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OTC Medicines Regulatory Process Review
Therapeutic Goods Administration
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Procter & Gamble (P&G) Australia's Comments to TGA's Consultation Paper on OTC Medicines Business Process Reform

We would like to thank TGA and Medsafe for taking the step towards improving OTC medicines application process. Greater transparency, better efficiency and more predictability of the timelines will greatly help the OTC medicines industry, and is a good step towards ANZTPA. We also thank the regulators for giving the industry a chance to comment on the proposed Business process reform. We have outlined our comments to the consultation paper.

Risk-based approach to regulating OTC medicines

I. General Questions:
   a. Do you support the concept of risk-based categories for OTC medicines?
   b. Do you agree with the proposed risk categories for new medicines?
   c. Do you agree with the proposed risk categories for changed medicines?

In principle, P&G is in full agreement with the concept of risk-based approach. However, we don't agree with the proposed risk model proposed by TGA which is based on data requirements (i.e., the availability or not of the data requirements). A more appropriate approach is to assign and evaluate risk based on the intrinsic nature of the product and factors like ingredients (toxicological profile, history, etc.), route of administration, dosage form, indications, significance of side effects. For example, a sunscreen product presents lower safety risk than an oral medicine, and should be accorded a more appropriate evaluation based on the benefit/risk ratio. The same is true for evaluating changed medicines.

II. Other Comments:
   a. The aspect on "umbrella branding" is very vague, and unless TGA/Medsafe comes up with clear guidelines on 'umbrella branding," sponsors will be at a loss of what is the appropriate application category. "Product name does not

include an umbrella segment" is a very vague description and is open to subjective interpretation.

Proposed OTC medicines evaluation process

I. General questions
   a. Do you support the proposed five-phase process?
   b. Do you agree with the principles that were applied when developing the proposed process?

   In general, we support and agree on the principles behind the process, but a few operational factors need to be considered. Please see below points.

II. Other comments:
   a. "Applications will be screened by the regulator upon receipt."
      Application form should include a checklist of the data requirements to be submitted.

   b. "Target timelines will be specified for the completion of each stage of the evaluation process"
      Target timeline should be specified as well for the screening phase, which is usually the bottleneck whereby applications are essentially 'idling' in queue waiting to be allocated to an evaluator.

   c. "When necessary, advice on specific issues relating to the application may be sought from an appropriate advisory committee."
      Clear guidelines are sought on what kind of issues are referred to the advisory committee, and how this is going to impact on the timeline. This information is critical in order to help with the predictability of timing.

   d. More clarity is sought from TGA and Medsafe on how to collaborate on and manage OTC medicine applications (of the same product). Until the ANZTPA is established in 2016, two separate applications (of the same product) will be submitted to both TGA and Medsafe presumably using the same OTC BPR process. Payment of the fees aside, the effort is unnecessary duplication on both the sponsor's part (i.e., having to make two applications) and on the evaluators' part (i.e., evaluation of the same application). Operationally, this dual handling creates complexity and confusion especially if the comments of the TGA evaluator and the Medsafe evaluator are not consistent with each other. As most medicines are to be marketed in both Australia and New Zealand, TGA and Medsafe should explain how they both will collaborate on the same medicine application.

   e. "There will be a maximum of two rounds of requests from the regulator for the applicant to supply additional information."
      The maximum of two rounds of RFI's (Request for Information) would work based on history of Medsafe applications. However, as discipline is expected of the applicant to provide complete application, the evaluator is also expected to provide a complete set of questions at the first RFI. Also, for applications of the

same medicine, both TGA and Medsafe are suggested to collaborate and consolidate the RFI for efficiency.

OTC medicine monographs

I. General questions

a. Do you support the concept of developing monographs for OTC medicines?
Yes, we agree with the concept of OMM's.

b. Do you agree with the proposed list of medicines that should be given priority for monograph development?
P&G believes that there should be clear plan and timeline to expand the list of OMMs to include majority if not all low-risk medicines. We recommend that TGA looks into the existing US FDA OTC Monographs and study what can be re-applied to the market.

Application categorization for umbrella branded medicines

Comments:

a. Clear guidelines on "umbrella branding" are sought. Without these, there will be confusion as to the (a) whether a certain name is under the scope of "umbrella branding" issue, (b) what then is the appropriate application category.

b. As part of the "umbrella branding" guidelines, it may also help for TGA to provide the industry the kind of data that they want to see in order for the sponsors to justify no issue with umbrella branding.

Target times

Comments:

a. "There should be target timelines."
It's in the best interest of the sponsor to provide a complete and quality application. On the flipside, there should also be some incentive for the regulator to meet the target timeline. If the regulator fails to meet the timeline, there should be a corresponding refund of the evaluation fee based on the time delay.

b. The target timelines presented do not include "screening" leadtime.
Based on history, the "screening" leadtime can take up to 6 months, wherein the application is just sitting there in the queue waiting to be evaluated. Regulator should also provide target leadtime for screening.

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