Procter & Gamble

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The TGA Labelling and Packaging Review
Therapeutic Goods Administration
PO Box 100
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AUSTRALIA

Dear Sir/Madam:

Thank you for the opportunity to provide inputs and contribute to the *TGA Medicine Labelling and Packaging Review Consultation Paper* released last 24 May 2012.

Procter & Gamble Australia Pty Ltd (P&G) is one of the leading Fast-moving Consumer Good (FMCG) companies in the market and has been responsible for a number of leading brands in the Australian household care. Our offering is diverse and includes skin care and sunscreen products (such as Olay), shampoos and conditioners (Herbal Essences, Pantene and Head & Shoulders) feminine hygiene products (Tampax), toothbrushes and toothpastes (Oral B), over the counter (OTC) health care products (such as Vicks and Metamucil). P&G has operated globally for 175 years and has been in Australia for 23 years. It would be fair to say that many, if not most Australians are touched by P&G products every day.

We value our relationship with the Australian Government and would like to thank you in advance for your consideration of our views on this consultation paper.

P&G has a considerable interest on this Consultation Paper as we have a number of products in the market that would fall within this review – therapeutic-cosmetic product interface such as sunscreens to over the counter medicines such as cough syrups and vaporubs.

GENERAL COMMENTS:

Although it is understood that the objective of the review is "to develop appropriate regulatory solutions that effectively address the consumer safety risks", it is unclear if stakeholders are made aware of the problem to be resolved, as no specific and concrete evidence of increased risk to consumers (across all products to be affected) were presented. The proposed changes undermine the risk-based approach principle of regulatory control, which we believe is the same principle that the TGA has strengthened in the last few years. It is sadly apparent that the Consultation Paper did not provide nor considered any alternative options but was focused just on one - a "one size fits all" solution, with no clear cost/risk/benefit analysis. The Consultation paper in general seems to be driven and more applicable to prescription medicines rather than to OTC medicines or to therapeutic-consumer interface products such as sunscreens.

Separately, P&G is in full support of the recommencement of ANZTPA joint agency which was announced June 2011. The Consultation Paper however, appears to deviate from that renewed commitment.

Prominence of Active Ingredients

To date, no evidence to prove that the prominence of active ingredients, such as having the same or almost the same font size of the brand name assist consumers with the right identification and correct usage of the product. In our humble opinion, this will not address appropriate use nor deter or limit adverse/allergic reactions. The clutter on the label will create more confusion amongst consumers, especially for products that contain a number of active ingredients. Further, the inclusion of the brand name and the active ingredient/s on at least 3 opposing faces of the packaging carton is impractical and non-feasible for medicines with multiple active ingredients, moreso if the proposal is brand name and active ingredient to be of equal prominence.

Look-alike/sound-alike (LASA) names and look-alike packaging, and look-alike medicine branding

We contend that the issue of LASA names mainly occurs in prescription medicines whereby the active names are quite similar, and consumers are not as familiar with these names, However, this should not be the case for OTC or in the therapeutic-consumer interface products. In both classifications, advertising help to educate consumers on the brand names, their uses and indications. In addition, OTC products are arranged on pharmacy shelves according their categories, which helps mitigate the risk of consumers taking a medicine different from what they intend to purchase.

Separately, we appeal to TGA to view umbrella branding with more open-mindedness. Umbrella branding (also known as family branding) is to be seen differently from individual product branding where each medicine in a portfolio is given a unique name and identity, which lends to clarity. In some cases, there are two parts of the medicine name: the mega-brand name, and the product brand name. It would be alright to have the same mega brand name across a portfolio of products (e.g., cough, cold and flu), but the product brand name has to be consistent with the actives present in the medicine and the indications for which it is intended for. A case in point is our own Vicks Sinex (Oxymetazoline), Vicks Vaporub, and Vicks Inhaler - each product is clearly identifiable and distinguishable from one another , thereby not lending confusion amongst consumers.

It is our view therefore that umbrella branding be addressed on a case-to-case basis. The Consultation paper proposes that the "sponsor needs to submit evidence of risk assessment of the proposed labelling and packaging." We strongly urge TGA to provide specific guidance on the kind of evidence to be presented.

Standardised Information format: Medicine Information Box

P&G fully agrees to the intent of the addition of the Medicine Information Box and deem it workable across Prescription, OTC and therapeutic-consumer interface products. However, the need for such a change must be clearly presented with a risk/cost/benefit analysis. The type and size of product packaging must as well be considered.

Dispensing Label Space

P&G believes that this not applicable to OTC medicines. We request that confirmation and clarification be made that this is not proposed for OTC medicines or therapeutic-consumer product interface.

Blister Strip Labelling

P&G believes that the current practice of having the brand name, active ingredient and amount of active is sufficient. Requiring the batch number and expiry date to be placed on every 2 positions however, is impractical and an improbable task for the industry from a technology standpoint. Printing or embossing of batch codes and expiry date once per strip on line after blistering has been seen as best practice locally and internationally.

Small Containers

P&G deems the current requirements per TGO 69 as sufficient for small containers. It already captures the most important information to assist consumer usage of the medicine. Hence, as long as the primary pack (i.e., outside container/carton) fully complies with the labelling requirements, and an instruction for the consumer to keep the carton for the warnings are complied with, a pack insert is not deemed necessary.

CONCLUSION:

P&G is committed to continuously provide safe, quality and efficacious products to the Australian consumers and will always support the Australian government for similar endeavours. Hence, we strongly appeal to TGA to help stakeholders better understand the need to change the current regulations via clear identification of the issues. We further urge TGA to provide more options that are based on a risk/benefit analysis and not just a "one size fits all" solution across all the categories.

We again thank you for considering P&G's submission and the opportunity to take part in this exercise. Please feel free to contact us should you require any further information.

Yours sincerely,

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