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Pharma in brief - Canada

Health Canada consults with Canadians on proposed changes to the regulation of self-care products

Summary

Health Canada is proposing to change the way that it regulates non-prescription drugs, natural health products and cosmetics in Canada, which will now be referred to collectively as "self-care products." While all self-care products fall under the *Food and Drugs Act,* they are currently regulated under three separate sets of regulations.

As part of this process, Health Canada has published a consultation paper that seeks to combine the separate regulatory frameworks for each of these products into one regulatory framework. Health Canada is requesting feedback on the consultation paper until October 24, 2016.

Background

Under the current regulatory framework, the three types of self-care products are governed by separate regulations and the requirements for bringing these products to market varies depending on the regulatory framework that the product falls under. For example, cosmetics do not require pre-marketing approval and manufacturers must only notify Health Canada within 10 days of the date of first sale to provide certain information such as the ingredients, the company's contact information and the purpose for which the product is to be used.

On the other hand, natural health products and non-prescription medications require pre-marketing approval and the manufacturer must demonstrate that the product is safe and effective. The types of proof accepted are, however, different for natural health products and non-prescription medications. Submissions for non-prescription medications must include scientific evidence in support of the claims made while those for natural health products can rely on a wide range of evidence, including non-scientific information such as proof of historical use.

Health Canada has identified several concerns with the current system of regulation, including inconsistencies in the regulatory pathway, the level of evidence required, fees paid, and Health Canada's post-market powers.

Proposed regime

Health Canada is proposing a risk-based classification structure where the level of oversight will depend on the risk posed to consumers by a particular self-care product. There will be three regulatory pathways to market dependent on the level of risk posed to consumers: lower risk, moderate risk, or higher risk. The level of risk identified will determine (a) the amount and type of information Health Canada will need to review, (b) the degree of scrutiny necessary before the product can be made available in Canada, and (c) the level of monitoring required for safety and compliance once the product is available on the market.

Lower-Risk Products. Health Canada will not review claims or license lower-risk products, such as vitamins, minerals and cosmetics. Products in this category may not make claims about the diagnosis, prevention, treatment or mitigation of a disease or condition ("health claims").

Moderate-Risk Products. For moderate-risk products, such as pain relievers, cough and cold medicines, laxatives and allergy relief products, Health Canada would perform some review of claims and license products based on scientific evidence of safety and efficacy, which would be published in a monograph (a licensing standard).

Higher-Risk Products. Higher-risk products, such as products containing new medicinal ingredients and products related to cardiovascular health, would undergo a full review and approval by Health Canada before being sold. Companies would be required to provide evidence to support the safety, quality and efficacy of these products, and Health Canada would approve health claims based on scientific evidence.

Consultation on the proposed regulatory framework

Health Canada is requesting feedback from Canadians on the consultation paper until **October 24, 2016**. Additional details on the consultation paper and how to provide comments can be found in the link below.

Link:

Consulting Canadians on the Regulation of Self-Care Products in Canada

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For more information, please contact your IP/Life sciences or healthcare practice professional at Norton Rose Fulbright Canada LLP.

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