



Submission to the TGA Medicine Labelling and Packaging Review

RE: consultation paper version 1.0 May 2012

Pharmaceutical Defence Limited (PDL)

PDL is the oldest and largest national pharmacy organisation in Australia. It arranges professional Indemnity Insurance for approximately 95% of all pharmacists, making PDL a key stakeholder in the pharmaceutical industry. Our membership includes pharmacists who practice in community, hospital, academia, industry, military and government settings.

PDL members are strongly advised to report all incidents as it is in the best interests of the patients and the pharmacist. PDL collects, collates and reviews all incidents reported by members as part of a risk management strategy.

Further information about PDL may be found on the PDL website:

<http://www.pdl.org.au>

Summary of Recommendations

1. PDL supports the concept of improving the prominence and standardising the location of active ingredients on medicine labels.
2. PDL supports the requirement that sponsors will be required to submit evidence of risk assessment (*re look alike sound alike*)
3. PDL supports a designated space for the dispensing label on prescription medicines consistent with international best practice
4. PDL strongly supports a proposed labelling and packaging committee

Proposed regulatory changes and Recommendations:

1. Prominence of active ingredients on medicine labels

Patients are often supplied different brands in different health care settings, e.g. hospitals, age care facilities and different pharmacies. Health practitioners are similarly required to handle a multitude of brands that may change over a period of time within their own area of practice. PDL supports the concept of improving the prominence and standardising the location of the active ingredient on the medicine main label, as a risk management strategy. Equal prominence will

- allow consumers to see the active ingredients
- remind health professional of the active ingredients contained in the product
- assist patients in identifying generics products

PDL strongly supports the concept of using colours in the packaging design, as a means of differentiating different strengths within a product range and between different products. We ask that any proposed regulatory changes (item 1.2.3) do not impede on the effectiveness of using colour as a risk management strategy.

2. Look-alike and Sound-alike medicine brand names.

PDL has worked co-operatively with many sponsors, providing advice and feedback on labelling and packaging issues. As well as the risk strategies outlined in the proposed regulatory changes, PDL would recommend consultation with health practitioners, and in particular pharmacists, as an important part of the process. Everyday, across Australia, hundreds of thousands of healthcare professionals procure, handle and administer medicines. They are often delivered in complex, high-pressure environments involving many practitioners. The impact of any labelling and packing issues would most likely be experienced and understood by these practitioners.

Many products have in the past been identified as having an increased risk due their similar appearance or similar name. Several examples of ARTG-listed medicines that continue to pose a risk have been included in the TGA consultation paper. PDL would like to seek clarity as to the process once a product has been identified as having a significant increased risk.

3. Dispensing label space

Allocating a dispensing label space will provide pharmacists with a predetermined area to apply a dispensing label without covering up other useful and sometimes vital information. This would include the barcode.

Arguably, the introduction of barcode scanning in dispensing has been the most significant industry wide initiative to reduce the likelihood of errors. Barcodes have improved the accuracy of the supply chain and are an important feature of any risk management strategy.

Evolving barcode technology (2 dimensional codes etc) will allow the capture of significantly more information. This may include batch numbers and expiry dates. This feature will assist with identifying out of date products or products subject to a recall. PDL suggests that any regulatory changes made do not impede the application of evolving technologies.

4. Labelling and packaging advisory committee

A significant part of PDL's membership is made up of community pharmacists. PDL provides initial advice to members when an incident occurs and has intimate knowledge of many of the circumstances surrounding these incidents. It is our belief that while much information is available on incidents occurring in hospital, information on incidents occurring in the primary health care area is very poor by comparison. PDL may be able to provide additional insight in these areas.

PDL welcomes this opportunity to provide a submission to the TGA and would be happy to work with the TGA and other stakeholders to improve the quality of medication labelling and packaging in Australia.

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