CHPA CONSUMER HEALTHCARE PRODUCTS ASSOCIATION
founded 1881

May 25, 2017

Regulatory Reforms Team
Therapeutic Goods Administration
PO Box 100
Woden Act 2606
Australia

Dear Sir or Madam,
Re: Consultation - Options for the future regulation of "low risk" products, Version 1.0 March 31st 2017.

Kindly accept the following comments from the U.S. Consumer Healthcare Products Association (CHPA) as our contribution to the Australian Department of Health Therapeutic Goods Administration's (TGA) Consultation on Options for the Future Regulation of "Low Risk" medicines.

Founded in 1881, CHPA represents leading manufacturers and marketers of over-the-counter (OTC) medicines and dietary supplements in the United States. We are committed to empowering consumer self-care through the preservation and expansion of choice and availability of consumer healthcare products. Our membership conducts business globally, including Australia, hence opportunities to harmonize regulations and remove barriers to trade are considered important.

We meet this commitment to innovation, quality and safety for consumers in the United States via the FDA OTC Monograph system and this is similar to the intent of TGA Self Care. Specifically, the OTC monograph system enables a go-to-market approach with no pre-market approval, as long as manufacturers meet those conditions defined in the monograph and those regulations that are designed to ensure the quality, safety and effectiveness of the product.

The OTC Monograph system is applicable to the category of OTC Drug products that are GRASE (Generally Recognized As Safe and Effective). These products meet criteria that ensure low-risk to consumers, including:

- An acceptable safety margin
- Low misuse and abuse potential under conditions of widespread availability
- Healthcare practitioner oversight is not needed for the safe and effective use of the product
- Safety and efficacy can be assured through monograph conditions (e.g. adequate labeling, ingredient, dosage forms, performance testing)
- Quality is assured though appropriate GMP regulations

The OTC Monograph process provides a way to deliver safe, effective, and affordable OTC Drugs products to consumers. With this background and experience, CHPA strongly supports TGA's direction to minimize the regulatory burden for low risk OTC product categories as identified in the consultation paper under "Other low risk registered non-prescription (OTC) medicines", Option 2: Review of eligibility of active ingredients to become listable.

Below are key points for consideration related to the proposed regulatory options.

1. CHPA is of the view that OTC products which are proven to be of low risk and with a strong safety profile require regulatory controls that are proportionate to the potential health or safety risk. An appropriate risk balanced regulatory framework for OTC products will benefit all key stakeholders. We applaud TGA's willingness to consider a risk-based approach towards OTC low risk medicines.

2. Of paramount importance is to establish a robust regulatory framework to ensure safety, efficacy & quality of OTC products. CHPA is of the view that these low risk OTC medicines should continue to be under TGA's regulatory oversight, but with further optimization to the regulatory processes.

3. Option 2 continues to prioritize consumer health & safety, yet reduces the regulatory burden to market entry. Further, we recommend to extend this consideration to other ingredients, i.e. excipients. We fully agree that a risk review of the ingredients typically used in these OTC product types is required to determine if they could be permitted for listed medicines. It is of CHPA's view that TGA should consider to recognize and accept the approvals granted by comparable and competent regulatory authorities, i.e. US FDA, Health Canada. Removing this major regulatory barrier will provide faster flow of innovation into the Australian market and a more agile environment for the category.

4. Critical to Option 2 will be the approach to determine ingredient safety. We urge TGA to consider a holistic approach going beyond purely hazard or toxicity profile based approach to an exposure based approach combined with global in market experience & appropriate label control.

CHPA sincerely appreciates the time and effort that TGA has undertaken in the preparation of this Consultation document and for providing an opportunity for all stakeholders to contribute towards the different regulatory directions.

Sincerely,

Barbara A. Kochanowski, Ph.D.
Senior Vice President, Regulatory & Scientific Affairs