CANADIAN COSMETIC, TOILETRY
AND FRAGRANCE ASSOCIATION

ASSOCIATION CANADIENNE DES COSMÉTIQUES,
PRODUITS DE TOILETTE ET PARFUMS

October 11, 2016

Health Canada's "Self-Care" Regulatory Framework Makes Sense!

Necessary Reform That's Long Overdue

Health Canada released its long awaited Consultation Paper on the Regulation of Self-Care Products this September, offering Canadians a modernized, consistent and consumer-focused framework for regulating everything from over-the-counter medications (OTC's) to natural health products (NHP's) and cosmetics. The existing regulation of this vast and growing array of self-care products is a patchwork of outdated definitions, inconsistent approaches and administrative fixes that makes little sense to consumers, manufacturers and government regulators.

Take for example a commonly used product like toothpaste. Toothpastes are regulated as either a "cosmetic" (cleans teeth), a "drug" (prevents gingivitis), or a "natural health product" (prevents cavities), with **VERY** different sets of requirements for each. Toothpastes falling under "drug" or "NHP" rules need pre-market approval while other toothpastes do not. Toothpastes classified as "drugs" must be "quarantined" in a warehouse and undergo "confirmatory re-testing" if imported into Canada, while imported "cosmetic" or "natural health" toothpastes do not. Health Canada can recall defective toothpastes that are "drugs" and their manufacturers can face up to $5 million in fines, while there is no power to order the recall of defective "cosmetic" or "natural health" toothpastes and any potential fine is limited to $5,000. Manufacturing and site-licensing requirements, product labelling, allowable claims and other rules vary so greatly for what is essentially the same product that it is no longer possible to offer any rational explanation that justifies these differences!

All of this applies to not only toothpastes, but to a host of other products including shampoos, hand sanitizers, sunscreens, lipsticks and other make-ups that include an SPF (Sun Protection Factor), and a wide range of other self-care products. In fact, a lipstick can be magically transformed from a "cosmetic" to a "drug" with the simple addition of "SPF" to its label.

So, how did we get to having three very different sets of regulations being applied to essentially the same products? Very simply, a failure to modernize regulations to keep pace with the growing diversity of "self-care" products on the market.

For over half a century, a product making any kind of a "health" claim has been defined as a "drug" and subject to requirements intended and designed for prescription pharmaceuticals. Suggesting that all self-care products are prescription drugs, whether it be a toothpaste, vitamin or SPF lipstick, makes no sense from a scientific, regulatory or consumer point of view.

To the credit of the work of the natural health community, the first successful effort for reform came two decades ago when then Health Minister Allan Rock carved out a specific sub-category for "natural health products". Although this provided some relief, and took many years to be implemented effectively, it left orphaned a growing number of low-risk self-care products in the world of "drug" regulation and totally ignored the emerging innovations in "cosmetics" including skin care, sunscreens and oral care. It also

created a system that no other major jurisdiction in the world has replicated: regulating health products on the basis of the molecular origin of ingredients rather than their health claims and risk to consumers.

If confusing and frustrating for manufacturers, it is certainly confusing for consumers who would be hard pressed to identify any reasons for the differences in Health Canada's oversight of these products. Nor would consumers view any of these products in the same way they view prescription pharmaceuticals.

As these differences became clear to then Health Minister and now Interim Conservative Party Leader Rona Ambrose in 2014, she launched the "Consumer Health Product" regulatory framework in which she proposed "***that lower-risk products be separated from the framework for prescription drugs, and be moved under a new framework for consumer health products….to take into account the potential risk of the product in order to ensure that the right level of oversight through regulations is applied***."

To the new government's credit, Liberal Health Minister Jane Philpott picked up this initiative on coming into office. With this support, and the benefit of what can be described as extensive consultations going back many years, Health Canada has now released the proposed self-care products framework for public consultations.

And what does this framework propose? First and foremost, it gets right to the core of the matter and recognizes that self-care products should be regulated according to their risk profile and how they are viewed and used by consumers. They should NOT be lumped in with prescription drugs whose use and risks require the supervision of health care professionals and different regulatory oversight.

This approach will ultimately require a new definition of "self- care" products that accounts for everything defined today as over-the-counter medications, natural health products and cosmetics, as well as appropriate rules that provide for the continuum of risk within this new category. The proposed framework offers the opportunity to develop appropriate rules and to adopt the best of the current three sets of regulations to ensure safety and efficacy.

It's time to seize this opportunity to have one modern, consistent regulatory framework for all self-care products!

Darren Praznik is President & CEO of the Canadian Cosmetic, Toiletry & Fragrance Association which represent companies producing products regulated as cosmetics, drugs and natural health products. He is a former provincial Minister of Health with a long history in regulatory systems & oversight.