Proposed Regulation for Self Care Products in Canada: Impact on Natural Health Products
Questions and Answers Update Nov 2017

What is being proposed by Health Canada?

It has been well over a year since this process started, so this update also includes some useful background information on Health Canada's consultation re. self-care products.

In early September 2016, Health Canada published a consultation document titled *Consulting Canadians on the Regulation of Self Care Products in Canada* proposing the replacement of existing individual regulatory approaches for non-prescription drugs, Natural Health Products and cosmetics with an overarching system for all **self-care products.** In this new system, products would be categorized as being either **lower**, **medium** or **higher risk** self-care products. Categorization would depend on such things as the type of claim being made and the ingredient it contains.

In this initial proposal, for lower risk self care products, Health Canada proposed a notification system with no pre-market review of information by the department. In this category, products would not be able to make claims about the diagnosis, treatment, prevention, mitigation of a disease or condition and may need to carry a disclaimer saying that the claim has not been reviewed by Health Canada. In effect, this is a similar approach taken to that in the United States.

For medium and higher risk products, Health Canada would review applications and allow a higher level of indication referred to as a Health Claim. Health Claims would need to be supported by "scientific evidence" or "scientific proof" either supported through approved monograph[1] or review by Health Canada or individually reviewed by Health Canada.

In addition to this classification system, Health Canada also plans to create a more comprehensive and consistent approach to items such as recall provisions, authority to require labeling changes, and cost recovery mechanisms.

There was quite a response from Canadians —Health Canada received over 3,500 comments to the initial proposal document with about 70% of the comments coming from consumers. Health Canada collected and summarized the these comments and feedback in a *What We Heard Report* available online.

The consultation process continued in 2017 with Health Canada holding a series of national town halls, in addition to having meetings with groups from consumers, industry, academia. An updated

[1] A monograph typically sets out information such as claims, dosage and potential side effects preapproved that are permitted by Health Canada.

proposal document has yet to be published, but various modifications to the original proposal document were presented at these town halls and meetings.

As for next steps, Health Canada is now planning to create a number of working groups and expert advisory groups that will work over the winter to come up with an updated proposal in 2018.

More information about what is being proposed and the process to date can be found at http://healthycanadians.gc.ca/health-system-systeme-sante/consultations/selfcare-autosoins/document-eng.php

What are self-care products?

Generally, self-care products are health care products available to consumers that can be selected and used without direction from a health care provider such as a medical doctor, pharmacist, naturopathic doctor or nurse. In this document, Health Canada considers a self-care product to be made up of three different product groups: cosmetics; Natural Health Products such as vitamins, minerals, herbal medicines and traditional medicine; and non-prescription drugs such as acetaminophen and conventional cough remedies.

How are self-care products currently regulated in Canada?

Though cosmetics, Natural Health Products and non-prescription drugs all fall under the Food and Drugs Act, they are actually regulated in three distinct ways:

- Cosmetics are regulated under a post-market system, that is manufacturers and importers must notify Health Canada within the first 10 days a cosmetic is sold in Canada providing details of such things as ingredients and company contact information.
- Natural Health Products (NHP) are regulated under the *Natural Health Products Regulations* (*NHPR*) that are the most current and up to date regulatory framework for any therapeutic product. The regulations are pre-market which means Health Canada is required to review information provided by the manufacturer or importer and approve all NHPs before they are allowed to be sold on the Canadian market. This information includes evidence to support the claim being made, as well as information about risks and dosage ranges. Companies must also submit information about where the product is made and a site license is required before a product can be sold. All approved NHPs for sale on the Canadian market must carry an 8-digit Natural Product Number (NPN) or a Drug Identification Number-Homeopathic Medicine (DIN-HM; for homeopathic medicines).
- Non-Prescription Drugs are regulated largely like other conventional drugs. Like NHPs, companies must submit evidence to support safety and efficacy as well as information

about where the product is made. Since all non-prescription drugs are conventional or mainstream health care products, unlike NHPs they only need to consider "scientific" evidence rather than that from traditional forms of health-care such as traditional Chinese medicine.

Isn't appropriate regulation of self-care products important?

Absolutely and in fact in its most recent strategy for traditional medicines, the World Health Organisation (WHO) has identified the regulation of self-care products as a key priority.[2] Health Canada should be commended and supported in recognizing the importance of self-care. The challenge is whether changing the newer regulations, such as the *NHPR*, should be the priority rather than continuing what was initially planned: to focus on revising the more dated regulations such as those for non-prescription drugs.

Why is Health Canada looking to change the way self-care products and NHPs are regulated?

Health Canada says that currently there are three separate sets of regulations—the cosmetic regulations, the *Natural Health Product Regulations* (*NHPR*) and the Food and Drug Regulations, depending on the type of self-care product. This may lead to confusion in market place making it difficult for consumers to understand how these products are regulated and what that means for product claims, the differences in the types of evidence used to support a use and what approval by Health Canada means for each of these three categories of products. There is also concern that the current complex set of regulations do not work well together and that there is the potential for the same product to be classified as a cosmetic, a NHP or a non-prescription drug depending on what claim the product is making and what ingredients it contains. Health Canada also cites inconsistencies in its powers to recall products deemed to be unsafe or to require label changes to reflect new evidence.

I thought the *NHPR* were very new, why change them now?

Yes, the *NHPR* are the most current and complete framework for any health product category in Canada and were developed through extensive consultation with all stakeholder groups, including the public. In addition, the *NHPR* were developed at the request of the Canadian government that recognized the importance of such things as the importance of evidence from traditional forms of health and healing.[3]

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[2] http://www.who.int/medicines/publications/traditional/trm_strategy14_23/en/
[3] http://www.hc-sc.gc.ca/dhp-mps/prodnatur/about-apropos/53_recommend_nhp-cps_tc-tm-eng.php

What is the problem with having claims based on "scientific evidence" and "scientific proof"?

Before we can answer this question we need to know what Health Canada means by these terms. Does this mean that the evidence used for conventional drugs such as randomized clinical trials can only be used to support health claims? Does this include scientific evidence currently respected within the *NHPR*? Should traditional forms of evidence such as traditional Chinese medicine and medical herbalism be recognized as valid proof by Health Canada and included in the definitions of "scientific evidence" and "scientific proof". One question that still needs to be answered is why Health Canada has moved from recognizing a broader and respectful range of evidence for a claim base that includes traditional forms of health and healing to requiring that everything to be scientifically proven.

So, has any progress been made?

Until Health Canada provides a new proposal document (expected in 2018) it is difficult to fully answer this question. Will it strengthen or limit consumers' ability to make informed choices? We still don't know.

Although Health Canada has presented various options at the town halls and consultations, they have been reluctant to share, officially, more detailed information. This includes the various presentations made at the recent town halls. The reason Health Canada cites for this is that the process is ongoing and that until they have reached a final proposal, they don't want to confuse participants in the consultation.

From the presentations made at the various town hall meetings, it does seem that Health Canada have identified product quality as an important topic, especially as it relates to good manufacturing practices and site licensing. In addition, the importance of accurate labeling, the role of product identification numbers and the need to ensure that consumers have the necessary information to make informed choices have been identified as key.

Despite having gone through a number of iterations, the presentations consistently present the idea of a three-category system within one regulatory approach. This concept still implies that similar claims should be based on similar forms of evidence and that "scientific" evidence will be needed to support therapeutic claims. The fundamental role of traditional and historic evidence in supporting product claims and informing consumers is still uncertain.

So, what do you think?

From what we have seen to date, Health Canada still wants to make quite radical changes to how NHPs are regulated in Canada—a lengthy and detailed process. If this is the case then, just as when the NHP regulations were developed, Health Canada will need to publish exactly what they are proposing in the *Canada Gazette I* and then provide a limited time for Canadians to respond with their comments. Health Canada will also need to conduct a detailed analysis of what impact any changes will have on the NHP sector.

Big questions still need to be answered before any formal regulatory changes are seen. Most notably, the importance of evidence from traditional forms of health and healing in a multicultural Canada, the role of product identifiers, and what exactly needs to be on a product label. Hopefully these questions will be answered by Health Canada and if changes to the regulations or guidelines are proposed that they will share a new official and complete proposal so that Canadians know the plans for the future. If changes are to be made, they should not be rushed.

Though I still commend Health Canada for highlighting the importance of self-care products and agree with the need to update the current dated regulations for non-prescription medicines and cosmetics, do we really need to radically overhaul NHP regulations that only came fully into effect a few years ago? It does seem that what is being proposed is to replace a three-category system (cosmetics, NHPs and non-prescription drugs) with another three-category system that could end up capturing the exact same set of products.

Though the current NHP regulations are modern, "state of the art" regulations, they are not perfect. After being in force for a number of years, we now know what works and what doesn't. We have an opportunity now to fix any problems as well as use lessons learned from the *NHPR* in updating the regulations for cosmetics and non-prescription medicines. This, in my opinion, is where the focus should be.

You can keep up to date with developments as well as the dates and times for the town-hall meetings by going to https://www.canada.ca/en/health-canada/topics/self-care-products.html. This is an opportunity for you to make your opinions heard.

About the author: Dr. Michael Smith is trained as a pharmacist and a naturopathic doctor and is recognized internationally as an expert in NHPs and Complementary and Alternative Medicine. For more than 10 years, he worked in senior regulatory positions at the then Natural Health Products Directorate, Health Canada and the Therapeutic Goods Administration in Australia. In addition to his work as a consultant, he is an Adjunct Professor at the National Center for Natural Products Research at the University of Mississippi in the USA and an Adjunct Fellow at the National Institute of Complementary Medicine at Western Sydney University in Australia. Michael is a member of ISURA's Scientific Advisory Committee.