Council for Responsible Nutrition
The Science Behind the Supplements

October 23, 2016

Health Canada
Health Products and Food Branch
Natural and Non-Prescription Health Products Directorate
250 Lanark Avenue, A.L. 2003C
Ottawa, Ontario K1A 0K9
Attention: Consultations
Email: nnhpd_consultation_dpsnso@hc-sc.gc.ca

RE: Consulting Canadians on the Regulation of Self-Care Products in Canada[1]

The Council for Responsible Nutrition (CRN)[2] is one of the leading global trade associations for the dietary supplement and nutritional products industry, representing manufacturers of dietary ingredients and national brand name and private label dietary supplements, many of which are multinational and already actively selling ingredients, finished products and services internationally. CRN membership is made up of many companies that sell into Canada, as well as Canadian companies selling into the U.S. and beyond.

[1] http://healthycanadians.gc.ca/health-system-systeme-sante/consultations/selfcare-autosoins/index-eng.php

[2] The Council for Responsible Nutrition (CRN), founded in 1973 and based in Washington, D.C., is the leading trade association representing dietary supplement and functional food manufacturers, marketers and ingredient suppliers. CRN companies produce a large portion of the functional food ingredients and dietary supplements marketed in the United States and globally. Our member companies manufacture popular national brands as well as the store brands marketed by major supermarkets, drug stores and discount chains. These products also include those marketed through natural food stores and mainstream direct selling companies. CRN represents more than 150 companies that manufacture dietary ingredients, dietary supplements and/or functional foods, or supply services to those suppliers and manufacturers. Our member companies are expected to comply with a host of federal and state regulations governing dietary supplements and food in the areas of manufacturing, marketing, quality control and safety. Our supplier and manufacturer member companies also agree to adhere to additional voluntary guidelines as well as to CRN's Code of Ethics. Learn more about us at www.crnusa.org.

INTRODUCTION

CRN appreciates the work of Health Canada on the proposal to examine the way self-care products are regulated in Canada. The current system in Canada, is a respected reference point when it comes to the regulations surrounding natural health products (NHPs), having been built in a logical and step-wise fashion through many years of substantive and interactive consultation and engagement with all affected stakeholders. Though there is always the opportunity for measured improvement, the proposal as outlined in the "Consulting Canadians on the Regulation of Self-Care Products in Canada[1]" (hereafter also referred to as the "Proposal") seemingly turns back the calendar, and starts from scratch in re-engaging with stakeholders, and it will substantively affect the ability of Canadians to make informed choices on the products they have relied on and that the industry has earned over the last decade under the current regulations.

CURRENT NHP PROCESS

The current NHP regulations are already risk-based and require substantive scientific support for the safety of the ingredients/products, and the efficacy/claims being touted in labeling. The original mission statement of the NHPD was "…to ensure that all Canadians have ready access to natural health products that are safe, effective, and of high quality, while respecting freedom of choice and philosophical and cultural diversity." NHPD's document describing how NHPs were to be evaluated for quality, safety, and efficacy, Charting A Course: Refining Canada's Approach to Regulating Natural Health Products, states that "The pre-market evaluation of a NHP must be based on an analysis of the benefits and risks associated with each product; the higher the risk, the greater the level of evidence required. Conversely, where the risk is low, evidential standards should be less onerous." This is entirely in line with the public concerns and risk-based approach proposed by the new system. ***It is not clear where the real basis for concern lies, because the NHP system already comprehensively addresses quality, safety, and efficacy through existing risk-based evaluations.***

The current NHP regulations balance the importance of scientific thinking with understanding and respect for traditional forms of health and healing. Canada is a multi-cultural society, and all Canadians should have the ability to explore and use with confidence, all currently allowable concepts of wellness. Restricting choices to only those categories and products that are approved via existing scientific paradigms that appear to mimic rigorous and inappropriate conventional pharmaceutical testing, is a disservice to Canadians wishing to exercise informed choice and reliance on traditional modalities. Philosophical and cultural distinctions and differences need to be embraced and not curtailed in the name of "pharmaceutical" science.

The current NHP regulations need to be enforced, especially in regards to the quality of the ingredients and final products available to consumers, and consumers need to be further educated on the different categories of products and how they fit with both traditional and contemporary health and wellness programs, at the individual and societal levels. The focus must be on educating Canadians about existing NHP Regulations, not reinventing them.

PROPOSED NHP PROCESS

GENERAL

The Proposal lacks significant detail regarding how ingredients, such as probiotics and botanicals are meant to be regulated under the new regime and how the over 100,000 existing approved NHP product licenses will be treated. Changing the current NHP Regulations is an expensive attempt to fix a system that is not broken.

The Proposal alludes to scientific evidence. However, the Proposal does not clarify the type, scope or amount of data that would constitute this scientific evidence. The levels of scientific evidence and their classification that was previously employed by Health Canada are well defined (Reference: Chapters 3, 4 and 5 of the Guidance document for Evidence of Safety

and Efficacy of Finished Natural Health Products[3]). Confirmation is needed that this classification of Scientific evidence and its ranking would still be used going forward by Health Canada in its reviews.

The Proposal already refers to NHPs as self-care products despite its being a ***proposal*** *t*o convert NHPs into self-care products (Second paragraph under "2. Objective of the Consultation Paper). The Proposal implies several times that NHPs are not scientifically evaluated and that NHP product claims are not based on scientific proof. This concern seems pointed at products having traditional use claims, which, in their defense, are based on the scientific findings of earlier generations and decades of safe use, and the NNHPD monographs for which are as painstakingly referenced as those of more "modern" ingredients; furthermore, the claims themselves clarify the "traditional use" distinction for consumers. The document seems critical of the fact that NHPs may not meet the evidence requirements of OTC medications without seeming to wonder whether it is appropriate to expect or require NHPs to do so. It further pronounces that self-care products may contain new or higher risk ingredients or make claims to treat serious medical conditions. ***It seems to be declaring that some party finds the NNHPD inadequate to meet the requirements of as-yet-uncommunicated 'self-care product' standards.***

TRADITIONAL MEDICINE

It is recognized that Health Canada respects the validity of traditional healing paradigms such as Ayurveda and Traditional Chinese Medicinal practices. This is evident from a number of NHPD's published Monographs that clearly allude to use of various herbs in their traditional paradigms (e.g., *Angelica sinensis* and its use in Chinese Medicine for tonification and blood harmony is the only claim supported by the published Monograph[4]). ***Based on this history of use and the long-standing position of Health Canada on such claims, clarification is needed in***

[3] Pathway for Licensing Natural Health Products Making Modern Health Claims; http://www.hc-sc.gc.ca/dhp-mps/prodnatur/legislation/docs/modern-eng.php

[4] Monograph: Dong quai – Angelica sinensis; http://webprod.hc-sc.gc.ca/nhpid-bdipsn/monoReq.do?id=842&lang=eng

the Proposal from Health Canada that statements alluding to traditional use would remain acceptable for self-care products in the future.

RISK CATEGORY

The Proposal stresses a new "risk-based approach", but the current NHP regulations already embrace these principles as there are Class I, Class II and Class III Product License Applications (PLA) with different review processes in place, based on how established the safety and efficacy information is. Risks related to safety and efficacy includes potential risks due to:

- An ingredient's physical or chemical form;
- The seriousness of the health claim and the conditions of use implied; and
- The health impact from lower than expected performance of the product.

A risk-based assessment approach is currently used to categorize evidence recommendations into three levels of risk: low, medium, and high. These levels are proportionate to the standard of evidence necessary to support safety and efficacy of a product[5].

It is recognized that there are certain health conditions that require intervention from a trained and licensed health care practitioner and are not suitable for self-care (e.g., treatment of myocardial infarction, osteoarthritis, etc.). It is also evident that statements such as "supports cardiac health" or "helps maintain kidney function" are broad all-encompassing terms that refer to a wide spectrum of health conditions, including those that are appropriate for self-care (e.g., use of Omega 3 fatty acids for improvement in lipid profile or use of methylsulfonylmethane (MSM) for relief from joint stiffness, etc.). According to the Proposal, products related to cardiovascular health would be considered "high risk" and thus subject to the strictest standards. ***As such, clarification is needed on the proposed risk category for products bearing language, such as cardiovascular (or heart) health or joint health, and that the appropriateness of the claim would be based on the claim statement as a whole.***

CLAIMS

[5] http://www.hc-sc.gc.ca/dhp-mps/prodnatur/legislation/docs/modern-eng.php#a23

The Proposal suggests redefining "health claims" to only include diagnosis, treatment, prevention, cure or mitigation of a disease (i.e., drug claims) and to exclude other traditional or structure or functional claims related to health maintenance and promotion (as stated in the Proposal; "Other claims, such as more general ones that speak to the function of a product, would no longer be considered health claims[6]"). ***Demeaning these currently allowed categories of claims would be confusing to consumers, as these claims are also related to health*** and the narrowness of the proposed definition (i.e., drug-style claims) would not align with international practices or the Canadian Food Inspection Agency[7] use of "health claims" made on foods (in Canada) and dietary/food supplements products on the international market.

The Proposal is misleading in indicating that "scientific evidence" is required for non-prescription drugs only and not for NHPs. Although there are differing standards of "scientific evidence" based on the type and strength of the claim, it is still "scientific evidence" and is misrepresenting the underlying science to consumers/general public as stated in this Proposal. Currently NHPs can make "health claims" with the details on category and level of evidence required such that they all satisfy "scientific credibility." The current NHP guidance states "A health claim is a statement that indicates the intended beneficial effect of a product when used in accordance with its recommended conditions of use. The term "recommended use or purpose" is often used interchangeably with "health claim" or "indications for use[8]." Categories include (1) serious disease/conditions, (2) major disease/conditions, (3) minor disease/conditions; and are further classified as those intended to help diagnose, treat or prevent a health condition or symptom (1-3 above), those intended to reduce the risk of a health condition or symptom (1-3 above), or those intended to have a more general health-related function. Products with general health claims include those that have low therapeutic impact and are therefore subject to the appropriate evidence requirements.

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[6] http://healthycanadians.gc.ca/health-system-systeme-sante/consultations/selfcare-autosoins/index-eng.php
[7] http://www.inspection.gc.ca/food/labelling/food-labelling-for-industry/health-claims/eng/1392834838383/1392834887794?chap=8.
[8] Pathway for Licensing Natural Health Products Making Modern Health Claims; http://www.hc-sc.gc.ca/dhp-mps/prodnatur/legislation/docs/modern-eng.php

Even recognizing that proposed claims categories are only vaguely described by the document, it is unclear where many current approved NHP claims would belong. It seems to classify by limited ingredient types and also by claims, but no example is provided for typical NHP ingredients such as botanicals or probiotics—leaving consumers and industry to wonder and worry about what will happen to their products. The questionnaire at the end (purporting to improve user-friendliness) asks questions that imply that the functions mentioned are not currently performed, e.g., "What are your thoughts on the proposal to require scientific data…/…having a product identifier number/…proposed safety oversight? The statement that "We may also need to explore whether our current powers and authorities are sufficient…" is concerning, and a much clearer presentation of intentions should be made public, particularly considering that the Inspectorate division has enforcement authorities including regulatory stop-sale, search and seizure, injunctions, license withdrawal, public advisory, detention, etc. A final concern comes from the fact that, it has taken 10 years to completely implement the current Canadian NHP regulations; how many more years will industry and consumers face under this proposal?

The Proposal states that consumers may believe that products situated in proximity in stores are equally effective, and seems to critique NHPs repeatedly because a lower percentage of consumers consider themselves well-informed when buying NHPs as compared to "other" self-care products (OTCs and cosmetics). Neither shelf proximity nor percentage considering themselves well-informed seems a reasonable basis for determining that NHPs need to be regulated in any different way (to which they refer, in further diminution of NNHPD, as "modernization"). The proposal further claims that concerns over "failed efficacy" are meant to be addressed by the new system, but provides no detail regarding how "failed efficacy" is meant to be evaluated, not to mention whether the proposed user fees will be sufficient to discover or track it. "Failed efficacy" is common enough among prescription drug users that we routinely refer to them as "non-responders;" besides which, NNHPD already performs post-market surveillance on NHPs. The document mentions "new medicinal ingredients," which

would seem to refer to "modern" NHP ingredients, since the main drug ingredients covered by the new plan are OTCs, which hardly constitute 'new' ingredients***. This clearly implies that NHP ingredients could be viewed as conventional medicines and regulated thusly.***

Changing the way NHPs are regulated will have a huge impact on the products found on store shelves. Requiring the same level of evidence as a drug, which is necessary for products developed in a laboratory, is not reasonable for NHPs when considering they are derived from nature, in many cases have been used for thousands of years, and are extremely low-risk.

RECOMMENDATIONS

Health Canada has garnered a substantial level of trust in the consumer sector. It is unclear from the Consultation Document whether consideration has been afforded to the impact of the proposed statement "Health Canada has not reviewed the product for effectiveness" on consumer perceptions. While other jurisdictions have used similar statements (e.g., U.S.), it must be recognized that Health Canada has a unique standing as a regulator in the way it regulates NHPs and vetting by Health Canada for safety and efficacy and quality provides product legitimacy in the marketplace. In the absence of solid evidence that the legitimacy is misplaced, forgoing review and compelling a company to add this statement may lead to confusion in the market place and could give rise to a sense of vulnerability and the notion of *Caveat emptor* in Canadian consumers. ***If not already done, it is recommended that Health Canada conduct consumer insight studies (consumer panels, etc.) assessing whether forgoing reviews and addition of the disclaimer would lead to buyer insecurity when it comes to such products.*** Further, a public education initiative to inform and educate consumers about the regulatory frameworks for all self-care products including NHPs should be part of any new proposal as well as current regulations. This will support the consumers' ability to make informed choices.

Recommend to better align "health claims" definition with international practices. For example consider including or referring to the Codex Alimentarius[9] definitions for "health claims" (i.e., nutrient function, other function and reduction of disease risk) and further to not conflict with the Canadian Food Inspection Agency[10] definition of "health claims", i.e., those listed on the "Table of Acceptable Nutrient Function Claims[10]."

Recommend to align "good manufacturing practices (GMPs)" for NHPs more strongly, more consistently and with more reciprocity with U.S. GMPs[11,12,13] for dietary supplement products, and in maintaining the current Health Canada approach as it relates to inspection and compliance.

CONCLUSION

Without question, "self-care" is an important concept and Health Canada should be commended for recognizing that the consumer/general public can and should have a hand in personal wellness. Further, Health Canada should be applauded for giving serious thought and priority to refining the regulatory framework. After significant work and considerable investment from both the private and public sectors, Canada has a regulatory framework for NHPs that blends the need for science with a respect for traditional forms of health and healing, that is globally respected and is reflective of multicultural Canada. The opportunity now exists to further support Canadians in making informed decisions about their self-care options by

[9] Codex Health Claims: http://www.fao.org/fao-who-codexalimentarius/sh-proxy/en/?lnk=1&url=https%253A%252F%252Fworkspace.fao.org%252Fsites%252Fcodex%252FStandards%252FCAC%2BGL%2B23-1997%252FCXG_023e.pdf.

[10] Canadian Food Inspection Agency Health Claims: http://www.inspection.gc.ca/food/labelling/food-labelling-for-industry/health-claims/eng/1392834838383/1392834887794?chap=8.

[11] http://www.fda.gov/Food/GuidanceRegulation/CGMP/ucm079496.htm.

[12]http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/DietarySupplements/ucm238182.htm.

[13] https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=111.

building on successes, updating where necessary to address issues, and importantly educating consumers and practitioners about what the regulations for all self-care products actually mean. The Objective of the Consultation Paper is that "Health Canada wants Canadians to be able to trust that self-care products are safe and do what they claim to do" and for the category, natural health products, this can best be done by supporting and refining the current regulatory framework. Based on the Proposal rationale, it appears that education of current substantiation standards is what is needed rather than an overhaul of current system.

Should Health Canada have further questions that CRN and CRN Members could address, please do not hesitate contacting me at your earliest convenience. CRN and CRN Members await a review of subsequent drafts.

Respectfully submitted,

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