REPORT OF ONLINE CONSULTATION ON MODERNIZING THE REGULATION OF SELF-CARE PRODUCTS IN CANADA (March 2017)

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Executive Summary

Context

Health Canada launched an online consultation on September 7, 2016, which closed on October 24, 2016, to provide Canadians with the opportunity to participate in the early discussions on a proposal to modernize the way self-care products (namely cosmetics, natural health products [NHPs], and non-prescription drugs [NPDs]) are regulated in Canada. Participants included consumers, industry, healthcare providers (including homeopaths, naturopathic doctors, and traditional medicine practitioners), academics, public interest groups, federal and provincial government representatives as well as all others who have an interest in the proposal. The input from this consultation will be used to inform further development of the proposal as well as to help shape other consultation activities to take place in the months to come.

The consultation document and questionnaire centered on the following themes:

A) Risk-Based Approach to Self-Care Products;

B) Health Canada Approval of Health Claims Only;

C) Use of a Disclaimer;

D) Unique Product Identifiers;

E) Compliance Monitoring and Addressing Inconsistencies in Post-Market Powers; and

F) Suggestions for Modernizing the Regulation of Self-Care Products.

The consultation generated 3,567 responses, of which 2,588 were from participants who self-identified as consumers. Participants were invited to read the consultation document for background information before answering the questionnaire.

Of the total number of responses received, 3,300 were submitted via the online questionnaire. The remainder were submitted via mail or email, and included 129 from consumers, 93 from industry, 29 from healthcare providers, 6 from public interest groups, 6 from academics, and 4 others.

Overall, there was a significant response from individuals and groups with a specific interest in NHPs.

By its nature, the feedback comprises the views of individuals and groups who were aware of the consultation and chose to participate. Thus, the results reflect the views and priorities of these individuals and groups but cannot be generalized to the wider population of Canadians with any known degree of accuracy.

A Diverse Perspective

The consultation feedback demonstrates widely divergent views of the proposed modernization and many questions which remain to be answered as the process unfolds. Participant views range from strong support for the principles and concepts included in the proposal to significant concern about the potential impact of the proposed changes, especially on NHPs.

Many participants in the consultation see considerable value in the clarity that would be provided by a single regulatory approach to the three affected areas of regulation (i.e. cosmetics, NHPs, and NPDs). The primary benefits they see are increased consistency and reliability of the information provided to consumers. They also welcome increased predictability and consistency for manufacturers.

Conversely, there are also many participants who have significant concerns about the proposed approach. These participants are worried that the proposed approach may reduce the range of NHPs available to consumers, either by explicitly prohibiting certain products or by discouraging manufacturers from bringing new products to the marketplace.

Echoing Health Canada's position from the start of this modernization work, the general agreement among participants, including those in the NHP sector, is that self-care products should not be regulated in the same manner as prescription drugs.

Participant reactions to the initial outline of the proposal reflect the need for additional information and details about how the proposed approach would function. This includes greater detail about how products would be classified and what types of evidence would be required to support claims in certain classes.

A) Risk-Based Approach to Self-Care Products

Generally speaking, most participants support the concept of better tailoring regulatory oversight to each product (or product class) based on the degree of potential risk it poses to consumers. They acknowledge that a risk-based approach makes sense because it will allow regulators to focus surveillance and enforcement action and resources on products with higher risk profiles while ensuring a transparent and predictable process for regulated parties that provides for appropriate oversight over lower risk products. However, there is considerable diversity of opinion among participants regarding how a risk-based approach should be implemented. Many from the NHP sector feel the current approach to these products is already sufficiently risk-based and are concerned that the proposed approach represents an unnecessary change. However, others in the NHP sector indicate that similar products (e.g. sunscreens, toothpastes, medicated shampoos, acne creams) as presently regulated are subject to different rules and oversight and acknowledge that there is disparity in the current system. Other participants are concerned that the proposed risk-based approach when ultimately implemented may not be sufficiently rigorous to prevent or identify problems that could potentially emerge (e.g. with those self-care products that would warrant a lower level of oversight under the proposed approach).

B) Health Canada Approval of Health Claims Only

The proposed requirement for scientific proof to support health claims is met with a polarized response. Support for this proposal is based on the view that a requirement of scientific evidence for health claims would provide clarity and certainty for Canadian consumers and reduce the frequency of false or misleading health claims. However, many participants from the NHP sector are not supportive of this proposed requirement for scientific proof to support health claims, fearing that it would negatively affect the affordability, availability and diversity of these products.

C) Use of a Disclaimer

On this topic, there is no clear consensus among participants regarding the use of a disclaimer on products to identify when health claims have not been reviewed by Health Canada. Participants who are supportive of the proposal to use a disclaimer suggest it would add clarity for consumers on whether claims have or have not been reviewed by Health Canada, leading to more informed purchasing decisions. However, there is considerable concern that such a disclaimer could raise doubts among consumers about the efficacy or safety of some products.

D) Unique Product Identifiers

Participants are somewhat divided regarding the utility of placing an identifying/tracking number on products with no authorization number (i.e. products that would not be reviewed or approved by Health Canada before being sold), as presented in the proposal. There is uncertainty about how this product identifier would interact with the current NPN/DIN-HM/DIN numbering and whether it would replace or duplicate their function. Some

even question whether it would be needed at all to meet the stated objective. Support for a unique product identifier derives primarily from the view that it would be a positive step to assist with compliance and enforcement, post-market surveillance, product recalls and traceability, and to differentiate self-care products from prescription drugs.

E) Compliance Monitoring and Addressing Inconsistencies in Post-Market Powers

Participants agree with the objective of ensuring that the products used by consumers are safe, effective and of high quality. There is nonetheless concern that the proposed approach may impose post-market requirements that would reduce the availability of current products or the number of new products brought to market. Regarding enforcement, some participants feel that current powers held by Health Canada are adequate to protect Canadians. In contrast, other participants feel the proposed approach is not robust enough and would prefer a more rigorous and restrictive approach. They cite inconsistencies in Health Canada's current post-market powers, including differing or lack of powers for mandatory recalls and for compelling label changes and differing fines for similar products when a company fails to follow certain rules.

F) Suggestions for Modernizing the Regulation of Self-Care Products

Asked to identify steps Health Canada may take to improve confidence in a new regulatory approach to self-care products, respondents provide a number of suggestions, including:

- Addressing allergen concerns
- Ensuring warnings are clearly stated on packaging
- Conducting a risk-assessment of impacts and costs for the proposed approach
- Ensuring the proposed approach does not inhibit exports, Health Canada should work with stakeholders and international regulators
- Assistance from Health Canada to industry, especially smaller enterprises, to comply with regulatory requirements and fulfill responsibilities
- Transition planning should ensure that timelines, impacts and costs on the entire supply chain are considered and addressed
- Public education
- Increased transparency from Health Canada
- Additional consultations similar to those used to develop/inform the current NHP regime

Mobilization Campaigns

The consultation attracted a significant response from individuals and groups with a specific interest in NHPs. This response volume was driven to some extent by two public mobilization campaigns.

Introduction

Health Canada launched an online consultation on September 7, 2016, which closed on October 24, 2016, to provide Canadians with the opportunity to participate in the early discussions on a proposal to modernize the way self-care products are regulated in Canada.

The approach presented in the consultation included the following main proposals:

1. Products of similar risk profiles would be treated in a similar manner.
    - This would ensure rules for bringing products to market would be:
        - more consistent
        - easier to understand
2. Health Canada would review claims based on a new definition of health claim.
    - Companies would require scientific proof to support these claims.
3. A risk-based approach to compliance and safety monitoring would continue.
    - This would allow Health Canada to continue to take quick action to protect consumers.

Participants included consumers who use these products, industry, healthcare providers (including homeopaths, naturopathic doctors, and traditional medicine practitioners), academics, public interest groups, federal and provincial government representatives as well as all others with an interest in the proposal.

Canadians were invited to provide input to Heath Canada in any manner they chose. To encourage and facilitate participation, Health Canada provided an online questionnaire (Appendix A). Nonetheless, feedback was also welcomed in the form of email, mail, telephone calls or written submissions. All the input received was synthesized to provide a single, comprehensive report.

The consultation document and questionnaire centered on the following themes:

A) Risk-Based Approach to Self-Care Products;

B) Health Canada Approval of Health Claims Only;

C) Use of a Disclaimer;

D) Unique Product Identifiers;

E) Compliance Monitoring and Addressing Inconsistencies in Post-Market Powers; and

F) Suggestions for Modernizing the Regulation of Self-Care Products.

The input from this consultation will be used to inform further development of the proposal as well as to help shape other consultation activities to take place in the future.

For reference, the consultation document is available online on the Government of Canada website.

Consultation Approach

The online consultation generated 3,567 responses. The primary vehicle used by participants was an online questionnaire.

The questionnaire invited participants to read the consultation document for background information before answering the questions. All questions in the questionnaire were optional except those used to identify respondents as consumers, healthcare providers, industry, academics, public interest groups, or government officials. Not all participants who used the questionnaire answered every question or section.

Response and Respondent Profile

Health Canada received 3,300 responses to the questionnaire and another 267 submissions which included written documents and comments submitted via email or mail.

The breakdown of questionnaire and mail/email responses by sector was as follows:

Respondent Type	Online Questionnaire	Email/Mail Responses	Total
Consumers	2,459	129	2,588
Public Interest Groups	12	6	18
Healthcare Professionals and Healthcare Professional Groups	418	29	447
Academia	50	6	56
Industry and Industry Associations (e.g. manufacturer, importer, distributor, health food retailer)	132	93	225
Federal Government Officials	15	1	16
Provincial Government Officials	2	1	3
Other (e.g. student, municipality)	212	2	214
All	3,300	267	3,567

Methodology

It is important to state that this was not a scientific survey, and as such the following is an objective summarization of the comments received. Every questionnaire comment, submission, response and letter was read and considered. Intersol used both qualitative and quantitative methodologies to summarize the feedback received. In reporting this feedback, Intersol gave appropriate consideration to organizations and associations who speak on behalf of a large number of members.

The questionnaire responses included a significant amount of text which was parsed and categorized systematically, in order to represent a fair and accurate summary of stakeholder input. The following four-step methodology using basic content analysis techniques was used:

- First, all the input was compiled into a single database, organized by question.
- Second, a list of the different and distinct views expressed by one or more stakeholder was compiled and categorized.

- Third, the content of the results of each question was “coded” into categories to provide numerical summaries. If a particular stakeholder respondent took a particular position, this was noted in the database in order to count the occurrences of specific views. Counting the occurrence of specific views does not imply equivalent value of the views of all stakeholders, nor does it imply that these numerical results might be generalized to the wider stakeholder population. Instead, this approach ensures an accurate picture of the feedback provided by stakeholders. The coded data was thoroughly reviewed to identify important variations in the underlying patterns and help support higher level themes.
- Finally, results were synthesized into this written report.

Following the summarization of the responses to the questionnaire, Intersol also compiled and reviewed the 267 other stakeholder submissions received and integrated these findings into this report.

The report provides an overview of all feedback in each of the six themes discussed, as well as insight into the feedback specifically provided by industry, healthcare providers, public interest groups and academics. It should be noted, however, that all of these sectors had diverse points of view. For example, the views of healthcare providers were typically differentiated between those who practice medicine and those who practice complementary medicine. Similarly, the industry perspective was often divided between the companies who manufacture only NHPs and those who manufacture NHPs as well as cosmetics and NPDs.

Key Findings

Context

This consultation process sought feedback from interested individuals and groups regarding the proposal for improving and modernizing the current regulation of self-care products. By its nature, the feedback comprises the views of individuals and groups who were aware of the consultation and chose to participate. Thus, the results reflect the views and priorities of these individuals and groups but cannot be generalized to the wider population of Canadians with any known degree of accuracy.

The consultation attracted a significant response from individuals and groups with a specific interest in NHPs. This volume was driven, to some extent, by organized mobilization campaigns. One such campaign was organized by a national industry association that provided a consultation response template for the use of stakeholders who shared the association's views. It is important to note that this association represents a subset of the NHP industry, not the entire sector. The impact of this campaign is examined in a later section of this report.

A) Risk-Based Approach to Self-Care Products

Consultation participants either support or accept the underlying concept that the regulatory framework should be better responsive to the level of risk related to each product. In other words, there is recognition that products which pose a greater risk of harm should receive greater scrutiny and be subject to more significant requirements.

However, there is considerable appetite in all sectors for greater detail about how a risk-based approach would affect specific products and classes of products. While many participants express opinions about the proposed approach, as noted below, many also indicate that more information will be required for them to fully assess the proposed changes.

Some participants - especially those from the cosmetics and NPD industry sectors and the medical professional sector - believe the proposed risk-based approach would be an improvement over the current regulatory system, which presently regulates similar products differently based on product definitions rather than risk to consumers. In contrast, participants concerned primarily with NHPs often feel the current approach to NHPs already incorporates a sufficient assessment of risk and does not need to be changed. They are concerned that the proposed approach may negatively impact the availability, cost and diversity of NHPs in Canada. They want Health Canada to build on the progress made in the regulation of NHPs over the past decade rather than starting afresh. To note, those participants whose interests encompass all self-care products (namely, cosmetics, NHPs, and NPDs) are largely supportive of a risk-based approach to self-care products and make suggestions for improvement in that regard.

Some participants express uncertainty about why a modernized risk-based approach is needed, and specifically what problem it is intended to address. This uncertainty is especially common among complementary healthcare providers, a segment of the NHP industry and some academics.

A somewhat smaller number of respondents are concerned that the proposed risk-based approach may not be sufficiently robust. Many in this group believe Health Canada should review all products (even lowest risk products) to ensure the safety of self-care products in Canada. They seek reassurance that the proposed approach would not expose consumers to risks related to products in the lowest risk category (Class I). Primary concerns in this regard are:

- False ingredient claims and predatory or misleading marketing practices;
- Failed efficacy of a product and the resulting harm to consumers if the product fails to do what it claims;
- Unreported presence of allergens;
- Generally low-risk products which nonetheless pose a greater risk for sub-populations, such as pregnant women or children.

At this early stage, there is no consensus that the proposed risk-based approach would create more confidence when purchasing self-care products.

Industry participants are especially interested in how the wide range of self-care products would ultimately be categorized within the proposed three classes and how disputes about classification would be adjudicated. One issue raised by industry is the suggested classification of all cardiovascular products in the higher risk Class III. There is also a view in industry that the lowest-risk products intended for Class I should be further divided to reflect the differing nature of such disparate products as cosmetics and vitamin supplements, for example.

The concept of a lowest risk category with less regulatory oversight is of concern to some healthcare providers and academic participants. They note that products which are innocuous on their own – such as vitamin and mineral supplements - may nonetheless pose a risk to consumers due to overuse or interactions with other products. Therefore, they do not want regulatory oversight to be relaxed for these products.

Traditional medicines pose a special challenge for participants when it comes to the proposed approach. On the one hand, healthcare providers and public interest groups express concerns about the validity of traditional claims and the sale of traditional remedies in new forms and for new purposes that do not necessarily reflect traditional use. On the other hand, a segment of the NHP industry and complementary healthcare providers are concerned that the proposed approach would prevent traditional medicines from making claims that they have been allowed to make in the past or present.

Healthcare providers, industry and some academic participants note that the proposal does not address the issue of product quality in significant detail. Adulteration and contamination are raised as concerns. They have questions about how a risk-based approach to self-care products would affect the quality requirements of products. Some suggest that manufacturing quality standards should be tied to product risk, requiring products with higher risk to comply with higher standards. However, healthcare provider participants with a special interest in allergens and contaminants are concerned about the presence of these substances in all products, regardless of class. They are therefore cautious about the idea of less stringent manufacturing standards for the lowest risk products.

Furthermore, some consumers and public interest groups stress the importance of robust post-market surveillance and enforcement to encourage and ensure compliance.

B) Health Canada Approval of Health Claims Only

Participant views on the proposed requirement for scientific evidence to support health claims are generally driven by expectations or assumptions about what types of evidence would be acceptable to Health Canada and what the threshold of evidence would be. That said, many participants express the desire for much more clarity on this proposal and how it would affect specific products and product types.

Support for this proposal is based on the view that a requirement for scientific proof of health claims would provide clarity and certainty for Canadian consumers. In other words, it would provide Canadians with information upon which to make informed choices among the products available to them. When these products are sold side-by-side in pharmacies and elsewhere, consumers may be confused or assume that similar health claims are always based on similar supporting evidence. Some academics and medical

professionals go further, to say that products should not be allowed to make claims of any kind which have not been scientifically proven.

Participants from a primarily NHP perspective are often not supportive of this proposal. Many of these participants are NHP consumers concerned that NHP manufacturers would no longer be able to make a claim due to restrictions related to the requirement for scientific proof of efficacy. They are concerned that this would have a negative impact on freedom of choice and result in a less diverse marketplace for health products. For example, they are concerned that some products would not be available while industry conducts tests and transitions to a new framework, while others could disappear entirely because companies could decide to stop making (or importing) certain products rather than comply with the regulatory changes. However, there is a segment of the self-care product industry, in particular those that manufacture all three types of self-care products, which supports the proposal with suggested modifications.

There is concern among consumers, complementary healthcare providers, the NHP industry and some academics that some NHPs, especially traditional medicines, would disappear or become more expensive because companies would not elect to invest in scientific research to support claims. Some of these participants note that evidence of efficacy need not necessarily be scientific evidence in all cases but may also include a range of other information including traditional knowledge and physician reporting. There is uncertainty in the homeopathic product sector regarding how its products would be affected by the proposed approach to claims. Some academics and public interest groups feel that homeopathic products should not be allowed to make claims at all.

Industry is interested in how standardized claims would be approved for lowest risk (Class I) products and the degree to which monographs would serve as an evidentiary basis.

C) Use of a Disclaimer

Participants are somewhat divided regarding the use of a disclaimer on products whose efficacy would not be reviewed by Health Canada under the proposed approach.

Participants who are supportive of the proposal to use a disclaimer often say it would add clarity for consumers on what claims Health Canada reviewed, leading to more informed purchasing decisions. However, these participants raise detailed questions and concerns about the implementation of this approach, especially regarding which products would be required to carry a disclaimer and the criteria that would be used to make that determination. Among those who are uncertain about this proposal, many are concerned that it does not go far enough to prevent the use of unproven or misleading claims.

Some healthcare providers express the view that the disclaimer may not be necessary or could be replaced with a positive statement (a ‘proclaimer’) for products whose efficacy would be confirmed by Health Canada.

Unsupportive responses are most common among participants primarily interested in NHPs. Many of these participants feel such disclaimers would be unnecessary and that the current regulatory approach to NHP labelling is adequate. Mirroring the response to evidence requirements discussed earlier, the participants are concerned that a disclaimer would confuse consumers, reduce consumer confidence in products which have information on traditional use to support efficacy, or inadvertently undermine confidence in the safety, efficacy and quality of NHPs. Again, there are some in the NHP sector, largely those that also have an interest in cosmetics and NPDs, who do acknowledge that the present approach for informing the consumer could benefit from some specific changes in an effort to facilitate informed consumer choice.

Regarding product labelling of traditional medicines, several participants suggest these products could also include a qualifier which would more clearly identify their traditional use. Alternatively, they could be treated

as a separate category of products in stores, separate from products whose claims are based on scientific evidence.

There is a considerable appetite among participants to better understand how this proposal would be implemented and the likely impact on manufacturers and consumers.

Finally, there are much wider concerns about label clarity in general and the perceived need for greater public education on how to read and use product labels when making purchasing decisions.

Beyond the use of a disclaimer, there are other concerns and suggestions regarding product labeling which focus on accuracy, legibility and usefulness. There is also some concern among academics and medical professionals that consumers may be influenced by messages which are not on the product label but are disseminated by other means, such as advertising or social media. This concern ties into a point, made by academics and public interest groups especially, that label wording is no substitute for public education on how to make informed purchasing decisions when buying self-care products.

D) Unique Product Identifiers

Participants are divided regarding the utility of placing a unique identifying/tracking number on Class I self-care products. The diversity of views reflects uncertainty about how the proposed product identifier would interact with the current NPN/DIN-HM/DIN numbering and whether it would replace or duplicate its function. Participants frequently ask for more information from Health Canada about this proposal.

Support for a unique product identifier derives primarily from the view that it would be a positive step to assist with compliance and enforcement, post-market surveillance, product recalls and traceability, as well as to more clearly distinguish between prescription drugs and self-care products.

Participants primarily interested in NHPs are mainly concerned about the financial impact on manufacturers and whether the use of identifying numbers would affect the availability, diversity and cost of NHPs. The homeopathic products industry expresses concern that a new numbering system would create confusion in the marketplace. Other participants, such as those concerned with cosmetics, have a difficult time ascertaining the purpose and value of the proposal and see the suggestion as unnecessary for the purposes stated in the consultation document.

E) Compliance Monitoring and Addressing Inconsistencies in Post-Market Powers

Participants agree with the objective of ensuring that the self-care products are safe, effective and of high quality. There is no consensus, however, that the proposed approach would do a better job of achieving this goal than the existing approach.

Those respondents who do not believe that the proposed approach would allow them continued access to quality, safe and effective products generally say that it would be too restrictive and/or that the current approach is adequate. Respondents with a specific interest in only NHPs are mainly concerned about whether this approach would affect the availability, diversity and cost of NHPs. They worry that the proposed approach would be too onerous for NHP manufacturers. Regarding enforcement, they also feel that current powers of enforcement held by Health Canada are adequate to protect Canadians.

Others in the NHP sector, who in addition to NHPs also have an interest in cosmetics and NPDs, do not share those same concerns or assumptions, support this proposal in principle, and tend to ask for more detail on the improvements being sought.

Furthermore, a number of respondents support the direction of this proposal but feel the approach is not robust enough. They would prefer a more rigorous and restrictive approach, citing inconsistencies in Health

Canada's current post-market powers, including differing or lack of powers for mandatory recalls and for compelling label changes and differing fines for similar products when a company fails to follow certain rules.

With regard to post-market surveillance, industry suggests increased consumer education, increased training for inspectors, and support for industry compliance. There is also a desire for transparency on post-market enforcement actions and/or a third-party "watchdog" to monitor enforcement and compliance.

There are diverse views about the idea of linking site inspection frequency to the risk of the product being manufactured. While many participants support the underlying idea that the frequency of site inspections should be related to risk, participants also note that product risk should not be the only criteria affecting inspections. They identify other factors which should be considered when assessing risk. These include the compliance history of the company involved, the manufacturing process, and consumer complaints. As noted earlier, healthcare provider participants concerned about allergens and contaminants see this as a quality issue which exists regardless of product risk.

Another concern raised primarily by academics and public interest groups is that because the proposed change would mean the lowest-risk products would no longer be reviewed, the onus would be on companies to provide information that identifies the risk category of their products, giving them too much influence over how often they would be inspected.

A minority of participants say that all sites should be inspected regardless of the product's risk category. In contrast, there is also a view among some participants that NHP manufacturers would not need to be inspected at all as their products are low-risk with a long history of safe use. In general, the NHP industry notes that any inspection process should reflect the specific nature of NHPs, which may be different than the approach used for other types of products, such as prescription drugs and NPDs.

F) Suggestions for Modernizing the Regulation of Self-Care Products

With so many details yet to be defined and clarified at this early stage, some participants are not convinced that the proposed approach would address the concerns they have about how self-care products are currently regulated. Many participants with a specific interest in NHPs see the current regulatory system for NHPs as being adequate and not needing improvement; however, this sentiment is not shared by all in the NHP sector, specifically not shared by those who in addition to NHPs also market cosmetics and NPDs.

Asked to identify steps Health Canada may take to improve confidence in a modernized regulatory approach for self-care products, participants often stress the value of a cautious and comprehensive approach, including consultations with industry, impact assessments and pilot projects, to ensure the proposed approach, if implemented, does not create unintended negative consequences for consumers or industry. Participants provide a number of additional suggestions listed in the following paragraphs.

- **Additional consultation** should be undertaken once details of the new approach are developed. Health Canada should seek opportunities to invite, hear and consider diverse points of view as it undertakes its decision-making processes.
- **Conduct a risk-assessment of impacts and costs for the NHP industry.** Some NHP stakeholders want a detailed analysis of potential impacts on different segments of the NHP industry so that appropriate measures to mitigate negative impacts can be developed.
- **Transition planning** should ensure that timelines, impacts and costs on the entire supply chain are considered and addressed.
- To ensure the new approach does **not inhibit exports,** Health Canada should work with stakeholders and international regulators.

- Health Canada should address **allergen concerns** which are a health risk for some sub-populations. The new approach should ensure labeling is truthful, accurate and complete (e.g. all ingredients are disclosed).
- Health Canada should ensure that **warnings** are clearly stated on the packaging if there is any risk to human health of excess dosage and/or interactions with other nutrients, drugs, or foods.
- Government should **assist industry**, especially smaller enterprises, to comply with regulatory requirements and fulfill responsibilities. Regulations should not burden smaller businesses or create an advantage for larger companies.
- **Increased transparency** is needed for an approval process and ongoing monitoring and surveillance. Health Canada's website should clearly describe the process for introduction of a self-care product to market, and a description of the oversight approach (monitoring, reporting, enforcement, fines issued, etc.). This would allow Canadians to better understand how and why decisions are made to make well-informed decisions about their health.
- A **public education** effort by government, industry and stakeholders is needed to educate consumers on changes to the product marketplace and avoid unintended impacts. This effort should include healthcare providers, as they are a key source of information for consumers. This type of campaign would assist consumers and stakeholders in understanding the new regulations. The government should leverage opportunities to work with partners and other stakeholders.

Mobilization Campaigns

Health Canada is aware of two public mobilization campaigns which were undertaken during the online consultation period.

First, a petition was developed and publicized that urged the Prime Minister and Cabinet Ministers to protect the interests of local producers of medicinal herbs against limitations that might be imposed by a regulatory requirement for proof of efficacy. This petition received 1,514 signatures.

A second campaign, which implied that Health Canada is proposing to regulate NHPs as prescription drugs, encouraged members and supporters to complete the consultation questionnaire using elements from a template of answers which was created and published online. The group generally opposed all aspects of the proposed modernization and encouraged members and supporters who shared this view to respond to the consultation and use its template when doing so. The template provided clearly affected the overall tone and content of responses to the consultation questionnaire. In fact, of the 3,300 questionnaires completed by participants, 493 (or 15%) responded to six or seven of the seven closed-ended consultation questions exactly as the advocating group had proposed. An analysis of the open-ended responses provided by these participants also showed a close match to the text content suggested by the advocating group, which suggests that respondents may have taken their lead from the campaign.

The impact of this campaign on the overall results of the consultation cannot be discounted. The results of the campaign are important overall context for understanding the consultation results, as these respondents are typically exclusively interested in the future of NHPs under the proposed modernization rather than in the future of all self-care products. It is important to note that presently, when looking at cosmetics, NHPs and NPDs, the most modern set of regulations and the most risk-based regulatory structure is the one in place for NHPs. As such, it is possible that the potential benefits the proposed approach would bring are less evident for NHPs specifically when compared to cosmetics and NPDs.

Lack of Detail and Misconceptions

In Intersol's discussions with Health Canada, we understand that Health Canada chose to consult with Canadians at a very early stage to allow Canadians an early opportunity to influence the development of the policy proposal. Conversely, providing such an early policy proposal proved to be a challenge for some who commented that it lacked the specificity they would like to have seen.

The reaction from Canadians clearly shows that more detail is needed on how the proposed modernization would improve the regulation of self-care products. As well, a more greatly defined proposal could dispel misconceptions, for example that some products, such as turmeric, would be regulated in the same fashion as a prescription drug under the proposed approach.

As the fall 2016 consultation progressed, a need to clarify some aspects of the proposal emerged and to this end Health Canada published a 'myths and facts' information page regarding the proposed changes to the regulation of self-care products (https://www.canada.ca/en/health-canada/programs/consultation-regulation-self-care-products/myths-and-facts.html).

Moving forward, there is a need for more details on how products would be classified, how risk should be defined, and what types of evidence would be required to support claims.

Conclusion

Those who engaged with Health Canada during this consultation have provided valuable input to assist the Department in refining its proposal.

There is clearly a need for further detail on the proposed approach so that stakeholders may provide more specific feedback to Health Canada as the framework continues to be developed. Additional information will help to reduce uncertainty, resolve concerns and focus discussions on key outstanding issues moving forward.

Some in the NHP sector, including consumers, industry and healthcare providers, are looking for reassurance that a modernized approach does not represent a step back from the system built over recent years and that NHPs will continue to be available and affordable.

Other stakeholders, including large portions of industry and healthcare providers, seek reassurance that the regulation of self-care products will be evidence-based and provide appropriate protections for consumers regardless of a product's risk category.

In response to the input received through the consultation and the preparation of this report, Intersol understands that Health Canada has committed to undertake further consultations on the proposed approach for self-care products. Furthermore, Intersol understands that based on what was heard:

- Health Canada is already working to improve the proposal subject of the fall 2016 consultation;
- Health Canada will continue to draw on the strengths of the current regulation of self-care products in refining its proposal for a modernized approach that is consistent in application and more equitable for all – while continuing to afford Canadians with access to wide range of self-care products and improving their ability to make informed choices about the products they use; and
- As part of the continuing dialogue with Canadians, Health Canada will be holding in-person and online consultation sessions, on this subject, across the country in the spring of 2017.

To stay connected, visit www.Canada.ca/selfcare-products where updates on this initiative will be provided.

Appendix A – Consultation Questionnaire

Self-Care Products in Canada

Health Canada wants Canadians to be able to trust that self-care products are safe and do what they claim to do. In order to achieve this, Health Canada is examining new approaches to the regulation of self-care products (i.e., cosmetics, natural health products and non-prescription drugs), including refocusing the approval of claims to those based on scientific proof. A new approach will continue to allow for a wide range of products to be available for Canadian consumers, while, at the same time, taking a more consistent approach to the oversight of self-care products that will ultimately better support consumers' ability to make an informed decision.

Public opinion research conducted in April 2016 revealed that the Canadians surveyed do not consider themselves well-informed when purchasing self-care products. The survey revealed that only 19% considered themselves well-informed when purchasing natural health products, followed by 29% for cosmetics, and 37% for non-prescription drugs.

The Department is proposing a new Framework for self-care products. The approach will include the following 3 main proposals.

1. Products of similar risk profiles would be treated in a similar manner.
    - This ensure rules for bringing products to market are:
        - more consistent
        - easier to understand
2. The Department would review health claims based on a new definition.
    - Companies would require scientific proof to support these health claims.
3. A risk-based approach to compliance and safety monitoring will continue.
    - This allows Health Canada to take quick action to protect consumers.

As a component of Health Canada's ongoing efforts to enhance transparency and openness, this is an early opportunity to provide feedback on how this Framework will be shaped. We are only at the early stages in the development of the Framework, which allows for your input to make an impact on the future of how these products are regulated in Canada.

We want to hear directly from the consumers who choose these products, as well as from industry, health professionals, and all others who have an interest in this proposal. This consultation is intended to build on public opinion research conducted with 2,500 Canadians in April 2016. Health Canada will be conducting other activities in the months to come to learn more about the views of consumers, industry, health professionals, and other stakeholders. This discussion paper also builds on a previous consultation on consumer health products, for which more information can be found at: http://www.hc-sc.gc.ca/dhp-mps/consultation/natur/sum_chpf-som_cpsc-eng.php

Please note that familiarity with the current regulatory approach for natural health products, non-prescription drugs and cosmetics is not a prerequisite to participate in this consultation.

You may find more information on this proposal and background information on how these products are currently regulated by reading the entire consultation paper: https://www.canada.ca/en/health-canada/programs/consultation-regulation-self-care-products/consulting-canadians-regulation-self-care-products-canada.html.

This online consultation will remain open until **October 24th, 2016**.

If you have any questions regarding the consultation, please send them to: nnhpd_consultation_dpsnso@hc-sc.gc.ca.

To safeguard privacy, you should ensure that any written comments you may provide are sufficiently general that you cannot be identified as the author and that individual identities are not disclosed.

Category

The category that best describes your perspective is:

- ○ Consumer
- ○ Healthcare professional
- ○ Public interest group
- ○ Academic/researcher
- ○ Federal government official
- ○ Provincial government official
- ○ Cosmetic manufacturer
- ○ Non-prescription drug manufacturer
- ○ Natural health product manufacturer
- ○ Other (please specify) _____

Risk-Based Approach to Self-Care Products

Self-care products are generally lower risk in comparison to other health products regulated by Health Canada (like prescription drugs, for example) if you use them as intended, following the label directions. However,

within this family of self-care products there is a range of risk depending on the type of product, its ingredients, how it is meant to be used, and what is on its label. Many self-care products have a long history of use and have been shown to be safe under specific conditions. Therefore, these products do not need as much oversight by Health Canada before they go to market.

Other self-care products that contain new or higher risk ingredients or make claims to treat serious medical conditions require more attention by Health Canada. The Department is considering a new structure for classifying self-care products that would be based on a product's risk. In this case, the risk level of the product is determined by the safety of the product (i.e., certainty around safety under established conditions) and the level of concern of failed efficacy (i.e., the impact to the user if the product fails to do what it claims).

What do you think of the risk-based approach proposal for self-care products proposed in the consultation paper?

Under the proposed Framework, there would be a group of **lower risk self-care products** that would ***not*** be reviewed by Health Canada prior to going to market. They would already have established safety (based on their history of use) and would not be making any diagnostic, treatment, prevention, cure, or mitigation claims. Products in this category would need to meet requirements set by Health Canada about what the product can and cannot contain, what information needs to be on the product label, and what should be done to provide a product of good quality. For this category of products, Health Canada would not be reviewing each product, and therefore, these products would **not** be approved by Health Canada. Instead, companies would have to notify Health Canada that their product is on the market, and they would be responsible for following our standards. This model borrows some features from the one currently in use for cosmetic products.

At the other end of the spectrum, there would be a group of **higher risk self-care products** for which Health Canada would ***review*** the safety of the product and whether there is scientific evidence to support the claim about what the product will do. If the product meets the necessary standards, it would be ***approved*** by Health Canada and there would be a number on the product to show that it has been approved. Products in this category would include new ingredients, new claims, or new uses in at risk groups like children, or pregnant or breastfeeding women.

In the middle, there would be a group of **moderate risk self-care products** whose approval would be based on documents called monographs, which outline specific standards for products. In contrast to the lower risk self-care products which have standards for safety only, the monographs established for moderate risk self-care products also outline acceptable statements and conditions for what a product can say that it does (i.e., efficacy). Companies would need to meet these safety and efficacy standards. If they do, they would be ***approved*** for sale by Health Canada and there would be numbers on the products to show that they have been approved.

What do you think about Health Canada's proposal to group self-care products according to the above-mentioned levels of risk, i.e., risk-based grouping?

How would risk-based grouping impact your decision-making and your purchases of these products?

- ○ More confidence
- ○ Less confidence
- ○ Same confidence
- ○ Not sure/Don't know
- ○ Other _____

Health Canada Approval of Health Claims Only

Health Canada, as a science-based regulator, wants to make sure that Canadians can trust that a standard has been met when we authorize a claim. We want to support consumers in making informed choices in selecting and using self-care products by providing them with the necessary information to do so. This means a proposal that redefines what is currently considered a claim and requiring scientific evidence to support these claims.

Under this proposal, only those claims that pertain to diagnosis, treatment, prevention, cure, or mitigation of a disease or serious health condition will be reviewed by Health Canada.

Other claims, such as more general ones that speak to the function of a product, would no longer be considered claims. Moving forward with such an approach would mean that Health Canada would only review and approve claims for self-care products as per the new definition. The reason is that if products with such claims do not do what they claim to do (e.g., not reducing a fever in children), there could be a risk to consumers. For these claims to be approved, companies would have to provide scientific evidence to support them. This would mean that two products making a similar claim, such as "relieves cough and cold," would have to provide the same level of scientific evidence.

What are your thoughts on the proposal to require scientific data in order to support a health claim?

- ○ Support
- ○ Do not support
- ○ Not sure/ Don't know
- ○ Other _____

If you do not support, please explain why.

Use of a Disclaimer

Companies could still bring a product to market that makes claims other than those five types of claims identified in the consultation paper. For example, a company could make a claim such as “source of omega-3” provided there are no safety concerns, and the claim is truthful and accurate.

Health Canada wants to provide Canadians with information that can assist them in making choices about health products and is exploring ways to do so. For products that are not reviewed by Health Canada for effectiveness, the Department is considering informing Canadians through the use of a disclaimer on the product label. This would allow consumers to do more research, if they wish, about those products. At the same time, under the proposed approach, Canadians would be able to have confidence in the claims present on products approved by Health Canada, as these would be reviewed by the Department and would have scientific proof to support them.

Health Canada is exploring ways to provide Canadians with information that can assist them in making choices about health products, including the use of a disclaimer on product labels to identify claims that are not reviewed by the Department. What do you think about this approach?

Would this type of information be helpful to you as a consumer?

Unique Identifiers for Products that Go to Market via Notification

The Department is also exploring the use of a unique "tracking" number or identifier for products with no authorization number (i.e., products that are not reviewed or approved by Health Canada before being sold). Such a number would not be used to indicate product approval and would not necessarily be included on the main display panel. The objective would be to enable a specific product to be quickly identified and traced. This is particularly important where products have the same or similar name but a safety issue occurs with only one specific product.

Do you think that a product identifier (i.e., a number on the product) is necessary to help consumers identify a product in the event that they wish to report an issue with a product?

- ○ Yes
- ○ No
- ○ Maybe

- ○ Not sure/ Don’t know
- ○ Other _____

Compliance Monitoring and Addressing Inconsistencies in Post-Market Powers

Compliance monitoring for health products means that Health Canada watches whether companies are following the rules. The Department already monitors products on the market and responds when a risk to the health and safety of Canadians is found. We propose to continue to do this in a way that is appropriate to the family of self-care products. The intensity of compliance activities would continue to be tailored for each of the three risk categories of self-care products. This means that as the potential risk of the product increases, Health Canada would apply more oversight to it. Our approach would continue to include a variety of actions, such as the inspection of facilities, responding to complaints about products, and testing of some products.

We may also need to explore whether our current powers and authorities are sufficient, or if additional tools are needed to enable Health Canada to do such things as order the removal of an unsafe product from the market, require a company to change a product label to reduce risks to consumers, or require a company to pay a fine when it does not follow certain rules.

Do you feel confident that the proposed safety oversight approach will allow you to continue accessing good quality, safe and effective products?

- ○ Yes
- ○ No
- ○ Maybe
- ○ Not sure/ Don’t know

If no, what are your concerns?

Do you believe that additional powers to change labels, require a recall and new penalties would help address safety issues and discourage companies from breaking the law?

- ○ Yes
- ○ No
- ○ Maybe
- ○ Not sure/ Don’t know

If no, why not?

Do you think the frequency of when a company is inspected should vary depending on the risk category of the product?

- ○ Yes
- ○ No
- ○ Maybe
- ○ Not sure/Don't know
- ○ Other _____

Suggestions for Modernizing the Regulation of Self-Care Products

Self-care products are generally lower risk in comparison to other health products (like prescription drugs, for example) regulated by Health Canada if you use them as intended, following the label directions. However, within this family of self-care products there is a range of risk depending on the type of product, its ingredients, how it is meant to be used, and what is on its label. Many self-care products have a long history of use and have been shown to be safe under specific conditions. Therefore, these products do not need as much oversight by Health Canada before they go to market.

Other self-care products that contain new or higher risk ingredients or make claims to treat serious medical conditions require more attention by Health Canada. The Department is considering a new structure for classifying and regulating these products. It would be based on a product's risk. In this case, the risk level of the product is determined by the safety of the product (i.e., certainty around safety under established conditions) and the level of concern of failed efficacy (i.e., the impact to the user if the product fails to do what it claims).

Do you feel that the proposed Framework addresses any concerns you have with self-care products?

- ○ Yes
- ○ No
- ○ Maybe
- ○ Other _____

What else could Health Canada include in the Framework to address your concerns?

Thank You

If there are any changes you would like to make to your responses, please do so now before you click the "Submit" button below.

Appendix B – Numerical Results

While feedback was welcomed in any form, a consultation questionnaire was provided so that respondents could provide feedback without preparing a written submission. Of key importance were the open-ended questions which allowed respondents to respond in their own words. However, there were also seven closed-ended questions. These closed-ended questions elicited an overall opinion and were usually followed by an open-ended question that asked respondents to elaborate on their view in their own words. The following tables summarize the results obtained from respondents in response to the closed-ended questions. The full preamble and wording for each question is provided in the main report.

Q4. How would risk-based grouping impact your decision-making and your purchases of these products?

Respondent Type	More confidence	Same confidence	Less confidence	Not sure / Don't Know	Other	Grand Total
Consumer	458	495	825	171	491	2,440
Healthcare professional	73	104	85	37	109	408
Natural health product manufacturer	6	22	36	11	24	99
Academic/researcher	20	5	7	7	11	50
Cosmetic manufacturer	2	12	4	6	3	27
Federal government official	4	3	4	1	3	15
Non-prescription drug manufacturer	2	1	0	1	1	5
Provincial government official	0	0	1	1	0	2
Public interest group	2	2	1	1	6	12
Other (please specify)	21	34	61	9	84	209
Grand Total	**588**	**678**	**1,024**	**245**	**732**	**3,267**

Q5. What are your thoughts on the proposal to require scientific data in order to support a health claim?

Respondent Type	Support	Do not support	Not sure/ Don't Know	Other	Grand Total
Consumer	723	1,365	124	228	2,440
Healthcare professional	138	213	19	44	414
Natural health product manufacturer	21	66	5	7	99
Academic/researcher	30	14	1	5	50
Cosmetic manufacturer	8	11	4	3	26
Federal government official	12	1	1	1	15
Non-prescription drug manufacturer	5	0	0	0	5
Provincial government official	1	1	0	0	2
Public interest group	2	5	1	4	12
Other (please specify)	41	106	13	52	212
Grand Total	**981**	**1,782**	**168**	**344**	**3,275**

Q8. Do you think that a product identifier (i.e. a number on the product) is necessary to help consumers identify a product in the event that they wish to report an issue with a product?

Respondent Type	Yes	Maybe	No	Not sure/ Don't Know	Other	Grand Total
Consumer	771	250	939	139	353	2,452
Healthcare professional	132	65	119	19	81	416
Natural health product manufacturer	29	8	31	0	32	100
Academic/researcher	27	7	8	2	6	50
Cosmetic manufacturer	1	3	18	1	3	26
Federal government official	9	0	3	0	3	15
Non-prescription drug manufacturer	3	0	1	0	1	5
Provincial government official	0	0	1	0	1	2
Public interest group	4	1	3	1	3	12
Other (please specify)	45	19	50	10	87	211
Grand Total	**1,021**	**353**	**1,173**	**172**	**570**	**3,289**

Q9. Do you feel confident that the proposed safety oversight approach will allow you to continue accessing good quality, safe and effective products?

Respondent Type	Yes	Maybe	No	Not sure/ Don't Know	Grand Total
Consumer	535	319	1,362	212	2,428
Healthcare professional	101	66	203	39	409
Natural health product manufacturer	20	10	61	9	100
Academic/researcher	17	6	24	3	50
Cosmetic manufacturer	10	1	14	2	27
Federal government official	4	3	6	1	14
Non-prescription drug manufacturer	3	0	2	0	5
Provincial government official	1	0	1	0	2
Public interest group	2	1	6	3	12
Other (please specify)	31	25	129	21	206
Grand Total	**724**	**431**	**1,808**	**290**	**3,253**

Q11. Do you believe that additional powers to change labels, require a recall and new penalties would help address safety issues and discourage companies from breaking the law?

Respondent Type	Yes	Maybe	No	Not sure/ Don't Know	Grand Total
Consumer	701	358	1,181	177	2,417
Healthcare professional	135	79	166	32	412
Natural health product manufacturer	20	15	58	5	98
Academic/researcher	27	6	12	5	50
Cosmetic manufacturer	4	8	14	1	27
Federal government official	11	3	0	1	15
Non-prescription drug manufacturer	2	0	3	0	5
Provincial government official	1	0	1	0	2
Public interest group	5	0	6	0	11
Other (please specify)	47	31	108	21	207
Grand Total	**953**	**500**	**1,549**	**242**	**3,244**

Q13. Do you think the frequency of when a company is inspected should vary depending on the risk category of the product?

Respondent Type	Yes	Maybe	No	Not sure/Don't Know	Other	Grand Total
Consumer	786	274	1,010	135	235	2,440
Healthcare professional	144	44	144	27	55	414
Natural health product manufacturer	36	13	31	1	19	100
Academic/researcher	21	4	10	6	8	49
Cosmetic manufacturer	15	1	7	3	1	27
Federal government official	10	0	1	1	3	15
Non-prescription drug manufacturer	4	0	0	0	1	5
Provincial government official	0	0	1	0	1	2
Public interest group	4	3	3	0	2	12
Other (please specify)	55	21	75	16	42	209
Grand Total	**1,075**	**360**	**1,282**	**189**	**367**	**3,273**

Q14. Do you feel that the proposed Framework addresses any concerns you have with self-care products?

Respondent Type	Yes	Maybe	No	Other	Grand Total
Consumer	452	351	1,373	254	2,430
Healthcare professional	92	70	194	53	409
Natural health product manufacturer	19	13	55	11	98
Academic/researcher	14	12	18	5	49
Cosmetic manufacturer	7	5	11	4	27
Federal government official	7	2	5	1	15
Non-prescription drug manufacturer	2	1	1	0	4
Provincial government official	0	0	1	1	2
Public interest group	0	4	6	2	12
Other (please specify)	24	30	105	47	206
Grand Total	**617**	**488**	**1,769**	**378**	**3,252**