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11 May 2017

Regulatory Reforms Team
Therapeutic Goods Administration
PO Box 100
WODEN ACT 2606

Dear Sir/Madam,

RE: March 2017 Consultation: Options for the future regulation of "low risk" products

On the behalf of Procter & Gamble Australia Pty Ltd (Procter & Gamble), I would like to express gratitude for the opportunity to provide a feedback on the proposals which are described in the March 2017 consultation paper concerning the options for the future regulation of "low risk" products in Australia.

Procter & Gamble is committed to continuously provide quality, safe and efficacious products to the Australian consumers. Procter & Gamble reaffirms its support for the objectives of the TGA's endeavour when seeking comments on the potential regulatory options of "low risk" products from industry members.

A number of Procter & Gamble's products in the Australian market which are currently classified as the registered OTC medicine fall within this review. Therefore, we would like to thank TGA for its commitment to seeking feedback from industry prior to any program to formally reform the existing regulatory framework.

Again, we sincerely thank TGA for the kind considerations of our views on this consultation paper. In this submission, we have responded to the three questions posed by TGA in the consultation. Please find below our responses to each of the questions on consultation:

Question 1: Do you have a view on which (if any) of the above options for these OTC products would be the most appropriate way forward?

[Response] Procter & Gamble remains strongly in favour of Option 1 which is to maintain the status quo regulation of low risk OTC medicines. In our opinion, the existing regulatory framework for OTC medicine fosters a reasonably high level of consumer confidence in the OTC medicines. The current process requires the sponsor of the registered OTC products to submit data for TGA pre-market review of quality, safety and efficacy data before products are launched in the market.

Even though 'over-regulation' may have a potential to drive up operational costs and extending time to market, the consumers' interests of a new registered OTC medicines are still well-protected today by the substantiated product claims through the regulatory expertise from TGA together with a regulatory oversight of the scientific evidences provided by the manufacturer during the pre-market assessment.

The Option 2 as stipulated in the consultation paper, on the other hand, has proposed for a review of the safety of active ingredients in order to identify low-risk OTC medicines that could move to the sponsor's self-assessment listed regulatory framework. Nonetheless, it is unclear in the consultation paper on how the sponsor will determine the cost/risk/benefit when re-classifying the existing registered OTC medicine if the registered formulation contains the permitted active ingredients under listed medicine.

Additionally, the argument for reducing the cost of OTC medicines by implementing the Option 2 is invalid unless a clear definition of the value proposition of OTC medicines to the targeted consumers is being provided. It is crucial to understand the states of consumer needs, the marketing paradigm as well as the key driver for OTC business before determining the Option 2 which could potentially reduce the costs of the OTC medicines to consumers. There is no clear advantage in reforming the existing regulatory framework for OTC medicines as the consumer benefits are not being manifested.

In view of above, the Option 1 affirmed by Procter & Gamble would be the most appropriate way forward for regulating the OTC medicines in Australia.

Question 2: Are there particular products which in your opinion definitely should (or shouldn't) be reviewed? If so, please provide details on potential impacts to public health, access in the marketplace, business operations etc.

[Response] Procter & Gamble suggests that the following products: nasal decongestants/blocked nose relievers and natural fibre products which are currently categorised as registered OTC medicines should not be reviewed to become listed medicines.

Below are key considerations from the potential impacts to public health, market access and business operations:

- **Potential impacts to public health**

There are still many ambiguities in the area on how self-assessment on the product's intended claims are made by the sponsor as there is no provision for labelling scrutiny. The sponsors may become complacent when designing the therapeutic claims on their OTC products. This is exemplified by the number of products mentioned in the "News room" on the TGA website that may pose a serious health risk if taken.

For the registered OTC medicines with a long history of safe use, we are inclined to see the products advertised with their intended claims as appropriate to reflect its intended use in common. The consumer may get confused over the "weakened" claims in the labelling of the same product or its line extension while they have been using it for a long time.

Furthermore, the consumer benefits on the awareness of the therapeutic claims in some registered OTC medicines will be undermined if they become the listed medicine and some therapeutic claims may not be adequately established.

- **Potential impacts to the access in the market place**

The Option 1 allows Procter & Gamble to keep the same momentum of how the product is going to be launched in the market place. There would be no significant impact to the turnaround time when obtaining a pre-market approval from TGA.

- **Potential impacts to the business operations**

If the reclassification takes place, there will be an impact on the current artworks of the affected OTC registered medicines. The existing AUST R number in the product labeling for the affected OTC medicines will be changed to AUST L number accordingly. The supply of the existing OTC medicines in the market may also be disrupted if there is any potential delay in the label remediation.

Question 3: Any alternative recommendations would also be welcome

[Response] Procter & Gamble has no recommendation other than Option 1 in response to Question 3. Procter & Gamble believes TGA premarket review assures the quality, safety and efficacy of these products. This has provided a positive impact by setting these products into the “low risk” category. Changing the status quo means the quality of low risk products may not be guaranteed and labelling may not be compliant with the TGA Labelling Order, Therapeutic Goods Advertising Code (TGAC) and/or Competition and Consumer Act (ACCC).

Once again, on the behalf of Procter & Gamble, thank you very much for the opportunity to contribute at reviewing the future regulatory options of “low risk” products in Australia. For more clarity and convenience, Procter & Gamble is available anytime to provide further information as required. Please feel free to contact us should you require any clarification or additional information.

Yours sincerely,