



strokefoundation

**TGA Labelling and Packaging Review
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To Whom It May Concern,

The National Stroke Foundation (NSF) welcomes the opportunity to respond to the TGA Medicine Labelling and Packaging Review. Stroke is a leading cause of disability and of an estimated 350,000 stroke survivors in Australia a great many rely on medication – often multiple medicines – to manage their health.

The wide-ranging and often complex effects of stroke, including cognitive impairment, paralysis, loss of vision and conditions such as Aphasia, can impact an individual's ability to safely understand their medicine requirements.

In order to assist stroke survivors to manage their medicine usage a range of issues need to be considered and we therefore welcome a review into medicine labelling and packaging and provide the following comments in relation to the proposed regulatory changes.

About the National Stroke Foundation

The National Stroke Foundation is the peak national non-for-profit organisation that focuses on reducing the impact of stroke by preventing stroke and improving treatment and support for those with stroke.

The NSF promotes evidence-based practice by developing and coordinating *the National Clinical Guidelines for Stroke Management 2010*. Significant advances in treatment over the last 20 years now means the provision of evidence-based stroke care (as outlined in the guidelines) can significantly reduce death and disability and is cost effective.

As the sole national organisation dedicated to supporting stroke survivors and carers, the NSF works to ensure that consumers receive high quality care that achieves excellent clinical outcomes and at the same time responds to the needs and experience of survivors and carers.

An overview of Stroke in Australia

Currently, an estimated 350,000 people are living after stroke in Australia (AIHW, 2010). Of those aged 16-85, 72% of stroke survivors are aged over 60, with the remainder predominantly in the 40-59 age category (AIHW, 2010). Stroke is a leading cause of death in Australia and a significant contributor to disability amongst adults.

Between 20% and 30% of stroke survivors go on to develop vascular dementia suggesting that the increase in strokes over the next decade will add between 100,000 and 150,000 new cases of vascular dementia to the Australian community (Mackowiak-Cordoliani et al, 2005).

The consequences of stroke can include paralysis, inability to speak, difficulty with memory and thinking, or problems completing everyday activities such as dressing and eating.

The impact of stroke

The impact of a stroke is profound:

- Stroke survivors are more likely to have profound limitations relating to self care, movement and communication than other people with disability (AIHW, 2010);
- Health related quality of life (HRQoL) for the majority of stroke survivors up to two years after their stroke has been rated as very poor (Sturm et al, 2004); and
- Depression is seen in approximately a third of survivors (Hackett et al, 2005)

The National Stroke Foundation welcomes the TGA Medicine Labelling and Packaging Review. Stroke survivors are frequently on a range of medications to manage their risk of further stroke, in addition to medication required for other conditions.

In addition to the fact that stroke affects mainly the ageing population, which brings with it issues related to possible declining vision and cognition, stroke leaves individuals with significant impairments which affect their ability to safely understand the medications they are taking.

Aphasia, for example, is an impairment of language and the ability to use and comprehend words. It is a common problem for many stroke survivors. Having aphasia may make it hard to:

- Talk;
- Understand what other people say;
- Read;
- Write; and
- Use numbers and do calculations.

This may impact on a stroke survivor's ability to read and understand what is written on medicines labels and to calculate dosage.

In addition, many stroke survivors are left with impairments post stroke which affect their ability to see. The damage to the brain caused by the stroke can leave many stroke survivors with significant impairments to their visual field, impacting their ability to read.

Comments on proposed regulatory changes

The NSF provides the following comments which do not address all proposed changes and questions, but rather those that are of particular significance to the stroke consumer community.

Prominence of active ingredients on medicine labels

The NSF supports the proposed recommendations and makes the following suggestions:

- Font size should be a minimum of 12 point, preferably larger (14) where the information is of particular significance, for example the ingredient name;
- Words printed over a background design should be avoided as it makes reading these words, for people with visual impairments, very difficult and in some cases impossible; and
- The overall design of the label should make use of as much white space as possible.

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

The NSF supports the intent to make medications distinct from each other. We would suggest:

- that any consumer testing include people over the age of 75 and also those with varying degrees of visual impairment, and
- that the packaging:
 - use a font size that should be a minimum of 12 point, preferably larger (14) where the information is of particular significance, for example the ingredient name;
 - avoid printing words over a background design; and
 - make use of as much white space as possible.

Dispensing label space

The NSF supports the designated space for a dispensing label on prescription medicines. Stroke survivors are frequently on multiple medications and it is critical that they have simple access to the information they need to safely take and manage their medication.

The NSF encourages consumers, as part of a self management approach, to make use of Home Medicines Reviews by pharmacists and requests a summary of medications from the pharmacists whenever a change is made in medication.

We would encourage the TGA to consider ensuring the information on the medication label, and the information provided to the consumer as a result of the Home Medicines Review, be consistent in order to decrease confusion and increase compliance

Small container labelling

The NSF comments regarding small container packaging echo those made above namely:

- Font size should be a minimum of 12 point, preferably larger (14) where the information is of particular significance, for example the ingredient name;
- Words printed over a background design should be avoided as it makes reading these words, for people with visual impairments, very difficult and in some cases impossible; and that
- The overall design of the label should make use of as much white space as possible.

We acknowledge that this is more difficult on small containers however the NSF would encourage the TGA to ensure information is able to be understood. For this outcome to be achieved on small containers the amount of information may need to be decreased ensuring an emphasis is given to critical information which can be read and understood.

Proposed establishment of a Labels and Packaging Advisory Committee

The NSF supports the establishment of a Labels and Packaging Advisory Committee. We would encourage the TGA to include consumers who have challenges associated with reading and understanding package labels – with recognition that this goes beyond just vision impairment to include conditions such as aphasia. In this way consumers will be able to assist the TGA to make decisions and changes which are more likely to have a positive impact on medicine usage. The NSF has a well developed consumer consultation process and would welcome the opportunity to assist the TGA in identifying appropriate consumers for the committee.

Conclusion

The NSF is supportive of efforts to improve regulation around labelling and packaging of medicines in Australia which will result in improved outcomes for patients. Survivors of stroke will benefit from a regulatory regime which takes into consideration the range of disabilities that can affect them.

We would encourage the TGA to adopt the recommendations that we have commented on above.

If you require any further information please contact Rebecca Smith, Government Relations Manager National Stroke Foundation on rsmith@strokefoundation.com.au.

Yours sincerely

A handwritten signature in black ink, appearing to read "Erin Lalor". The signature is written in a cursive style with a light grey rectangular background behind it.

Dr Erin Lalor
Chief Executive Officer