



# Medicines labelling

*Daniel Lalor, Project manager, Medication Safety, Clinical Excellence Commission, Sydney*

## Summary

**The design and content of labels on medicines can have a significant impact on the quality and safety of medicines use. Labels must clearly identify a particular product and provide sufficient information to allow people to make safe and informed decisions about its use. Some advances have been made in the regulation of medicines labelling in Australia, however problems related to poorly designed labels and packaging still exist. Improving labelling by applying knowledge from other fields can support the quality use of medicines.**

Key words: drug information, drug regulation.

*(Aust Prescr 2011;34:136–8)*

## Introduction

From their most basic function of identifying a product, through to providing information about its use, medicines labels are crucial to the safe and effective use of prescription and non-prescription medicines. Medicines can only provide optimal patient outcomes if used as intended. If the end user is unable to identify a product or to understand the instructions for its use, the effort made in developing and manufacturing it, and in correct diagnosis and appropriate prescription of evidence-based treatment, is in vain. Much is known about which information is important and how it should be presented on the label in order to maximise its effectiveness. The challenge is for regulators, researchers, health professionals and the pharmaceutical industry to work together to ensure medicines labels support the quality use of medicines and prevent harm to patients.

## Current regulatory requirements

The content of medicines labels is dictated by the Therapeutic Goods Administration (TGA) through its labelling order, Therapeutic Goods Order 69 (TGO 69)<sup>1</sup> and its amendments, as well as other legislation such as the *Competition and Consumer Act 2010*. These documents set minimum standards to which a product sponsor must adhere when developing a product label. By dictating that such information as the medicine's name, batch and expiry date, dose, quantity and form are present on the label, the TGA aims to ensure that the information required

to facilitate the quality use of medicines is included. TGO 69 also specifies standards such as the minimum height of text and warning statements that must be included for various medicines. However, the way in which this information is presented, including prominence or position of key information, is not specified and this can have a considerable impact on the utility of the label.

The TGA recognises the limitations of TGO 69 and has produced companion guidance documents such as 'Best practice guideline on prescription medicine labelling'.<sup>2</sup> The TGA also requires adherence to industry codes of practice such as those related to the labelling of non-prescription medicines.<sup>3</sup>

## Product confusion

The primary role of a label is to ensure that the medicine is clearly and easily identifiable by health professionals and consumers. Confusion between products that have similar names, labels or packaging is acknowledged as a major cause of error by health professionals supplying medicines to patients.<sup>4</sup> This confusion can happen in any part of the medicines management pathway and is a significant risk to patient safety in hospitals, managed care facilities and in the community. These errors often result in the patient receiving the wrong medicine, or the wrong strength of the intended medicine. The patient may suffer from omission of the intended therapy or from the adverse effects of the unintended therapy. Depending on the medicines involved, these outcomes can range from minor to catastrophic.<sup>5,6</sup>

Such problems have recently been highlighted with Coversyl (perindopril) and Coumadin (warfarin) products. Similarities in the labelling of these two products have resulted in a number of significant errors where patients have been unintentionally exposed to warfarin. The risk posed by the similarity between these packages has been significant enough to bring about a change to the labelling and packaging of Coversyl.<sup>7</sup>

This particular example also highlights risks associated with products that have similar looking or sounding names. Pre-market product assessment should be used as an opportunity to identify potentially similar and confusable medicine names. Where similarity is seen to be an acceptable risk and names are approved, proposed product labelling should be given additional scrutiny to ensure it reduces, rather than compounds, the risk of confusion.

## Identifying the active ingredient

The design of medicines labels impacts on the consumer's ability to identify their medicines. With the increasing use of generic medicines and patients switching between multiple brands of the same medicine<sup>8</sup> there is increased potential for patients to be confused about their therapy and inadvertently take multiple products with the same active ingredient.<sup>9</sup> This is particularly important considering the medicine's generic name is typically far less prominent and in a much smaller font size than the brand name on the product label. Consumer groups strongly advocate for greater prominence of the generic name on product labelling as a mechanism to facilitate product identification and reduce the opportunity for error.<sup>10</sup>

## Understanding instructions

Research into the effectiveness of labels shows that people have difficulty in both finding and interpreting the information on the labels of over-the-counter<sup>11,12</sup> and prescription medicines.<sup>13</sup> Manufacturers and healthcare practitioners may both provide information that is not easily understood by consumers. Much of the information required by TGO 69, such as warning statements, is often disregarded or not well understood by consumers.<sup>14</sup> Language that is commonly used by doctors and pharmacists to provide instruction on prescription medicines use is often misinterpreted.<sup>15</sup> Statements such as 'take two tablets twice daily' are only correctly interpreted by 71% of consumers with adequate literacy skills and by as few as 33% of consumers with literacy problems.<sup>15</sup> These problems can be partially overcome through use of explicit instructions such as 'take two tablets in the morning and take two tablets in the evening'. Ambiguous and unclear instructions such as 'use as directed' are not adequate and should never be used.

## Developing better labels

Introducing outcomes-based standards for the labelling of non-prescription medicines in Australia has been an advancement for the quality use of medicines.<sup>3</sup> This outcomes-based approach to regulation does not dictate label content, appearance or design, but rather outlines what information a consumer must be able to readily and easily extract from the label. Outcomes-based standards are governed by an industry code of practice for non-prescription medicines. These standards are used in addition to the minimum standards set by the TGA and dictate that all labelling of non-prescription medicines must enable consumers to:

- locate and read the product name (including the ingredients)
- locate and read the quantity contained within the pack
- identify what the product is used for and the circumstances under which it should and should not be used.

By applying sound design principles to the layout and composition of medicines labelling, their usability has been

considerably improved.<sup>16</sup> Various design techniques, such as the use of particular fonts,<sup>14</sup> judicious application of colour<sup>17</sup> and the layout of information,<sup>18</sup> can also be used to produce labels that are more easily read and identified. These principles can be equally applied to both manufacturers' labels and those produced by healthcare professionals. The National Patient Safety Agency, in collaboration with the Helen Hamlyn Centre of the Royal College of Art in the United Kingdom, has produced a series of guides to the construction of medicines labelling and packaging.<sup>19-21</sup> These guides apply human factor principles, and information and graphic design principles to provide advice to the industry and healthcare professionals.

A typographic technique known as 'tall man lettering' has also been recommended as a tool for highlighting the differences in similar names (for example fluOXETine and fluVOXAMine).<sup>22</sup> Presenting similar drug names in a novel format may act as a warning about the risk of confusion associated with these products and help prevent product selection errors by health professionals.<sup>22,23</sup> Tall man lettering was recommended by the Food and Drug Administration in the USA for 16 products with confusable names.

## Conclusion

The labelling and packaging of medicines can have a considerable impact on their use. Labels must facilitate ready identification of medicines by health professionals and patients alike. This must include easy identification of the active ingredient. Labels, whether produced by the manufacturer or applied by health professionals, must give patients enough information to use the medicine correctly and must be constructed in such a way as to provide easy access to this information. Knowledge from the fields of graphic design and human factors and ergonomics can be used to assist in developing labels and packaging that are distinct and easily identifiable, reducing the risks associated with product confusion and product selection errors. Simple measures, such as increasing the prominence of the generic name and standardising its position on the label, may also improve patient safety by reducing the risks of inadvertent duplication of therapy.

Application of sound information design principles can significantly improve the effectiveness of the label. Researchers, health professionals, manufacturers and the TGA must work together to increase the application of these principles to enhance the quality use of medicines.

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### Further reading

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*Mr Lalor has received unconditional grants from Roche, DBL and Amgen, all administered through independent third parties.*

## Patient stories about labelling

For examples of consumer experiences with medicines labelling, see this article at [www.australianprescriber.com](http://www.australianprescriber.com) in Vol. 34 No. 5

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