Submission on TGA consultation document:

Medicine Labelling and Packaging Review

About Arthritis Australia

Arthritis Australia is the peak arthritis organisation in Australia and is supported by affiliate offices in every state and territory.

Arthritis Australia provides support and information to people with arthritis as well as their family and friends. It promotes awareness of the challenges facing people with arthritis across the community, and advocates on behalf of consumers to leaders in business, industry and government.

In addition, Arthritis Australia funds research into potential causes and possible cures as well as better ways to live with the disease.

Ease of Use Packaging

In 2009, Arthritis Australia and Arthritis New Zealand established the Ease of Use program to recognise and encourage widespread adoption of user-friendly products and packaging. Arthritis Australia sees this not only as an issue for the 6.4 million Australians living with arthritis or disability but for the one in three Australians aged 50-plus who often do not regard themselves as 'old' and struggle with packaging that is difficult to read and open.

We offer Ease of Use design, testing and evaluation services for industry and as a result of the program have developed extensive expertise in safe and user-friendly labelling and packaging. Major clients include NSW Health, Goodman Fielder, Amcor and Nestle.

NSW Health has adopted packaging accessibility standards developed under our Ease of Use program as part of its tender requirements for suppliers providing food for patients in NSW hospitals. Other state and territory health departments including Health Purchasing Victoria are considering introducing similar requirements.

The initial focus of the Ease of Use program is on food packaging, but we also have a major interest in the labelling and packaging of medications.

Introduction

Arthritis Australia welcomes the opportunity to provide feedback on the TGA draft consultation document on medicine labelling and packaging. People with arthritis are major users of both prescription and non-prescription (over the counter and complementary) medicines. For example around 60% of people with arthritis try a range of products in an effort to gain relief from the chronic pain and disability associated with their condition. 1 Consequently we welcome measures such as improved packaging and labelling that help ensure safe and quality use of medicines.

In addition to responding to questions raised in the consultation paper (see below) we would like to provide some brief comments in the following areas.

Medicine packaging

Arthritis Australia acknowledges that labelling issues for medication are of great importance and we commend the TGA for addressing medicine labelling as part of this consultation. However, we are disappointed that the consultation does not address issues surrounding medicine packaging which we consider to be of critical importance with respect to safety and compliance issues affecting the quality use of medicines.

Medicine packaging is often difficult to open, particularly for the elderly and people with reduced strength and dexterity in their hands because of arthritis. Difficult to open medicine packaging, especially child-proof packaging, is an issue that is frequently raised by people with arthritis who often need to seek assistance from others to open their medication.

Over-the-counter medicine bottles featuring the 'push and turn" and 'align and push' lids present major accessibility issues for people with arthritis. Testing of these bottles was conducted by the Georgia Tech Research Institute in the US, a world leading accessibility testing facility. The results of this testing were unfavourable with a number of design issues identified. For example the operating forces for using the products to dispense medicine were too high for users with limited strength in their hands.

Difficult to open medication packaging can create significant safety and compliance issues. We are aware for example of cases where children have required emergency treatment because they have inadvertently taken arthritis medications that a family member with arthritis has transferred into easier to use containers. That is, the child-proof packaging has led to the very result it was intended to avert.

We strongly recommend that TGA conduct a major review and user study of medicine packaging to ensure ease of use for all people including the elderly and people with arthritis.

Safety and efficacy labelling for complementary medicines.

We are also disappointed that the current consultation explicitly does not address labelling issues relating to the safety and efficacy of over the counter and complementary medicines. In our recent submission to the TGA consultation on evidence requirements to support indications for listed medicines we recommended the adoption of a traffic-light system for the classification and labelling of complementary medicines. This system would greatly assist consumers, health professionals and pharmacists to make informed decisions about the use of complementary medicines and assist in meeting the TGA's responsibilities with respect to the quality use of medicines.

An extract from our submission addressing this issue is provided in Attachment 1 for easy reference.

Response to consultation questions

1. Prominence of active ingredients on medicine labels

Arthritis Australia generally supports the recommendations in the consultation paper for increasing the prominence of information on the active ingredient/s of a medication and providing warnings for paracetamol and ibuprofen.

However we consider that the minimum font sizes specified in the consultation paper (1.5-2 mm high letters) are much too small to be legible for a large proportion of the population.

Studies examining the influence of font size on readability and comprehensibility of text have found that consumer information acquisition, especially in older people, is significantly greater for text in medium and larger font sizes and that the optimal font size is between 9-12 points. [2 3] Given the prevalence of medication use in older people, low print readability on medicine labels poses a potential health hazard.

The Australian and international standard for legibility in the legal profession is 12 point type. For example Commonwealth specifications for the Attorney-General's Department require that any legal documents filed in the High Court are 'in clear, sharp, legible and permanent type of at least 12 point size' (High Court Rules 2004.

A minimum of 12 points in a common sans serif typeface such as Univers, Arial or Helvetica is also recommended in Vision Australia's Legibility Guidelines for font choice, typeface and print size. These guidelines also suggest that text should be printed with the highest possible contrast (ideally with black text on a white background) and careful use of bold type to ensure it is no so thick that that it becomes difficult to distinguish between some characters. [4]

In addition, the European Commission's Guideline on the readability of the labelling and package leaflet of medicinal products for human use (January 2009) 5 recommends that the type size should be as large as possible to aid readers and specifies larger font sizes than those proposed by the TGA, namely a minimum of 9 points (3mm) for text in package leaflets and 7 points (2.5mm) for labelling.6

Finally, a global consumer study of people over 60 years across 23 countries found:

> *"Product packaging is often difficult to open, and labels, prices and directions in stores are hard to read. Of the study's participants, 52 percent in the 60-70 group, 58 percent in the 70-80 group, and 66 percent aged over 80 say they cannot read labels properly, even when wearing glasses or contact lenses…..mature consumers want legible labels, directions and prices in sufficiently large font sizes: Nutrition, health and supplements will all need special attention."* [7]

We strongly recommend that TGA requires larger minimum font sizes of between 9 and 12 points for labels on medicine packages: 12 point font (4.25mm) should be used on larger pack sizes (pack size total surface area of greater than 100 square centimetres) especially for warnings, directions, allergy information and active ingredients, while 9 point font could be used on smaller packs. Any proposal to adopt smaller fonts should be subject to satisfactory results from user trials of legibility and comprehension.

Examples of what 1.5mm, 3mm and 4.25mm type actually looks like

1.5 mm text

Existing requirements for Warnings, directions and active ingredients of 1.5mm/4.25 type point size on medicine packaging are unreadable for most people

3mm text

Arthritis Australia guide for TGA on the size of Warnings, directions and active ingredients for small medicine packaging (less than 100cm squared) is a minimum 3MM /8.5 point size

4.25 mm text

A guide for the TGA on the size of Warnings, directions and active ingredients for medicine packaging is a minimum 4.25MM/12 point size for regular packaging

Look-alike sound-alike names and packaging

We support these recommendations.

Standardised Information Format: the Medicine Information Box

Arthritis Australia supports the concept of providing a standardised information format for key information in the form of a Medicine Information Box. As indicated above we recommend that a minimum font size of between 9 and 12 points (depending on package size) should be used for information on medicine labels and this should apply equally to the Medicine Information Box

Small containers

The placement of relatively large amounts of information on the label can be a problem when the surface area of the product container is relatively small. Nonetheless, Arthritis Australia objects to any reduction in font size when there are space restrictions on a label, because it will increase the risk that consumers cannot read the label and therefore increase the potential for harm.

If there is not enough space on the container, then alternative methods should be used including tag or fold out labels which expand the available surface area to print information.

Dispensing label space

Arthritis Australia strongly supports the retention of the standard dispensing label size currently used in Australia of 80 x 40 mm. We do not support the proposed reduction in size to 70 x 30 mm as we consider this will create issues related to the legibility and comprehensibility of labels.

Blister packaging

We support the recommendations

Labels and Packaging Advisory Committee

Arthritis Australia strongly supports the recommendation to establish a labels and packaging advisory committee to provide advice to the TGA on labelling and packaging issues as we believe that these issues are very important to ensure the safe and quality use of medicine.

As outlined earlier, Arthritis Australia has extensive expertise in relation to packaging accessibility through its Ease of Use program and would be happy to assist TGA in this area.

Attachment 1

Extract from Arthritis Australia submission to the TGA consultation on Evidence requirements to support indications for listed medicines

Background

Use of complementary medicines is widespread in Australia and growing. Estimates are that up to two in three Australians have taken complementary medicines at some stage, with expenditure on these products over $1.3 billion in 2004.[8] People with arthritis and musculoskeletal conditions are major users of complementary medicines with around 60% of people trying a range of products in an effort to gain relief from the chronic pain and disability associated with their condition. [9]

Despite the widespread use of complementary medicines, there are a number of issues relating to the safety and efficacy of these products and the way they are regulated.

Many consumers have a false perception that complementary medicines are safer than conventional medicines because they are natural. While this may be true in many cases, some consumers are unaware that complementary medicines may carry the risk of side-effects, adverse reactions such as allergies, or interactions with conventional medications.[10] A recent review of complementary compounds taken for arthritis found that one in four of the compounds for which evidence from randomised controlled trials was available were associated with common adverse effects (both minor and serious); however in general relatively little information on safety was available. The review also found that for more than half of these compounds there was no or little evidence that they might work.[11]

In Australia, there is considerable evidence that the claims made by sponsors about their listed medicines are not always supported by evidence. Post-marketing reviews by the TGA between July 2009 and December 2010 indicate that half of the products for which evidence reviews were conducted did not have adequate evidence to substantiate the claims made about the medicines.[12] Many consumers are also unaware that complementary medicines listed on the Australian Register of Therapeutic Goods (ARTG) have not been assessed by the regulator for efficacy.[13] A recent report by the Auditor-General also found that the regulatory system for complementary medicines in Australia was largely ineffective.[14]

This situation is unacceptable because it is can mislead consumers seeking relief from a chronic condition into spending money on false hope or may expose them to poorer health outcomes as a result of safety issues associated with the listed medication or because consumers may choose ineffective listed medications instead of other therapies which are more soundly based on evidence.

Much more must be done to effectively regulate listed medicines and provide the information to consumers that they require to make informed decisions about their use of listed medicines. The current consultation document outlining more rigorous evidence requirements to support listing of medications is a welcome first step in this direction.

Evidence requirements for listed medications

Arthritis Australia fully supports the more rigorous and comprehensive approach to the requirements for evidence to support medicines listed on the ARTG, as outlined in the draft consultation document and recommends its implementation. In particular we fully support the requirement that a suitably qualified expert be required to provide a comprehensive evaluation of the evidence in support of a product's listing.

However, we consider that the requirements specified in the document would be enhanced with the following additions.

Safety and efficacy classification system

Arthritis Australia proposes the introduction of a new classification system for listed medicines that will assist in evaluating listed medicines and could provide the basis for a consumer information strategy. The proposed classification system is based on a system used by Arthritis Research UK in its recent review of complementary compounds taken for arthritis.[15]

Safety

With respect to safety, we propose that all compounds be categorised according to their safety profile by using a traffic light system. Where information is available the compound would be categorised on the assumption that it is being taken within the range of recommended doses. Compounds which are safe at the recommended doses may have serious adverse effects when taken at higher doses. The proposed categorisation is:

 Traffic light at green	Compounds with reported adverse effects which are mainly minor symptoms and infrequent. A classification of green does not mean that the compound has no reported adverse effects.
 Traffic light at amber	Compounds with reported adverse effects which occur frequently (even if they are mainly minor symptoms) or with more serious adverse effects.
 Traffic light at red	Compounds with reported serious adverse effects. Consumers should carefully consider these before deciding whether to take these medicines

Efficacy

With respect to the scientific evidence surrounding complementary medicines, we propose the use of a rating system based on the Jadad system for rating randomised control trials (RCTs).[16] This scoring system is commonly used to evaluate the quality of published RCTs in the field of complementary medicine. The Jadad scale has levels from 1 (very poor quality) to 5 (very good quality). In simplified form this rating assesses evidence as follows:

1. There is, overall, no evidence to suggest the compound works or only a little evidence which is outweighed by much stronger evidence that it does not work.
2. There is only a little evidence to suggest the compound might work. The evidence from studies in this category often come from only a single study which has reported positive results and therefore there are important doubts about whether or not it works.
3. There is some promising evidence to suggest the compound works. The evidence will be from more than one study. However there may also be some studies showing that it does

not work. Therefore there remains uncertainty as to whether compounds in this category work or not.

4. There is some consistency of evidence, which will come from more than one study, to suggest that the compound works. Although there are still doubts from the evidence it works, on balance it is more likely to be effective than not.
5. There is consistent evidence across several studies to suggest that this compound is effective.

If the RCTs were for specific indications, for example, osteoarthritis or rheumatoid arthritis, then this would be specified in the effectiveness rating. The following table illustrates how this system would work.

Therapy	Condition	Effectiveness	Safety classification
Fish oil – Omega-3	Rheumatoid Arthritis Osteoarthritis	5 1	Green Green
Thunder God Vine	Rheumatoid Arthritis	3	Red
Glucosamine sulphate	Osteoarthritis	3	Green
Glucosamine hydrochloride	Osteoarthritis	1	Green
Willow Bark	Osteoarthritis Rheumatoid Arthritis	2 1	Amber Amber

The expert preparing the expert report that a sponsor must hold to support listing of its product on the ARTG would provide an assessment of the evidence relating to the medication based on the classification system outlined above. In many cases the classifications would already exist, for example glucosamine and Omega -3, and the additional work required to classify the product would be minimal.

The TGA should list the safety and scientific evidence classification for each complementary medicine on its website and should require this information to be included on product packaging as well. Consumers, health professionals and pharmacists can then make an informed decision about a product.

Once consumers become familiar with the scoring system, it will assist them in making more informed decisions quickly and easily. An explanation of the rating system can be displayed at point of purchase.

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[1] Bishop FL, Yardley L, Lewith GT. A systematic review of beliefs involved in the use of complementary and alternative medicine. *J Health Psychol* 2007; 12:851-67

[2] Fuchs J, Heyer T, Langenhan D Hippius M 2008. Readability and comprehensibility of package inserts. *Pharm Ind* 70(5) 584-592.

[3] Wogalter MS, Vigilante WJ 2003. Effects of label format on knowledge acquisition and perceived readability by younger and older adults. *Ergonomics* 46 ($) 327-344

[4] Vision Australian Readability Guidelines http://www.visionaustralia.org/info.aspx?page=785

[5] http://ec.europa.eu/health/files/eudralex/vol-2/c/2009_01_12_readability_guideline_final_en.pdf

[6] http://www.convertunits.com/from/pt/to/Mm

[7] Walker M, Mesnard X. *What do Mature Consumers Want?* Global Business Policy Council 2011.

[8] Williamson M, Tudball J, Toms M, Garden F, Grunseit A. Information Use and Needs of Complementary Medicines User. National Prescribing Service, Sydney. December 2008

[9] Bishop FL, Yardley L, Lewith GT. A systematic review of beliefs involved in the use of complementary and alternative medicine. *J Health Psychol* 2007; 12:851-67

[10] Williamson M, Tudball J, Toms M, Garden F, Grunseit A. Information Use and Needs of Complementary Medicines User. National Prescribing Service, Sydney. December 2008

[11] Arthritis Research Campaign. Complementary and alternative medicines for the treatment of rheumatoid arthritis, osteoarthritis and fibromyalgia. Available from http://www.arthritisresearchuk.org/arthritis-information/complementary-therapies.aspx

[12] http://www.tga.gov.au/industry/cm-post-listing-compliance-reviews.htm Cited 23 May 2012

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[16] Jadad AR, Moore RA, Carroll D, et al. Assessing the quality of reports of randomized clinical trials: Is blinding necessary? Control Clin Trials 1996;17:1-12.