Consumers
Health Forum
of Australia

Submission to the Therapeutic Goods Administration Medicine Labelling and Packaging Review

August 2012

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Introduction

The Consumers Health Forum (CHF) of Australia welcomes the opportunity to respond to the *Therapeutic Goods Administration* (TGA) *Medicine Labelling and Packaging Review Consultation Paper* (the Consultation Paper).

CHF is the national peak body representing the interests of Australian healthcare consumers. CHF works to achieve safe, quality, timely healthcare for all Australians, supported by accessible health information and systems.

Labels and packaging are intended to be the first line of communication for medicine users and make an important contribution to the safe and effective use of medicines. Several studies indicate that poor packaging and labelling of medicines contributes to errors in medicine dispensing and consumer use, which underlines the importance of achieving a best-practice approach to labelling and packaging.[1]

With the trend towards greater self-medication likely to continue, and increasing rates of chronic disease requiring the use of multiple medications, it is important that medicine users can understand the information contained on medicine labelling and packaging, and that there is consistency with what they can expect to find on labelling and packaging.

The Consultation Paper highlights some key issues of concern for consumers regarding labelling and packaging and proposes some welcome options for regulatory reform to address those concerns.

CHF has consulted extensively on labelling and packaging. Recent consultations include a national consumer workshop on best practice in the packaging and labelling of medicines (2010) (workshop recommendations at Attachment A), and an online survey addressing issues raised in the TGA Medicine Labelling and Packaging Review (2012). This submission is informed by these and other CHF consultations.

CHF's work has highlighted a number of key issues regarding medicine labelling and packaging which are outside the scope of the TGA's consultation. While CHF appreciates that the focus of the TGA's consultation is predominantly on the appearance of medicine labelling and packaging, we stress the importance of addressing issues such as the lack of public awareness surrounding the regulatory process for therapeutic goods, and evidentiary requirements for AUST L and AUST R products. CHF would welcome the opportunity to contribute to future TGA reviews in these areas.

[1] In 2010, CHF undertook a review of the evidence relating to the role of packaging and labelling in the quality use of medicines. The evidence was presented in a Consumer Information and Discussion Paper, available at https://www.chf.org.au/pdfs/rep/rep-649-CQUMDiscussionPaper-oct10.pdf.

Comments on the TGA Medicine Labelling and Packaging Consultation Paper

Overall, CHF supports the majority of the proposed regulatory reforms. Further detail is provided below under each of the issues that pose a risk to consumer safety, as outlined in the Consultation Paper. CHF notes that these proposals are supported by robust evidence, recognition of best-practice principles established in previous work on labelling and packaging, and comprehensive consumer testing.

Prominence of active ingredients on medicine labels

CHF's consumer consultations on this issue have indicated strong support for the active ingredient to be more prominent than the brand name on prescription medicine labels. Increasing the prominence of the active ingredient on medicine packaging has the potential to enhance quality use of medicines (QUM) as it may contribute to reducing the risk of consumers taking multiple doses of the same active ingredient.

Consumers who participated in CHF's 2010 consultation on packaging and labelling recommended that the active ingredient should have greater prominence than the brand name. While this would be CHF's preferred option, equal prominence is an acceptable minimum.

CHF supports the TGA's proposed regulatory changes to increase the prominence of the active ingredient on medicine packaging and labelling.

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

The issues of look-alike and sound-alike (LASA) names and look-alike packaging and branding ('umbrella' branding) were discussed extensively during CHF's consultations in 2010. LASA medicine names pose a risk to consumers if incorrectly dispensed by a pharmacist or health professional, or incorrectly self-selected. Look-alike branding poses a risk to consumers who have come to expect that a medicine will contain a particular active ingredient and mistakenly use a product with the same brand name. It also poses a risk when a brand name is extended to a product designed to treat different conditions; for example, when the same brand name is used for products with the same active ingredient but designed to treat different conditions (for example, pain medications with separate products for headache, joint pain etc). With the trend toward self-medication set to continue, look-alike and umbrella branding particularly poses a risk to consumers who do not check the active ingredient. The proposed regulatory changes that aim to increase the prominence of the active ingredient, discussed above, will be beneficial in this regard.

Consumers participating in CHF's consultations made a number of recommendations addressing the issues associated with LASA names and umbrella branding. These included:

- Name testing for LASA medicines involving consumers
- Displaying the active ingredient with equal or greater size and prominence as the brand name
- Clearly displaying the information relating to the quantity of active ingredient per dose or unit
- Printing the name or names of active ingredients on the ends of the boxes.

CHF supports the TGA's proposed regulatory changes to reduce the risk of consumer confusion and medication errors resulting from look-alike sound alike names, look-alike packaging and look-alike branding.

Standardised Information Format: the Medicine Information Box

The TGA's Consultation Paper proposes the introduction of a medicine information box, which would assist consumers to quickly locate the information they need and interpret that information easily, enabling them to make effective decisions about their medications. This would be a major improvement, as there is currently no requirement for consistent placement and presentation of key medicine information that consumers need to make informed choices about their medicine use. Standardised information may also help consumers to determine whether a medicine is suitable for them and compare different brands.

CHF notes the importance of consumer consultation on the mandatory headings (currently proposed to be *Active ingredient*, *Uses*, *Warnings and allergy information*, *Directions* and *Storage information*); the order in which information should be presented; and the format and design of the Medicine Information Box.

CHF supports the TGA's proposed regulatory changes to introduce a standardised Medicine Information Box.

Dispensing label space

Important information on medicine packaging can be covered by dispensing labels, such as dosage instructions, instructions for appropriate storage or additional warnings. One of the key recommendations from CHF's 2010 consultation was:

> *Where possible, packs should include space for the placement of the dispensing label. It is recommended that this should be a blank white space in which there is no text of any kind, to aid legibility of the dispensing label.*

Without access to this information, there is a risk that consumers may not use the medicine appropriately, contributing to adverse events, or the desired health benefit not being achieved. CHF does however acknowledge that this is not possible in some instances where there is insufficient space on the packaging to include a space for a dispensing label, for example a container for eye drops. In these instances, a designated space on the container where dispensers can affix an edge of the label would be optimal.

CHF supports the TGA's proposed regulatory changes regarding the space provided for dispensing labels.

Blister strip labelling

The primary concern regarding blister strip labelling is that consumers often store blister strips away from their outer wrapping or packaging that contains the critical information related to the medicine's use. The blister strip itself often does not include all the information necessary to support QUM. Without this information, the medicine may not be taken in accordance with the dosage instructions.

Regarding proposed reform 6.5, '*Blister strips that have a "race track format" must include the trade name, the active ingredient(s) and their amount(s), batch number and expiry date in a single location*', CHF recommends that the information on blister strips be located in a location that, as much as possible, will be unaffected by the breaking open of the containers housing the individual units of medication.

CHF supports the TGA's proposed regulatory changes regarding the presentation of key information on blister packaging.

Small containers

Medicines supplied in small containers have obvious restrictions on the space available to display key information. As a result of these size restrictions, it is not possible to provide consumers and health care practitioners with all the information they need to support QUM on the packaging.

Pack inserts and primary packaging compensate for the paucity of space on small containers; however, they are only effective if the insert or primary packaging is not discarded and is kept with the medicine. Therefore, it is critical that the small container displays the most important information needed by consumers or health care practitioners to support QUM.

CHF supports the TGA's proposed regulatory changes regarding the presentation of information on small packages, particularly information critical to ensuring the safe use or administration of the medication.

Pack inserts

CHF strongly supports the view that pack inserts should only contain information that supports consumers to use the medicines appropriately and safely. If other information, such as an advertisement, is included as an insert, consumers may perceive other information contained within the pack as non-essential and discard it with the advertisement. Furthermore, information critical to the safe use of the medicine should not be printed on the inside of primary packaging, as consumers: (i) may not be aware of its location and discard the packaging before reading this information, and/or (ii) may be discouraged from reading the information given as they would need to dismantle the packaging to do so.

CHF supports the TGA's proposed regulatory changes that would prevent advertising material from being included as a pack insert, and prevent pack insert information from being printed on the inside of a carton.

Labels and packaging advisory committee

CHF welcomes the TGA's acknowledgement of the need to consult consumers and other experts with knowledge of best-practice in medicines labelling and packaging. Establishing a panel with a broad membership, comprising people who represent medicine users (including carers), community and hospital pharmacists, nurses, doctors, other healthcare practitioners and the pharmaceutical industry, will contribute to the effective implementation of regulatory reforms in this area.

CHF argues that this committee should include several consumer representatives, to ensure that the implementation of these reforms takes into account the experience of people who will be affected by them.

CHF supports the establishment of a Labels and Packaging Advisory Committee to advise on the regulatory reforms proposed in the Consultation Paper.

Conclusion

CHF strongly supports the TGA's proposed regulatory reforms to improve medicines packaging and labelling. We note that existing best-practice and evidence regarding labelling and packaging have been taken into account in the development of the proposed regulatory reforms.

While CHF is pleased that the TGA's proposed regulatory reforms address many of the labelling and packaging issues of concern to consumers, CHF stresses that improving public awareness of these proposed reforms, as well as the transparency of the TGA's regulatory process more generally, will be critical to maximising the impact of these reforms.

CHF looks forward to the outcomes of the TGA Packaging and Labelling Review. We would welcome the opportunity to contribute to future TGA reviews relating to medicines safety.

Recommendations from CHF National Consumer Workshop, December 2010

(Report published January 2011)[2]

1. The full name of the medicine should appear on at least three non-opposing faces of the pack to aid accurate identification of the drug.

2. Where the common name appears after the brand name, it should be given due prominence. Generally, this will be determined by the relative size of the text, but other factors may be relevant, such as colour of text and the font used.

3. The critical information, such as 'directions for use,' should appear in as large a font as possible to maximise legibility, on at least one face of the presentation. It should not be broken up or separated by non-critical information.

4. Adoption of innovative pack design incorporating the use of colours or symbols to help identify medicine and its intended use should be encouraged.

5. Where possible, packs should include space for the placement of the dispensing label. It is recommended that this should be a blank white space in which there is no text of any kind, to aid legibility of the dispensing label.

6. Where possible, positive statements should appear on medicines labelling to avoid ambiguity of the message.

7. Undertaking a user test to ensure the maximum clarity of the critical information is desirable and recognised as best practice.

8. Colour for the text and the font style on blister packs should be chosen carefully, as the legibility of the text on the foil is already impaired.

9. The active ingredient should be displayed in equal size and prominence as the brand name.

10. Information relating to the *quantity* of active ingredient per dose or unit must be displayed clearly on the packaging.

[2] Full report is available at https://www.chf.org.au/pdfs/rep/rep-689-PackagingandLabellingReport-Jan11.pdf.

Consumers Health Forum of Australia

The Consumers Health Forum of Australia (CHF) is the national peak body representing the interests of Australian healthcare consumers. CHF works to achieve safe, quality, timely healthcare for all Australians, supported by accessible health information and systems.

CHF does this by:

1. advocating for appropriate and equitable healthcare
2. undertaking consumer-based research and developing a strong consumer knowledge base
3. identifying key issues in safety and quality of health services for consumers
4. raising the health literacy of consumers, health professionals and stakeholders
5. providing a strong national voice for health consumers and supporting consumer participation in health policy and program decision making

CHF values:

- our members' knowledge, experience and involvement
- development of an integrated healthcare system that values the consumer experience
- prevention and early intervention
- collaborative integrated healthcare
- working in partnership

CHF member organisations reach thousands of Australian health consumers across a wide range of health interests and health system experiences. CHF policy is developed through consultation with members, ensuring that CHF maintains a broad, representative, health consumer perspective.

CHF is committed to being an active advocate in the ongoing development of Australian health policy and practice.

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