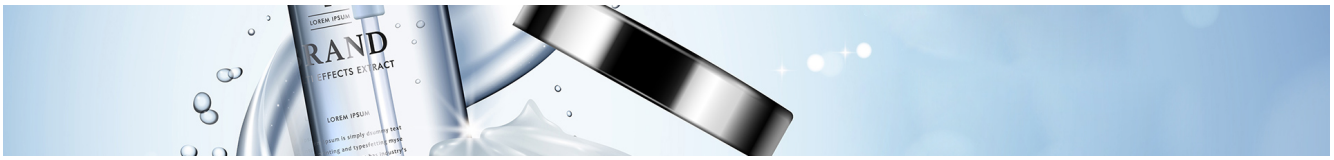

Self-Care Regulations to Get a Make Over

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By Liz Afolabi and Amanda Branch

Health Canada not only regulates prescription drugs sold in Canada, but also it regulates a wide variety of "self-care" products that can be purchased at health food stores, pharmacies and grocery stores. Self-care products include three different major categories: cosmetics (for e.g., creams, deodorants, shampoos, skin products), natural health products (for e.g., vitamins, probiotics, homeopathic remedies) and non-prescription drugs (for e.g., "over the counter drugs" such as pain relievers and allergy medication). Currently, these products all fall under the *Food and Drugs Act*; however, they are regulated under three distinct sets of regulations.

Health Canada is now moving forward with a plan to modernize its approach to the regulation of self-care products, in order to help ensure consumer safety and to help consumers make informed purchasing decisions. From September to October 2016, Health Canada solicited feedback on its consultation document titled Consulting Canadians on the Regulation of Self-Care Products in Canada. Health Canada received over 3,500 comments, and in March 2017, it published the What We Heard Report, which summarizes the key findings. The What We Heard Report indicates that little consensus was reached by Canadians except in two respects: one, self-care products should not be regulated in the same manner as prescription drugs, but rather according to risk; and two, Canadians wanted more information and details about Health Canada's proposals, which include a two-class risk level categorization system for all products, and "scientific proof" of any "health claims" made by manufacturers.

Regarding the two-class risk level categorization system, Health Canada's proposal would classify products based on at least two considerations, namely, the safety of the product, and the harm of the product not doing what it is meant to do. The response of Canadians to this proposal was mixed: while some participants felt that a two-class risk level system could oversimplify the current market for self-care products, others supported it, believing it to be easy-to-understand. However, there were concerns expressed regarding: how the harm from failed efficacy would be defined; how past product classification decisions would fit into the new two-class system; how "historical use" would be defined when describing the evidence needed to support a therapeutic claim; and further clarity would be needed regarding which products, claims, factors and conditions would be acceptable for each risk category.

Regarding the requirement for scientific proof of any health claims made, Health Canada's proposal would include a new definition of scientific proof. This was met by a polarized response: supporters liked that scientific proof would provide clarity and certainty; while detractors fear it would negatively affect affordability, availability and diversity of products, especially considering that clinical evidence may not be available for some products. Further, it was felt by some Canadians that Health Canada's proposal would make it difficult to get and give evidence for therapeutic claims for traditional and homeopathic remedies in particular. Similar polarization resulted regarding Health Canada's proposal that a disclaimer could be used on products to identify when a health claim had not been reviewed by Health Canada prior to the sale of the product.

One thing for certain is that Health Canada is actively engaging the opinions of Canadians, which underscores the government's desire for transparency. It must now weigh and balance the feedback of Canadians as it continues to refine the new self-care product regime. More details and an updated proposal are expected in 2018.

help you.