size of not less than 3.0 millimetres on the front panel directly under the trade name. The name(s) of active ingredient(s) in listed medicines with less than four active ingredients must be on the front panel directly under the trade name.	TGO 92: 9(6) and 9(7) <4 actives: main label, (Aust R - NLT 3.0 mm) >= 4 actives: side/rear panel, (Aust R – NLT 2.5 mm)	Industry concern that many medicines will not comply due to text size requirement. Request that Aust L with 2 or more actives, side/rear and not main label.	New definition of 'medium container' size (see above). Difficulty including the required additional information, at required text size, recognised. TGO 69 requirement 3(3)(b) to be reinstated such that if 2 or more herbal, vitamin and mineral active ingredients are present, active ingredient information does not need to be on the main label. This would apply to both Aust R and Aust L.

Requirement	TGO 91/92 (Oct 2015 draft)	Issue	Current (Feb 2016)
Haemofiltration and haemodiafiltration solutions	TGO 91: 9(7)	New type of goods previously considered devices but now considered medicines following recent redesign of sponsor's labels approved by TGA.	New subsection added.
Section 10			
Haemofiltration and diahaemofiltration solutions	TGO 91: 10(7)	New type of goods previously considered devices but now considered medicines following recent redesign of sponsor's labels approved by TGA	New subsection added.
Small containers – specific text size requirements	TGO 91: 10(10) TGO 92: 10(7)	Submissions have proposed smaller text and less information should be required as currently many small containers will be unlikely to meet the requirements.	Maintained.

Requirement	TGO 91/92 (Oct 2015 draft)	Issue	Current (Feb 2016)
For medicines packed in strips or blister packs, the name (and the names and strengths of the active ingredients) must appear at least once across every two dosage units enclosed in the strip or blister, when a dosage unit can be readily detached.	TGO 91: 10(13)(c) TGO 92: 10(9)(c)	Industry concern about extent of information to be included on blister packs. Non-industry stakeholders concerned about removal of requirement for non-detachable blisters.	Maintained. Relevant parts of Section 10 in each Order are being re-drafted to improve clarity on requirements for medicines containing multiple active ingredients.
Ophthalmic use- TGO 69 reference to eye lotions and eye drops	TGO 91 & 92: 10(1) Only refers to drops	The reference to eye lotions has been removed (equivalent text requirement for eye drops has been retained).	Reference to 'eye lotions' has been removed as this is not an approved dosage form. A recent review of the ARTG confirmed that there are goods using this dosage type.
Individually wrapped goods- requirements concerning transdermal patches (previously paragraph 10(16)(d) of TGO 79)	N/A Draft TGO 79 required that a patch on the skin is identified by a code, or the name of the medicine and strength if more than one medicine, or the name of the active ingredient and how much release in a given time.	Non-industry groups have maintained that labelling requirements for transdermal patches should be retained while industry groups previously submitted that imposing this requirement would come at an additional cost (including stability studies) and privacy concerns.	Maintained (no requirement).

Requirement	TGO 91/92 (Oct 2015 draft)	Issue	Current (Feb 2016)
Individually wrapped goods- requirements batch and expiry date	TGO 91:10(12) TGO 92:10(8)	Certain goods will not be able to comply with the requirement for batch and expiry on individually wrapped goods. This would result in an increase in section 14 exemptions.	TGO 69 provision in 3(12) reinstated to remove requirement for batch and expiry on unsealed individually wrapped goods.
Section 11			
Use of the word microgram vs µg	TGO 91/92 : 11(1) Allows µg in small containers (not primary packs)	Variance of views on allowing use of abbreviation. Industry raised practicality issues for writing 'micrograms' in full with limited space constraints. Non-industry groups have raised concerns about potential confusion where µg is permitted on labels.	TGOs contain a note that: *The abbreviations 'mg' and 'g' can be used on all labels but 'microgram' should be used in full unless the medicine is in a small container. Then the abbreviation 'µg' may be used.*

Version history

Version	Description of change	Author	Effective date
V1.0	Original publication	Therapeutic Goods Administration	August 2014
V2.0	Revised publication	Therapeutic Goods Administration	June 2016
V3.0	Revised publication following OBPR feedback received	Therapeutic Goods Administration	July 2016

Therapeutic Goods Administration

PO Box 100 Woden ACT 2606 Australia
Email: info@tga.gov.au Phone: 1800 020 653 Fax: 02 6203 1605
https://www.tga.gov.au

Reference/Publication #