Consultation on New Health Canada Regulations for Self-Care Products (over-the-counter drugs, natural health products and cosmetics)

Life Sciences Bulletin

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Health Canada is seeking consultation on new standards for self-care products, over-the-counter ("OTC") drugs, natural health products ("NHPs"), and cosmetics.

Health Canada is planning a major overhaul of the current regulatory system, in a stated effort to address concerns over misleading claims on product labels. In particular, the federal regulator is proposing a risk-based regulatory system that will require varying standards of approval depending on the potential health risks they pose.

Current Regulatory System

Currently, all three (3) types of self-care products are all regulated differently:

- OTC drugs are regulated in a manner similar to prescription medications. Health Canada must review and approve the safety, efficacy and quality of the product and any related claims must be based on scientific evidence.
- NHPs are regulated for the most part like OTC drugs, although the level of proof required can vary and non-scientific information is accepted to demonstrate efficacy.
- In contrast, the regulation of cosmetics is managed through a post-market system. Cosmetic manufacturers must simply notify Health Canada within 10 days of first sale of a cosmetic in Canada and provide information about the product, such as the nature and quantity of the ingredients. All cosmetic products must nevertheless be prepared under sanitary conditions.

Proposed New System

Under the proposed new system Health Canada would bring all self-care products under a single set of rules and regulate them based on the foreseeable risk to consumers.

Products of similar risk profiles would be treated in a similar manner to help ensure that the rules for bringing products to market are more consistent and easier to understand.

In addition, Health Canada would review only "health claims", i.e. representations that relate to diagnosis, treatment, prevention, cure, or mitigation of a disease or serious health condition. Companies would be required to provide scientific proof to support

these health claims. Other claims, such as more general ones that speak to the function of a product, e.g. "source of Omega-3", would no longer be considered health claims and would be permissible, provided that they are truthful and accurate.

Accordingly, products deemed "low risk", such as vitamins, minerals and cosmetics, would not need to be reviewed or approved by Health Canada, although they will have to meet quality standards. Health Canada may also set exclusions as to which ingredients/products would not be in this group. These products will be prohibited from making health claims on product labels. All other claims will have to be accompanied by a disclaimer stating the information has not been verified by Health Canada.

Products deemed "moderate risk", such as, pain relievers, cough and cold products, laxatives and allergy relief products, would require some review by Health Canada. Licensing of products would be based on evidence of safety and effectiveness published in a product monograph. Full review would not be required because there are standards already in place for the products in this group. Heath claims contained in the product monograph or those based on science would be permissible, subject to Health Canada's approval.

Products deemed higher" risk, such as products that contain new medicinal ingredients and products related to cardiovascular health, would require full review by Health Canada. Companies would have to provide evidence to support the safety, quality, and effectiveness of products. Health claims substantiated by scientific evidence and approved by Health Canada would be allowed.

Greater Enforcement Powers?

Finally, Health Canada may explore adopting new enforcement powers for NHPs and cosmetics, including the power to issue mandatory recalls of products, require label changes and/or increase fines for non-compliance. OTC drugs have been subject to these powers since the enactment of Bill C-17, the *Protecting Canadians from Unsafe Drugs Act* (Vanessa's Law) on November 6, 2014. We note that currently, NHP and cosmetic companies may face fines up to $5,000, whereas the maximum fine for OTC drug companies is $5 million. The new regulations should provide more consistency.

The consultation is now open and available online until October 24, 2016.