MEDICINES Australia

BETTER HEALTH THROUGH RESEARCH AND INNOVATION

Medicines Australia Submission To The TGA Medicines Labelling and Packaging review, Consultation Paper

August 2012

The Therapeutic Goods Administration (TGA) is responsible for administering the *Therapeutic Goods Act 1989 (The Act)*, with the principle aim of assessing products making a therapeutic claim for suitability for the Australian market. In the case of prescription medicines, the TGA evaluates the quality, safety and efficacy of the product against the therapeutic claim.

Medicines, particularly prescription medicines, are highly regulated. *The Ac*t and the associated *Therapeutic Goods Regulations 1990 (the Regulations)* and *Therapeutic Goods Orders* (*TGOs*) outline requirements medicines must meet to enable registration or listing on the Australian Register of Therapeutic Goods (*ARTG*). TGOs are periodically updated or revised over time to reflect technological and process advances, as well as to harmonise with international best practice.

Executive Summary

Medicines Australia is the peak body representing the research-based medicines industry in Australia, bringing new medicines and vaccines to the Australian market. It represents as much as 85% of the prescription medicines market, by value. Medicines Australia principally represents producers of innovative prescription medicines, although a significant proportion of Medicines Australia members also produce generic prescription medicines, over the counter medicines, complementary and consumer care products and medical devices.

Medicines Australia affirms its support for appropriate measures to enhance Quality Use of Medicines and medicines safety; particularly those also promoting harmonisation with global best practice.

Medicines Australia is concerned that the *TGA Medicine Labelling and Packaging Review Document* released for public consultation in May 2012 does not reflect global best practice and has not been developed in a manner supporting the principles of the National Medicines Policy objectives for Quality Use of Medicines or a responsible and viable medicines industry.

A series of stakeholder discussions and consumer calls for a review of medicines labelling resulted in a multi-stakeholder roundtable in May 2011. They proposed a packaging and labelling review to be undertaken by the TGA with proposals developed from broad consultation. An external reference group (ERG) was established to assist the review.

During the subsequent meeting of the ERG (the ERG met only once face to face), all sectors of the medicines industry highlighted three critical elements to the review:

1. An evidence-based approach to categorise the causes of medication errors that may be attributable to packaging and labelling and determine appropriate remedial measures
2. Consideration of the extent that medication errors can be reduced by packaging and labelling standards and mechanisms to measure the impact of packaging changes on frequency of medication errors
3. Consideration of the impact of regulatory changes on industry from a cost and viability perspective; including harmonisation with international best practice as a preferred option to ensure proposals are implementable

The review appears to have disregarded these essential concerns. The recommendations made, demonstrate limited understanding or examination of the impact of the proposals on either the causes or prevalence of medication errors related to packaging and labelling. Neither does the paper consider the regulatory burden of creating unique Australian requirements on either the cost or viability of maintaining access to products in the Australian environment.

Whilst the intent of the document is to provide recommendations on regulatory changes to packaging and labelling requirements for medicines, there is little (or no) evidence presented to support the notion that the changes proposed will result in either a change in behaviour or in the extent of medication errors currently being experienced.

Additionally, although some of the proposals may be feasible to implement in some cases, it is clear from industry responses that the proposals cannot be implemented uniformly across products. Developing a mandatory regulatory standard that cannot be applied uniformly will

create greater inconsistency of labelling, which will intensify confusion for users, as well as potentially causing non-compliance by industry and requirements for regulatory exemptions.

Medicines Australia's submission will provide a general overview of the regulatory recommendations being proposed and highlight some identified concerns. It will further examine the complexities of the ability of the industry to comply with some specific recommendations in the context of consistency with international best practice and provide a recommendation for further work.

Recommendations

Medicines Australia recommends that the mandatory standards are ***not*** implemented as they are currently proposed within this consultation document.

Medicines Australia recommends additional work is conducted in partnership with the TGA, industry and other stakeholders to establish an evidence-based and harmonised approach to determining appropriate and valuable labelling reforms.

Medicines Australia recommends the TGA consider development of a comprehensive best practice guidance document for packaging design (similar to design guidelines developed by the United Kingdom's, *National Patient Safety Agency*), to provide up to date, evidence-based approach to promoting best practice. This may be done in partnership with the Industry and the Australian Commission for Safety and Quality of Health Care (ACSQHC).

General overview of the regulatory approach

The regulatory approach adopted by the TGA in seeking labelling and packaging reform has been called for by numerous stakeholders who attribute medication errors to manufacturers packaging and labelling practices.

However, the current review falls short of providing achievable regulatory solutions, as the standards cannot be applied uniformly or consistently across products. Additionally it does not demonstrate adequate consideration of the multi-factorial nature of medication errors. Causes of medication errors may arise from a number of factors between the manufacturer and the patient; from treatment selection, through dispensing selection, to patient administration. The manufacturers' packaging and labelling standard is only one component designed to address varying needs across a diversity of users.

The consultation is further complicated by conflating the review of *prescription medicines* labels with the review of *non-prescription medicines*. This demonstrates insufficient regard for the complexity of the issues being examined and diminishes the magnitude of the distinction between the requirements for medicines selected under close medical supervision versus those relying on self selection; and the wholly different needs for labelling evidence and information delivery.

Moreover, the proposals are made in a sparse document, deficient in evidence and detail, coupled with a relatively short response time. This demonstrates limited regard for the complexity of packaging and labelling manufacture and the impact of the recommendations on the industry. Additionally, many proposed recommendations are incongruous, both within the document and compared to international standards and the onerous State requirements have not been considered

When reviewing mandatory requirements for medication packaging and labelling, it is critical to establish the evidence base clearly identifying aspects of a manufacturer's package or label that may contribute to medication error; and further to demonstrate how packaging and labelling reforms will make any difference to their incidence. There has been insufficient time to locate or collate evidence on these matters; however a recent literature review was conducted by the Medicines Partnership of Australia and can be provided.

Nevertheless, the paper does highlight the need for a comprehensive multi-stakeholder approach to reviewing standards of this type. Therefore, Medicines Australia urges further collaboration and consultation on this issue to ensure an appropriate agreed approach.

Medicines Australia remains committed to Quality Use of Medicines and a harmonised approach to regulatory best practice. Industry is keen to work with the TGA to create a positive regulatory environment supporting the principles and objectives of the National Medicines Policy.

Medicines Australia believes there is a considerable amount of work still to be done to reach appropriate guidance on packaging and labelling design for prescription medicines. There are diverging opinions on the feasibility of the recommendations across the sector and the diversity of products. Implementation of the recommendations in this consultation paper, without appropriate industry collaborations will be unlikely to resolve the concerns of broader stakeholder groups and will impose unreasonable regulatory burden on companies, with insufficient evidence of positive impact on medication error rates.

Specific recommendations

Prominence of active ingredients on medicine labels

Medicines Australia agrees that the active ingredient name should be prominent and easy to locate on a product label. The prominence of the active ingredient name is an important factor in product identification and assists in correct product selection and administration.

However, the *definition of prominence* is not clear from the consultation paper and should consider much broader parameters than font size as suggested by the TGA. Currently, Industry has divided opinions on relative merits of font size versus other mechanisms to improve prominence of brand and active ingredient names. More detailed examination of this issue is required to define terms and agree to a regulatory approach.

Recommendations should also consider the amount of other information included on the label and how it is presented in context of brand name and active ingredient prominence requirements. Increasing size and quantity of information may increase cluttering of information or may lead to changes in packaging size with resultant unreasonable manufacturing and regulatory implementation costs.

The TGA consultation paper provides limited guidance on requirements for difference in *font style, letter spacing or font colour* demonstrating there is a large piece of missing work. Detailed advice is needed on how best to achieve a harmonised and measurable regulatory standard.

No evidence is presented demonstrating that mandating font size of the active ingredient (to 100% of the brand name) will reduce medication error. Nor is evidence presented supporting contentions that beginning the active ingredient name with a capital letter and

writing the rest with lower case letter, will impact prominence and understanding or reduce error. Similarly, there is no evidence presented to suggest that writing the brand name and the active ingredient in *either* different font *or* with different letter spacing *or* in a different colour is the most effective way to increase prominence of the active ingredient name, nor guidance on how these selections should be made. Similarity between active ingredient names and salts can also be confusing and may further impede quality and safe use of medicines when made more prominent.

Medicines Australia contends the recommendations for increasing *prominence* must include clear evidence based assessment supporting the proposals. Clear guidance on the elements of font size, style, location, colour, and other tools of differentiation, with further guidance on how to make appropriate selections and assess the impact of those selections, must be provided. Adoption of agreed International guidance documents may facilitate this.

Medicines Australia asserts the issue of prominence is broader than font size and that naming prominence is only one of many contributing factors leading to product confusion and medication error. Industry is keen to work with the TGA to determine labelling changes proposed by the TGA will be effective in achieving objectives.

The cost of changing product labelling is a substantial burden to industry and it is vital any changes imposed demonstrate an impact on the desired outcome.

Medicines Australia would be pleased to work with the TGA and other stakeholders to achieve improved prominence of active ingredients on product labelling and to define appropriate outcome measures.

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

Medicines Australia agrees that ability to clearly identify medicines is an important contributing factor in determining whether a patient receives the intended medication. Medicines Australia also agrees it is vital patients receive their intended medication.

There are some commonly identified relationships between look-alike/sound-alike (LASA) names in relation to selection errors (by the prescriber, dispenser or end user). However, it is well documented that a number of other factors influence whether or not a patient receives the correct medication, aside from look-alike sound-alike names, look-alike packaging or look-alike medicine branding.

These may be product related or environmentally influenced. Some product related issues have been highlighted in the TGA consultation document such as prominence of active ingredient, standardisation of data presentation, dispensing labels potentially covering important information, product placement on pharmacy shelves and challenges of small labels, to name just a few. Environmental factors influencing supply of correct medication include the role played by the prescribing doctor and dispensing pharmacist as well as factors specific to each patient and their situation.

The specific proposal, for example, *"if a proposed medicine brand name differs from one already on the ARTG by 3 letters or less, then product labels should be different colours"* does not seem to have examined the long term impact or feasibility of this proposal. Nor is it clear why the TGA recommend selection of 3 letters versus other compilations. It would be

useful to understand how these recommendations were reached and align with international standards.

It would also be pertinent to establish whether mandatory standards are appropriate or whether development of better and more comprehensive (or adoption of existing international) design guidelines should be considered.

Product Brand name is a valuable company asset which cannot be changed quickly or without significant cost. Similarly, changes to product packaging are expensive and time consuming. Medicines Australia contends changes diminishing the value of product branding or packaging must be supported by evidence and robust assessment of regulatory cost against measurable benefits.

Medicines Australia members were generally supportive of a risk assessment approach for proposed labelling and packaging for a new medicine. However, clarity is required around the framework and impact of this course of action on the current TGA evaluation process, timelines and decision making.

Standardised Information in a Medicines Information Box

Medicines Australia agrees the importance of providing clear, useful information on product labels for non-prescription and complementary medicines.

However, Medicines Australia reasserts that proposals for labelling changes should be supported by reasonable evidence demonstrating measurable benefits. Additionally, measures should be designed in the entirety of the system; from manufacturing standards through to dispensing practice and user education.

Dispensing label

Medicines Australia members support in principle a designated space on product packaging for a dispensing label, where space and/or pack size permits. The space should be consistent with international best practice (70 x 30mm) to ensure global labelling templates for label generation can be utilised.

The standard size of the dispensing label used in pharmacies in Australia should also be selected to fit within this space. If the desired outcome of the review is to ensure Australian pharmacy dispensing labels do not obscure manufacturers' information then there needs to be ongoing consultation with the pharmacy sector to introduce labels fitting within the designated dispensing label space.

The cost to the manufacturer in imposing a larger dispensing label space requirement unique to Australian products must be compared to the potentially simple and cost-effective solution of recommending alternative pharmacy dispensing label selection.

Blister strip packaging

Medicines Australia member companies have expressed concerns regarding mandating a requirement to print the brand name, active ingredient, strength, batch number and expiry date once for every two units for all blister strip packs, including where the units are not segmented.

Medicines Australia supports recommendations that will avoid medication error and there may be value in repeating information for segmented blister strips that patients may separate into units for convenience.

However, mandating additional text will increase the clutter of information and may impact on readability. The feasibility of introducing these mandatory measures appears not to have been fully considered. Batch numbers and expiry dates are variable and cannot be pre-printed, requiring additional and multiple changes to tooling. The costs of this measure may be significant.

Moreover, embossing is a commonly utilised mechanism for presenting this information. Modifying tooling to perform multiple embossing on blister strips could be very costly (if even possible), noting the requirement for very accurate embossing due to limited free space on the strips. Where embossing is performed, special attention is required not to compromise closure integrity around the tablets/capsules by the increased quantity of embossing on the strips.

Medicines Australia is keen to work with the TGA to establish standards to improve information provided on the primary blister strip packaging without diminishing quality of product packaging.

Small Containers

Mandating a primary pack for all small containers will be costly with uncertain impact on safety. The consultation acknowledges consumers regularly store medicines separately from the primary packaging and therefore the impact of this measure has not been fully examined. Additionally, there are environmental impacts on increasing primary packaging. Many measures already support delivery of relevant information on small packs such as flag labelling, CMIs, online resources.

Medicines Australia is keen to work with the TGA to determine a regulatory solution ensuring appropriate and relevant information is made available with medicines in smaller containers.

Pack Inserts

Medicines Australia does not oppose this recommendation and draws the TGAs attention to the Medicines Australia Code of Conduct providing clear guidance to industry on restrictions around advertising material and provision of information on patient support programs.

Labels and Packaging Advisory Committee

Medicines Australia does not oppose the establishment of an expert advisory committee and further recommends the inclusion of a member representing the medicines industry. It is crucial that the functions of the committee do not impede the existing evaluation process and timelines and are timed to provide relevant advice at an appropriate interval to allow adequate industry response prior to market authorisation. Medicines Australia is interested to know whether the committee will function as a sub-committee to the existing Therapeutic Goods Committee (TGC) who currently provide expert advice on therapeutic goods standards.

Conclusion

Medicines Australia affirms support for evidence-based measures that improve Quality Use of Medicines and promote safety. Whilst not all of the recommendations within this consultation document have been addressed individually, it is clear further work needs to be done to determine the best approach for packaging and labelling.

Medicines Australia recommends joint development of a comprehensive design guideline to improve design of packaging and labelling for prescription medicines. This guideline should include an evidence based approach to determining packaging and labelling measures that improve safety and quality use of medicines and consider work already undertaken in international jurisdictions on packaging design and patient safety.

Medicines Australia further highlights the need for enhanced education across industry, healthcare professionals and the community on information about, and safe use of, medicines.

Medicines Australia looks forward to working with the TGA to further develop an appropriate, evidence-based approach to regulatory reform in packaging and labelling and to further promote the objectives of the National Medicines Policy.