



Blind Citizens Australia submission: TGA Medicine Labelling and Packaging Review

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Therapeutic Goods Administration
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This submission is available in large print, audio, Braille and in electronic formats on request for access by people who are blind or vision impaired.

About Blind Citizens Australia: Who we are and why we say what we say

Blind Citizens Australia is unique in that our organisation is solely made up of and represents people who are blind or vision impaired. All of our Board of Directors and our committees are required by our Constitution to be a person who is blind or vision impaired. Many of our staff are also vision impaired. We have over 3000 members around Australia who are all people who experience blindness – whether they be a parent, professional, job seeker, volunteer or student. This is why we are best placed to comment on the specialist needs of people who are blind or vision impaired.

We are driven by our mission to achieve equity and equality by our empowerment, by promoting positive community attitudes and by striving for high quality and accessible services which meet our needs.

People who are blind or vision impaired and their access to medicine

Clear, accessible information on medication is important for all consumers. For someone who is blind or vision impaired, clear, accessible information is critical to ensure that the right medication is being taken at the right dosage and at the right time. As one of our members noted:

“It's great that this issue is being addressed. It is a daily area of risk for us oldies and anyone with blindness and low vision. There must be many premature deaths and hospitalisations which an inclusive labelling system would have saved. I think I would have been a casualty by now if it were not for my partner who is sighted. Statistically we know that a high proportion of us elderly blindies live solo”.

At present, medicine related information is largely inaccessible to people who are blind or vision impaired. It is important to note that not all people who qualify as being legally blind are completely blind – the vast majority of people who experience blindness or vision impairment may have some vision but find it difficult to independently and safely access the medication they need due to the size of printed information and/or the poor levels of access to medical information in other formats. Large print, audio, electronic information and Braille are methods used by people who are blind or vision impaired to access information.

“It always amuses me that the pharmacist has to stick on a label telling you how to take the medication regardless of the fact that I can't read it”.

In this submission, Blind Citizens Australia provides comment on the proposed reforms outlined in the TGA discussion paper. This submission also provides recommendations by Blind Citizens Australia for consideration by the TGA regarding how the accessibility of medical information for people with print disabilities can be improved.

Blind Citizens Australia would welcome an opportunity to meet and work with the TGA regarding our proposals below, specifically our proposals for Braille and tactile markings on medication packs and the development of accessible pack inserts.

These recommendations are examined in detail in the section titled “Other issues for consideration by the TGA”.

For more information on the health information needs of consumers who are blind or vision impaired, please view Blind Citizens Australia’s [Access to Health Services](#) policy.

General comment

Blind Citizens Australia supports many of the proposals that have been made throughout the TGA discussion paper. Responses are provided under each section below.

Prominence of active ingredients on medicine labels

Blind Citizens Australia, in principle, supports proposed regulatory reforms 1.1 to 1.7 including the proposal to increase the size and prominence of the name of the active ingredient and to have this placed directly below the brand name in a larger font. This may be helpful for some individuals who have usable vision who can read some standard print. There are however further considerations that Blind Citizens Australia would like to bring to the attention of the TGA in relation to these points.

1.1 We support the proposal that the active ingredients must be listed immediately below the brand name, with the first letter of the active ingredient directly below the first letter of the brand name. It is however important that sufficient ‘white space’ is provided between the brand and active ingredient/s to assist people who are blind or vision impaired to distinguish between the words presented.

1.2.3 TGA recommends that “for improved differentiation between the brand name and the active ingredient, there should be a difference in font style or letter spacing or font colour.” Blind Citizens Australia notes that the best of the three options is the use of a different font, however it is important that a sans serif font is used for both the brand name and active ingredient/s. Arial, which this submission is written in, is an example of a sans serif font. Serif fonts can pose problems for people with some visual conditions who may find it more difficult to distinguish or identify particular letters of the alphabet which can look similar in a serif font.

The use of coloured text on a light or white background can also present issues for people who are vision impaired. Light colours, red and green should be avoided. If the TGA do proceed with coloured text as the preferred option, Blind Citizens Australia recommends additional consultation with our organisation regarding colours which will provide the optimal contrast needed.

1.2.4 Blind Citizens Australia supports the proposal for use of sentence casing. Packaging should also avoid the use of italics or capital letters as this can make it difficult for people who are vision impaired to differentiate between letters.

- What is the smallest size font you consider readable?

Blind Citizens Australia maintains that the font size used on medication should be as large as possible, with necessary white space to enable individuals to be able to read the content. As an example Figure 4 includes an example of a medication box. In the top right hand corner is the paracetamol warning. While this is highlighted by a box and is placed prominently, this information would be largely inaccessible to the vast majority of people who are blind or vision impaired due to the very small font size.

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

Blind Citizens Australia supports proposed regulatory changes 3.1 to 3.3, particularly the mandatory use of colours and designs that contrast with the medicine label and packaging of existing products with similar sounding names.

The discussion paper notes that during the implementation of this change, the TGA will work with the medicines industry to develop guidelines to provide clarity about these proposed requirements. In the development of these guidelines, Blind Citizens Australia recommends that further consultation is undertaken with stakeholders, including our organisation, to ensure that optimum levels of contrast and legibility are adopted so that the information presented is clear, legible and can be read without constraint.

Standardised information format: the Medicine Information Box

Blind Citizens Australia supports the proposed regulatory changes 4.1, 4.3, 4.4, 4.5 and 4.6.

While Blind Citizens Australia supports the TGA's proposal to standardise the location of important information on the medicine box (such as the active ingredient, dosage, warnings and allergy information, directions and storage information), we are mindful that this proposal will not address the current barrier to this type of information by people who are blind or vision impaired.

Blind Citizens Australia notes the TGA's proposal that where there is insufficient room, a pack insert may also be included which contains the Medicine Information Box as a continuous table (noted in recommendations 4.4 and 4.6). The TGA also propose that alternative arrangements or formatting of information can also be supplied to the TGA for assessment and approval.

Blind Citizens Australia maintains that the proposed information must also be accessible via other means. While the discussion paper notes that pack inserts will not be considered as part of this Review, it is imperative that these inserts are provided in accessible formats for people who are blind or vision impaired. More detail about the pack inserts is included later in this submission.

Dispensing label space

Blind Citizens Australia supports a designated space for the dispensing label on prescription medications.

Blister strip labelling

Blind Citizens Australia supports the proposed regulatory changes 6.1 to 6.5, particularly the inclusion of the brand name of the medicine, the active ingredient, amount of active ingredient and expiry date which is repeated at least once every two units. Blind Citizens Australia recommends that the font used to convey this information is as large as possible.

- Identifying differences in day and night formulations and race track formulations

It can be difficult for people who are blind or vision impaired to correctly identify between day and night medications and medications which are distributed in a race track format, such as the oral contraceptive. Blind Citizens Australia recommends that the TGA give consideration to reforms which make it easier to identify the differences between medication types and recommend additional consultation outside of this review with Blind Citizens Australia. A possible option which requires further consideration and evaluation before implementation is the use of tactile markings on blister packs which differentiate between sugar pills and standard pills for the oral contraceptive and the incorporation of a tactile dot on the underside of the cells containing night time formulations for day/night tablets.

Small containers

While Blind Citizens Australia supports the proposals made in the discussion paper in principle, we reiterate our concerns that information about how to use the medication, dosage, expiry date and other key information needs to be available in other accessible formats.

The TGA paper makes a number of recommendations regarding the additional information required for ophthalmic preparations including the name of any antimicrobial preservatives and how long the preparation can be used after it has first been opened. Many people who are blind or vision impaired are required to self administer ophthalmic treatments such as eye drops and have commented that it is extremely difficult to confirm the required dosage and double check warnings about how it should be used, stored and the possible side effects of the medication. As one member noted:

“It has always seemed ludicrous to me as someone who has used eye drops since birth that the info sheet for eye drops which are used by people with problematic vision is so small and virtually inaccessible.”

If a pack insert is adopted for small containers, it is imperative that this information is also available in other formats. An improvement in information for all consumers should not isolate consumers who are blind or vision impaired.

Pack Inserts

Blind Citizens Australia, in principle, supports the recommendations that advertising material should not be permitted to be included as a separate pack insert or incorporated into an approved pack insert (8.1) and that a pack insert must be in a form separate to the packaging (ie. it cannot be printed on the inside of a carton) (8.2).

Patient information leaflets or pack inserts in medicine boxes are often only provided in very small print. Many of our members have noted that this has made it difficult to be fully across the side effects and disclaimers of the medication as the information is inaccessible. While the discussion paper notes that electronic access to information leaflets is outside the scope of this review, the accessibility of this information is a significant health barrier for people who are blind or vision impaired.

Internationally, particularly in the EU, it is mandatory that the patient information leaflet is supplied in a format that is suitable to patients who are blind or vision impaired¹. The different formats that may be requested include Braille, large print, audio formats (including cassette, audio CD and DAISY formats), CD-Roms and text files by email and delivery over the phone (audio recordings of leaflets with an ordering facility).

In terms of the proposals being considered, it is important that pack inserts duplicate the information proposed to be contained on medicine packs, particularly as medicine packs will not be accessible to the vast majority of people who are blind or vision impaired. As noted by one of our members

“There also needs to be some work done with pharmacists to provide accessible info sheets. I remember when I was given immune suppressant drugs about 4 years ago by a public hospital pharmacy they came with printed info sheets (A4 size) which at the time I couldn't read because of retinal haemorrhages. I scanned them and read them on my computer but it would have been better if the pharmacy had provided them in alternative format such as audio CD (they just need to have a disk copy of each sheet in stock in case it is required). I can remember those sheets referring to side effects and recommendations for use such as not to have milk within a couple of hours of using them or to take with food.”

Labels and packaging advisory committee

Blind Citizens Australia supports the proposed reform to form a specific expert group focusing on the quality use of medicines and labelling and packaging.

¹Medicines and Healthcare products Regulatory Agency, 'Braille on labelling and in patient information leaflets', last accessed 23/08/2012 via <http://www.mhra.gov.uk/Howweregulate/Medicines/Labelspatientinformationleafletsandpackaging/Brailleonlabellingandinpatientinformationleaflets/index.htm>

Blind Citizens Australia supports the proposal that this group include medicine users including carers, pharmacists, nurses, doctors and health care practitioners. Blind Citizens Australia recommends that the group also include representation of people with print disabilities to ensure that reforms to medicine labelling and packaging also encompass the needs of the large segment of the Australian population who currently experience difficulties in their independent access to medication.

Other issues for consideration by the TGA:

Accessibility of medical information in other formats

While we are supportive of the proposals to increase the legibility of information on medicine packets, we would encourage the TGA to consider additional reforms to improve access to medication by people with print disabilities.

In reading the discussion paper, Blind Citizens Australia is disappointed that the TGA has made no reference or recommendations for the mandatory inclusion of Braille or tactile markings on medicine packs and small containers nor any recommendations regarding accessible medical information, such as pack inserts.

There are a number of provisions within Australian and international law which support the provision of information in formats which are accessible to people with disability. The Disability Discrimination Act 1992 (Cth), Section 24 references access to goods, services and facilities². Medicines are considered as “goods” as they are made available to the public to purchase.

Health and wellbeing is also a core focus of Australia’s National Disability Strategy³, which sets out a ten year national plan to improve life for Australians with disability, their families and carers. The Strategy includes work to ensure that all health service providers have the capabilities to meet the needs of people with disability and timely, comprehensive and effective prevention and early intervention health services for people with disability.

Australia is also a signatory to the United Nations Convention on the Rights of Persons with Disabilities (UNCRPD)⁴. Article 21 of the UNCRPD references access to information and outlines that state parties (Australia is considered as a state party as a signatory to the UNCRPD) are required to

“provide information intended for the general public to persons with disabilities in accessible formats and technologies appropriate to different kinds of disabilities in a timely manner and without additional cost”.

² Commonwealth of Australia, 1992, *Disability Discrimination Act 1992* accessed via <http://www.comlaw.gov.au/Details/C2012C00110>

³ Commonwealth of Australia, 2011, *2010-2011 National Disability Strategy* accessed via http://fahcsia.gov.au/sites/default/files/documents/05_2012/national_disability_strategy_2010_2020.pdf

⁴ United Nations, *Convention on the Rights of Persons with Disabilities* accessed via <http://www.un.org/disabilities/default.asp?id=259>

Article 25 of the UNCPRD on Health references that persons with disabilities have the right to “the enjoyment of the highest attainable standard of health without discrimination on the basis of disability”.

Inclusion of Braille on medicine

Internationally, there have been significant developments in the provision of Braille on medication. In the EU, it has been mandatory in 25 member states to include Braille on all EU pharmaceutical packaging since 2005, with full compliance required by October 2010⁵. Braille is required for the name of the medicine, appropriate strength (where more than one strength is available) and the dose form (where more than one dose is available).

This directive applies to all medicinal products for human use which will be handled by patients, including complementary medicines. Other important points to note are:

- The size of the Braille used cannot be reduced to fit the size of the packaging – a standard height has been developed for pharmaceutical Braille.
- it is advisable that the Braille is placed on the front of the package however this can be placed where “white space” is available.
- The Braille must not be placed over statutory information – the placement of Braille should not impair the readability of the statutory information for sighted patients.
- Bottles that are presented with only a paper label applied to the container surface with no medicine pack are also required to comply with the Braille provision.

We refer the TGA to the British Standards Institute who have developed a standard specific for Braille labelling of medication titled BS EN 15823:2010 Packaging. Braille on the packaging of medicinal products. This specifies the requirements and provides guidance for the application of Braille to the labelling of medicinal products. More information about Braille on medication can also be obtained at the Pharmabraille website www.pharmabraille.com/.

In May 2009, the International Association of Diecutting and Diemaking (IADD) announced "Can-Am Braille"⁶, a set of guidelines and recommendations for the use of Braille on packaging in USA and Canada.

In July 2012, President Barack Obama signed into law the Food and Drug Administration Safety and Innovation Act. The Act includes provisions that “establish national best practices for retail and other pharmacies to use in providing accessible prescription drug labelling to customers with vision loss”⁷. According to the American

⁵ Pharmabraille, ‘Frequently Asked Questions’ last accessed 23/08/2012 via <http://www.pharmabraille.com/support/pharmaceutical-braille-faq.htm>

⁶ International Association of Diecutting and Diemaking, 2009, *Let your fingers do the talking: Braille on folding cartons* via http://www.iadd.org/chapterpdfs/IADD_BANA_Braille_Standards.pdf

⁷ American Foundation for the Blind, July 11 2012, ‘President Obama signs landmark accessible prescription drug label bill’ last accessed 23/08/2012 via www.afb.org/section.aspx?FolderID=1&SectionID=47&DocumentID=6078

Federation of the Blind, this includes proper dosage, the name of the medication and accompanying information about possible side effects.

In Australia, Blind Citizens Australia is aware of a few medications that our members have been prescribed which voluntarily include Braille on the medicine pack. This include Somac, a medication for reflux, with the Braille referencing the brand name and the strength of each table and Genrx which includes the brand name, dosage and a 1800 phone number to obtain a leaflet. Both members shared their appreciation that the medication had been labelled in Braille and was accessible.

Blind Citizens Australia strongly encourages the TGA to investigate the provision of Braille on medicine packaging including on small containers. We would also welcome further discussions with the TGA to further this initiative.

Extending the information available via the Australian Register for Therapeutic Goods

At present, there is an adhoc process in how people who are blind or vision impaired access critical information about medication. Some members rely on the close relationship with their local pharmacist to answer queries about medication and its side effects. While discussion with a pharmacist is important, this does not enable a person who is blind or vision impaired to have the information at hand when they need it. Blind Citizens Australia sees merit in developing a more systematic approach to access medicine related information.

A question asked of BCA members in the development of this submission was whether the development of an online database which includes information about the medication's intended use, side effects and other medicinal information would be helpful. Members who responded to our request for input noted that this would be an important development which would be very helpful.

“Yes, definitely. I often look up medications online and there are some good sites around, but often it's hard to know where to look or which sites to trust. Perhaps a couple of websites could be brailled on a card which is put with instructions inside the box or accompanying bottles.”

Blind Citizens Australia has reviewed the Australian Register for Therapeutic Goods (ARTG). The ARTG includes the product name and ingredients, sponsor and manufacturer details and whether the medicine is registered or listed. Blind Citizens Australia would like to see the ARTG extended to include downloadable patient information leaflets which are available in a Word format.

Blind Citizens Australia also recommends that the ARTG is tested for compatibility with W3C accessibility standards to ensure that the website can be used by people with disability who may use screen reading software which reads information presented on the screen audibly to the user and via other devices such as Braille notetaking devices.

With over 70% of people who are blind or vision impaired aged over 70, other mechanisms in addition to an online database should also be considered.

Many of our older members who provided input to this submission noted that a 1800 phone line would be useful, where pack inserts could be read audibly over the phone. A number of existing options could be modified including utilising existing state based medical telephone information services where nurses or a nurse practitioner can assist with inquiries or extending the scope of the 24 hour Health Advice line. The development of a database could provide a ready go-to-point for hotline staff to access pack inserts and product information which could be supplied by the manufacturer at the time of the registration of the medication with the TGA. A retroactive process for current medications would also need to be investigated.

“A 1800 number is an excellent [idea]. There are many people who do not use braille and are not computer literate so a call to a nurse/pharmacist professional who could answer questions and provide information about possible side effects of drugs would be a great asset.”

Investigating additional technological options to access medical information

Increasingly, people are turning to other forms of technology to access the information they need in a timely manner. This is no different for many people who are blind or vision impaired, particularly members who have access to and the skills to use the internet, mobile phones and other electronic devices. I devices (such as the Ipad and Iphone) and Android systems have opened up a world of information access for people who are blind or vision impaired, as these systems incorporate in-built screen reading software which reads information displayed on the screen audibly to the user. The development of I applications is a possibility which would improve access to medicinal information to a significant proportion of people in addition to people who are blind or vision impaired who are technologically savvy.

Other devices which can access print material, such as barcode scanners and reading devices, which are used by some people who are blind or vision impaired could also increase access to medical information if these were linked to pharmaceutical databases. Once again, these developments would only be beneficial to individuals who have the skills to use the technology as well as access to the technology to begin with.

Closing remarks

Blind Citizens Australia is available to provide further comment or clarification on the recommendations contained in this submission and would welcome an opportunity to meet with the Therapeutic Goods Administration to discuss our proposals further. For more information about Blind Citizens Australia, visit www.bca.org.au or contact us on (03) 9654 1400.