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24 August 2012

TGA Labelling and Packaging Review
PO Box 100
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Dear Sir/Madam,

Thank you for providing the opportunity to comment on the packaging and labelling review which was released for public consultation in May 2012.

Please find enclosed our comments for your reference and consideration.

We look forward to the next stage of the review process and remain available to offer further comment or assistance as necessary.

Yours sincerely,

Mary Flannery
Regulatory Affairs Manager
ELI LILLY AUSTRALIA PTY LTD

TGA Medicine Labelling and Packaging Review - consultation paper
Eli Lilly comments – Aug 2012

Eli Lilly wishes to thank the Therapeutic Goods Administration for the opportunity to respond to the Medicine Labelling and Packaging Review. For ease of reference our comments are provided below, following either the reference number or heading in the consultation paper. While the nature of the review is such that it captured a broad range of medicines, the comments provided are very much from the perspective of an innovative R&D based company focused predominantly on the introduction of novel prescription only medicines.

Section	*Company comment*
1.1	**Prominence of active ingredients on medicine labels** In principal the intent of readily identifying the active ingredient name is fully supported. However, ensuring that a consumer can readily acquaint themselves with the active ingredient(s) of a given product can be achieved in a number of ways. The proposed imposition of expectations such as equal prominence requirements which may be suitable for some elements of the industry, does not provide the industry with adequate flexibility to adapt a solution that best fits their circumstances. Further detail is provided below.

1.1	*General questions* - specifically regarding size and position:
	• The recommendation for consistent placement of active ingredient immediately below the brand name is supported as consistency improves ready access to reference information.
	• The specific proposal of *"equal prominence"* (i.e. 100% of the font size of brand name) for active ingredients has multiple limitations which must be considered, particularly in light of the suggested mandatory nature of the proposal:
	  • active ingredient names particularly for innovative biological molecules are becoming increasingly complex, potentially consuming significant label space
	  • *added value* from a consumer perspective in having two headlines on one label is questionable. This could possibly lead to as much confusion as it seeks to reduce since it is not a convention used in other forms of mainstream communication
	  • the value of a clear, obvious and readily pronounced tradename has always been a cornerstone of innovative new product introductions. The rationale for changing this convention is not clear
	  • in an era where there are acknowledged gaps in mainstream health literacy the benefit of highlighting an often difficult to pronounce and complex name to the same extent as the brand name is not intuitively beneficial. Health literacy initiatives could be best focused at smaller incremental improvements.
	  • there is potential that such a requirement (without discretion) would increase the overall size of the labels in order to accommodate equal prominence
	  • this potential to increase the overall size of the labels has two consequential implications, the first being the difficulty in retrospectively accommodating such a requirement without potentially increasing packaging size and the second, even for progressive implementation, the potential to force an increase in pack size and thus packaging material, with the knock on cost and environmental considerations.
	  • whilst acknowledging SUSDP signal headings are outside the scope of this review it should be noted that there are prescriptive proportionality linkages between the size of the current tradename and the signal heading. Proposals that may result in a reduction in the overall size of the brand name (to accommodate equal prominence of the active ingredient name) could equally reduce the size of the signal heading.

1.1	**General questions – specifically regarding size and position**: We recommended that the wording acknowledges the challenges with small labels and

	cartons such as that used in the EU guideline on the readability of labelling and the packaging leaflet. Critical information that must be shown on small cartons and labels should be clearly identified in TGO 69 or in a guidance document.
1.1	**General questions – smallest font size?** It is difficult to specify the smallest font size that is readable in the absence of specifying the font itself, as different fonts of the same point size may be different sizes when measured. It might be better to specify the minimum requirement in terms of "equivalent to a specific font and size" See example below from the EU guideline: *The type size should be as large as possible to aid readers. A type size of 9, as measured in font times new roman (not narrowed) with a space between lines of at least 3 mm should be considered as a minimum.*
	Look-alike sound-alike names and look alike packaging
3.1	• The global nature of innovative medicine development dictates that this work will need to be conducted early during the global product labelling development for a new product. Consideration must be given to global requirements so that the final product name and packaging will comply globally. This is time-consuming work and sponsors will need to build it in to the drug development program early enough so that if changes are requested there is adequate time to change course. • Of particular importance to the sponsor at a local level is the need to separate the TGA decision on the acceptability of a trade name from the overall and subsequent decision on the risk/benefit assessment of a new molecule. Specifically the sponsor would need to achieve assurance on the suitability of the trade name in advance of the new chemical entity submission. • Ongoing uncertainty regarding the acceptability of a tradename up to the point of final risk/benefit assessment does not support the principal of timely access to new medicines as the measures necessary to change course can be time consuming. • Additionally, it should be noted that a sponsor has no sight of proposed trade names from other sponsor that are under concurrent TGA evaluation. Particularly relevant here is the large number of generic brands that are under review at any one time. • Importantly, from an operational perspective it will be necessary to know what the TGA needs in terms of testing before the product labelling is submitted. Ideally as stated above, it should be separated from the product submission package, with evidence of product name approval being part of the Module 1 data package. There would be no objection to providing a reference copy of the testing results in the data package.
	Contrast colour and design requirements for brand names that differ by 3 letters or fewer – new medicines
3.2	While acknowledging the intent it is difficult to conceive how the 3 letters or less criteria can be implemented in a practical manner as a trigger for colour/design contrast requirements. With thousands of entries on the ARTG a sponsor is unable to identify a comprehensive list of the relevant trade names. A more pragmatic approach to achieving this intent is necessary. Examples could include creating a hierarchy based upon, for example: • Products identified on sound alike software • Products likely to be stacked side by side on pharmacy shelves • Products likely to be used concomitantly • Similar schedule products • Other relevant factors

	Contrast colour and design requirements for brand names that differ by 3 letters or fewer – existing medicines
3.3	• There needs to be increased definition on the extent of artwork changes that would trigger this requirement. For example numerous changes can be triggered simply by the need to contrast background colour where b/n and expiry date information is printed on an end flap. It would appear to be an unnecessary additional impost on sponsors if it is applied across the board in the absence of specific information that there is an error risk for a given product. In instances where there are known concerns these would be better dealt with in a proactive fashion. • The operational limitations and need for an alternative approach cited above in terms of identifying products that differ by 3 letters or fewer equally apply in this case. • In terms of the expectations to implement changes to existing artwork it will be important to ensure that the timing of the revision to Appendix 12 of the ARGPM is synchronised with the finalisation of the packaging guidelines, to ensure consistency of message.
5.1	***Dispensing Label space***
5.2 5.3	• There is in principal support for the designated dispensing label space on prescription medicines. It should be noted however that such an initiative would need to be fully support by institutions such as the Pharmaceutical Society of Australia to realise the maximum benefit. • For small containers there will be unique challenges and therefore it should not be a requirement but an expectation that sponsors will comply where space permits. • Particularly in relation to small containers it is important to know if existing products are expected to comply with the proposal and if so, the expected implementation time. • For existing small container products compliance with the guidelines may be challenging. Most space is currently consumed by the required regulatory text and allowing additional blank space may not be possible without increasing the size of the container/carton. • This could incur significant manufacturing costs to design new labels and implementation time would need to be agreed with industry, bearing in mind that it may also trigger colour contrast design requirements as above. • Any retrospective application of requirements would need negotiation with industry to avoid unnecessary cost, unachievable timeframes and supply chain disruption.
6.1	***Proposed regulatory changes – brand name, active ingredient, strength, b/n and expiry must be repeated at least every 2 units.***
	• Due to the relatively small size of blister strips, it may be challenging to print the proposed information (brand name, active ingredient and amount, expiry date and batch number) in a legible fashion in the limited space available. Therefore, it may be necessary to increase the blister (and carton) size for some existing products. • Most importantly, the majority of packaging lines currently in use do not have the capacity to print ***batch variable*** information at the proposed frequency (*i.e. the major limitation is the b/n and expiry date information).* • Establishing the capability to print and verify this information at the time of packaging will require the investment of significant time and resources. • By way of example, currently 2 of 30+ packaging lines used globally have capacity to meet this proposed repeated b/n and expiry date requirement. To meet Australian demand if this proposal were to be adopted 7 additional lines would need to be upgraded. Installation, qualification and integration of necessary equipment would require extensive capital investment and implementation periods of 3-4 years.

7.3	***Small containers – further suggestions*** White space is also important when considering how patients can locate important information to use a product safely and effectively. White space does not appear to be captured in the consultation paper. The TGA may wish to consider white space guidelines where possible. In the case of very small containers the most critical elements should be identified so if sponsors have space for only certain information, there is clear guidance on what to consider critical. As mentioned previously, allowing space for pharmacy labels can present challenges. Refer section 5.
8.1	***Proposed regulatory change - advertising material will not be permitted to be included as a separate package insert or incorporated in to an approved package inserts***
	It is agreed that advertising material should not be included on package inserts or provided separately with packs. However, to ensure clarity of this requirement it is important to ensure that recent agreements that have been reached between the TGA and Medicines Australia regarding the ability to use a package insert to inform patients of patient support programs is not compromised. Thus it must be clear that this is not regarded as "advertising material". Equally the ARGPM (section 4.1.3.6) requires revision to ensure consistency of message across the Medicines Australia Code of Conduct, the TGA published regulatory guidelines and the resulting medicine packaging guidelines. Further in relation to package inserts, through the introduction of risk management plans (RMPs) sponsors may commit to provision of various patient education materials. Flexibility to deliver education tools to the patient within the package (where appropriate and necessary) should be retained. There may be value in the TGA setting forth basic guidelines regarding font size, layout, and white space to help ensure readability of the insert, taking into account the sponsors limitations as it related to paper size and packaging line equipment.
8.2	***Proposed regulatory change - a pack insert must be in a form separate to the packaging i.e. it cannot be printed on the inside of a carton***
	Agreed
	Do you have any further suggestions regarding package inserts
	• There remains from a past era a requirement to provide the approved product information document (PI) as a package insert for parenteral products distributed in Australia (Ref: 4.1.3.6 ARGPM). Of note is that this is required irrespective of whether the preparation is self administered, in which case a user manual would be more useful. In the current environment where prescribers and dispensers have ready access to electronic data repositories and particularly where an electronic environment allows for timely updates of PI and CMI documents, the merit of this legacy paper based system should be questioned. • A suggested alternative is to provide basic information in a legible font size detailing basic indication and dosage and administration instructions with the reader referred to the TGA website or other repositories for further information. This would assist greatly in eliminating prolonged implementation periods for paper insert revisions, particularly in light of the efficient processes and accessibility available today for electronic updates. It would also assist in reducing the number of outdated leaflets that remain in circulation until product expiry.
9.0	***Labelling and packaging advisory committee*** • TGA is urged to strive for harmonisation with other major regulatory agencies when they consider such activities. See comments in section 3 • Labelling and safe use of medicines particularly in the prescription medicine arena is dependent on the contributions of many parties namely, sponsor development of differentiated trade names and packaging, correct prescribing, correct dispensing and

	a well instructed patient. The extent to which the TGA and their advisors alone can influence the reduction in medication error is questionable in the absence of a collective approach across the full health care delivery system. An institution such as the NPS may be already well placed to advise the TGA on issues of concern.