Preparing for our Future
CHP Canada’s recommendations for the Stakeholder Engagement Session

Submitted to the Health Products and Food Branch

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1.0 Who we are

CHP Canada is the industry association that represents the companies that make evidence-based over-the-counter medicines (OTCs) and natural health products (NHPs). These are the products you can find in every Canadian home. From sunscreens and vitamins, to pain relievers and allergy medications, people use consumer health products to maintain their health and manage their minor ailments. This is a fundamental part of self-care, which is vital to the health of Canadians, to the sustainability of our healthcare system and the strength of our economy.

![Figure 1: CHP Canada’s Active Members](image)

Together, our industry generates $5.6 billion in sales annually, produces $1.5 billion in exports and sustains over 56,000 jobs.
2.0 Purpose of this Submission

CHP Canada participated in the June 2018 stakeholder engagement session on regulation and health innovation. As a follow up to this session, our further considerations on regulatory review and modernization initiatives are provided within this enclosed submission as well as our responses to the discussion questions “Preparing for our Future.” We appreciate this opportunity to provide input into the regulatory review initiative.
3.0 Discussion Questions: Preparing for our Future

3.1 Pre-Evidence-based Regulating/ Ad hoc Regulation

**Question A)** We have heard from various stakeholders that outdated regulatory requirements in the *Food and Drug Regulations* are posing challenges. If this applies to you, can you identify what requirements in the regulations are of greatest concern and examples of the impact of these outdated provisions had had for you and your constituents?

**Issue 1:** Division 8 of the *Food and Drug Regulations* is inappropriate for regulating OTCs and creates inconsistencies with natural health products.

Consumer health products are currently governed by two different sets of regulations. The regulations for OTCs are contained in Part C of the *Food and Drug Regulations (FDR)*, which also cover prescription drugs, while the regulations for NHPs are separate from Part C. The result of this division is that similar products that have been deemed suitable for consumers to use without the need for supervision by a health professional, have different requirements.

Following the Thalidomide disaster of the early 1960s, the FDR were amended to provide for more stringent evaluation of new drugs. While established drugs, including OTCs, continue to be regulated under Division 1 of the FDR, “new drugs” that have not been sold in sufficient quantity or for sufficient time to establish their safety and effectiveness are regulated under Division 8. Some OTCs are regulated as ‘new drugs’ under Division 8. One of the results of being classified as a “new drug” is that manufacturers are required to file an extensive submission prior to marketing. However, the very nature of the majority of OTCs found in Division 8 is that they have been switched from prescription status based on the fact that they already have well established safety and efficacy profiles through many years of human use. In addition, once designated as “new drugs” there is no way for a product to be removed from the New Drugs List, even as the evidence of safety continues to develop. For example, ibuprofen has been regulated as a “new drug” since the 1970s. For Division 8 products, Health Canada’s policy is that all novel combinations of ingredients, even ingredients that have been marketed separately (with no substantive safety concerns) for decades, are ‘new drugs’.

None of the above applies to NHPs as the more modern NHPR do not make distinctions between “new” and other drugs. As such, we believe that the current prescription drug framework is inappropriate for OTCs that often puts products such as a cough cold remedy with a new combination of ingredients that have been sold separately but used concomitantly for years to be considered a new drug.

In 2016, Health Canada acknowledged the need to address the current regulatory inconsistencies between OTCs and NHPs and establish an appropriate, risk-based approach to regulation with the proposal for the Self-Care Framework. CHP Canada continues to work closely with the Natural and Non-prescription Products Directorate to continue to build upon our 2016 Self-Care Framework submission (attached separately) and specific regulatory amendments needed to both the FDR and NHPR to
achieve the desired outcome of establishing a consistent, risk-based regulatory regime as policy continues to develop and shift.

**Issue 2: Prohibition in the Food and Drugs Act against direct-to-consumer sampling of consumer health products**

The Food and Drugs Act prohibits sampling of all drugs unless under prescribed conditions to a limited list of health practitioners. This prohibition was enacted in 1962 in response to concerns that the large number of prescription drug samples being distributed at that time were contributing to a high prescription drug prices. With the evolution and growth of the consumer health sector, this prohibition against sampling of all drugs has resulted in unintended consequences. The prohibition unduly restricts the distribution of direct-to-consumer samples of consumer health products that are otherwise accessed directly by consumers without a prescription. An amendment to the Food and Drugs Act is urgently needed to address this issue as outlined in Annex I along with a supporting policy framework in order to guide enforcement to ensure compliant direct-to-consumer sampling.

The inability to sample consumer health products in Canada actually runs contrary to many public health initiatives as it prohibits manufacturers from supporting actions in favour of those such as:

- Distributing sunscreens at outdoor events
- Making vitamins more accessible to lower socio-economic groups
- Distributing hand sanitizers at public events

Canadian consumers would directly benefit from the ability to obtain samples of OTCs, natural health products and disinfectants. Enabling greater access to safe and effective self-care options will help Canadians maintain and improve their health.

**Issue 3: Limited list of health professionals that can distribute drugs as samples**

The Food and Drugs Act establishes that only physicians, dentists, veterinary surgeons or pharmacists may distribute samples of drugs. However, this limited list as set out in the Act has not kept pace with health care delivery and prescribing practices. For example, the legislation prohibits nurse practitioners working in remote communities from distributing samples of drugs where access to a physician and medicines may be limited. Amendments are required to the Food and Drugs Act to recognize a broader scope of health practitioners who are entitled under provincial legislation to prescribe drugs. More information and proposed legislative text is provided in Annex I Appendix 1.

**Issue 5: Prohibition against professional sampling of NHPs**

The Food and Drugs Act enables professional sampling of drugs under prescribed conditions as outlined in the FDR. However, these prescribed conditions do not explicitly exist in the NHPR, and as such it has been interpreted that currently health professionals are prohibited from distributing any samples of natural health products. To address this regulatory inequity between OTCs and NHPs, amendments to the NHPR are required to establish consistent prescribed conditions as set out in C.01.048(1) of the FDR. More information on this issue and proposed regulatory text is included in Annex I Appendix 1.

**Issue 5: Need for a consistent approach to security packaging for topical self-care products**
Section 95 of the NHPR applies the security packaging requirements to all NHPs however, this is inconsistent with Section A.01.065 of the FDR which only applies the requirements to “drugs for human use” excluding drugs only intended for external uses, e.g., sunscreen products, anti-dandruff shampoos, and antiperspirants. This creates a situation where topical OTCs and NHPs sit side by side on store shelves, whereby only the NHPs require a security feature. The NHPR should be amended under Section 95 to limit the security packaging requirements to NHPs for internal uses only consistent with the requirements for OTCs and with the level of risk imposed by these products.

For economic and trade reasons, it is important that Canada has similar security packaging requirements to enable manufacturers to retain this flexibility and efficiency, particularly as there is no health or safety reason to establish new trade barriers. The US FDA and Australian TGA approach to security packaging requirements also exempt dermatological/ topical products. The current inconsistencies between NHP and OTC requirements in Canada create a burden for NHP companies to purchase additional packaging and labelling equipment for their Canadian topical NHPs. For example, the cost of a shrink wrap packaging machine is approximately $250,000 and this in turn raises the cost of the product for Canadian consumers. For more information and history on this issue, see NNHPD’s Draft Issue Analysis Summary (attached separately).

CHP Canada recommends that Section 95 of the NHPR be amended to mirror the exemption for products intended for external use contained in Section A.01.065 of the FDR.
3.2 Evidence-based Regulating

**Question A** As we work to consolidate and streamline regulatory requirements for health products in Canada, can you identify some examples of key inefficiencies within the current framework or with respect to international alignment that could be addressed through this process?

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**Issue 6: Policy for product-based switch in Canada would align regulatory processes**

Canada's current system for switching prescription drugs to OTC status is ingredient based, rather than product based. The result of this is that the "switch" applies to all competing products with the same formulation at the same time. Because the act of switching an ingredient is considered a technical regulation as per the World Trade Organization's (WTO) Technical Barriers to Trade Agreement, Health Canada must notify the WTO and its member countries and delay the finalization of the switch for at least 6 months in order to give enough time for competitors to adapt to the change. This is not the case in other countries, where switches are product-based, affecting only one manufacturer, and therefore do not require WTO notification. In the absence of any form of data protection, this six-month delay, combined with the delays associated with drug scheduling and the shorter federal approval time for second entry products, means that competing products often hit store shelves before the innovator’s product has had time to establish itself, and sometimes even get there first.

To address this key inefficiency and to better align processes with international jurisdictions like the US and the EU, CHP Canada recommends a policy for a two-stage switch that would switch the innovator’s product first, followed by the ingredient as outlined in Annex 2.

**Issue 7: Integration of the provincial drug scheduling decisions into the federal drug approval process will generate efficiencies by streamlining processes and align would with the Australian approach**

As described in CHP Canada’s Submission on the Canadian Free Trade Agreement (attached separately), integrating the provincial drug scheduling decision into the federal drug approval process would enable faster access for Canadians to new consumer health products, reduce duplicative decision making and result in more consistent and predictable outcomes for Canadians and Industry. There is also a need to improve this process to better align with international practices. Canada is the only country in the world that leaves the last step in product regulation, which is to determine the appropriate conditions of sale in a retail environment, to regulators of the pharmacy profession. Not only has this created a conflict of interest, as decisions are made to limit sale outside of their own pharmacies, but it has set our process apart from that of other jurisdictions resulting in unique Canadian barriers to innovation in Canada. In the US, EU and Australia, scheduling decisions are managed federally.
**Question B)** In your opinion, to what degree is product classification an impediment to innovation? If Health Canada were to advance a more agile classification system to simply and clarify what requirements apply to a specific product, how might this impact your business practices?

**Issue 8: Need for classification certainty under the Self-Care Framework**

Product classification is the central point of discussion as a part of the ongoing consultations on the proposed Self-Care Framework in order to achieve a consistent, risk-based approach to regulation for all self-care products. A clear, predictable classification system is a prerequisite for business predictability, innovation and growth. Classification certainty is needed in the advanced stages of business planning to coordinate compliance with the relevant requirements. For example, depending on whether a self-care product ends up in the proposed Category I or II impacts the selection of contract manufacturers to meet the GMP standard and potentially new packaging and labelling equipment to accommodate reconfiguring packages to meet labelling requirements. The consequences of product classification have impacts throughout the supply chain that have consequences on global product introduction in Canada. Failure to provide such certainty, or a misalignment of categorization with our major trading partners, will result in fewer new product introductions into Canada and continue to impede innovation.

Towards the goal of an agile classification system, a consultative, predictable and transparent process needs to be established for product reclassifications and timelines need to be appropriate to give manufacturers sufficient time to adjust to increasing requirements. This process should also include a fair and equitable process for sponsors to appeal classification decisions as per the current *Reconsideration of Final Decisions Issued for Human Drug Submissions*. The critical element of this process is the panel approach to re-assessment where outside advice from experts can be sought if needed, pursuant to security and confidentiality agreements. This approach also permits the sponsor to gain reviewer feedback before submitting their case for consideration and present their case directly to Health Canada. These elements are all crucial for ensuring industry has a fair opportunity to build and deliver a case to appeal a classification decision.
3.3 Regulating Advanced Technologies

**Question A)** To what extend would you say that advanced technologies are challenging the current health product regulatory frameworks in Canada? Can you share examples of challenges that you, your constituents or others are seeing in this area?

**Issue 9: Regulatory definition of a device prohibits risk-based approach for self-care mobile applications**

Technology has created new platforms for consumers to know more and to have access to more health information than ever before. Mobile applications can help people manage their own health and wellness, promote healthy living and gain access to health information when and where they need it. For example, by 2018 it is estimated that 50% of the 3.4 billion smartphone users worldwide will have downloaded a mobile health application. Innovative prescription-to-OTC switches could be made possible by a regulatory framework that accommodates greater use of tools and technologies such as mobile health applications to assist in the self-selection process and to promote safe use. However, the mobile health application may fall within the definition of a regulatory device, for which Health Canada has a responsibility to oversee safety and efficacy. It is important to clarify a path to market for these product-device combinations in accordance with a risk-based approach to assure safety and effectiveness. The FDA has already experienced this challenge and developed the Mobile Medical Applications Guidance\(^1\) that describes their risk-based approach for mobile medical apps that meet the definition of a medical device but pose a lower risk to the public, exercising enforcement discretion over these devices in absence of regulatory change. **CHP Canada recommends that Health Canada consider amending the regulatory definition of a medical device to enable a risk-based approach to medical health applications, consistent with the scope proposed by the US FDA.**

**Question B)** What considerations do you think would be important in advancing a new or innovative approach to regulating advanced technologies?

**Issue 10: Enabling electronic label extensions should not prescribe certain technological solutions**

With the implementation of the Plain Language labelling Regulations, additional flexibilities within the Labelling Requirements for Non-Prescription Drugs Guidance (formerly the Good Label Package and Practices Guide) to reduce the compliance costs associated with these regulations by amending formats to reduce the need for packaging reconfigurations. As a part of these consultations, the concept of an

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electronic label extension was leveraged as a means to provide “point of use” label content electronically instead of physically on the product package. The *electronic Canadian Drug Facts Table Standard Guide* prescribes the principles for electronic label extensions and how to apply technical standards to meet the principles and comply with the Plain Language Labelling Regulations. Should the concept of electronic label extensions be integrated into regulation in the future, it is imperative that the text not unduly limit or prescribe one certain technological solution in order to keep up with the evolution of technology and consumer preference. For example, the minimum universal standard leverages a URL (i.e. [www.website.com](http://www.website.com)) printed on packaging as a means to access electronic labelling standards, yet at the same time this approach enables the use of QR codes (which are falling out of favor with consumers) or RFID enabled packaging (which will be more prevalent in the future). It will be important for Health Canada to consult with technology companies, consumer behavior experts, manufacturers and users themselves when developing regulation, policy and guidance in order to avoid an overly prescriptive approach that remains relevant.
3.4 Moving Forward

**Question A)** With respect to supporting and reducing barriers to innovative products, what would be the most significant outcome that you would like to see as part of the Regulatory Review and Modernization Process?

**Issue 11:** A regulatory framework that is flexible enough to account for the rapidly changing retail and information environments that will increasingly influence the conditions of sale for consumer health products.

The transition of drug scheduling to full integration with the federal regulation of consumer health products under the *Food and Drugs Act* would create an opportunity to vastly modernize the tools available for the regulation of these products. We have previously outlined the greater efficiencies and sounder decision-making that would be made possible by federal drug scheduling. These alone would foster more innovation in the consumer health product marketplace. But the transition to federal drug scheduling would also allow the regulatory control itself to be modernized, moving away from its current, limiting place-of-sale approach, to a more flexible and comprehensive conditions-of-sale approach.

In the current approach, drug scheduling only dictates where a product may be sold; whether within a pharmacy or not, or within a pharmacy area to which the public has no direct access. This is inadequate in numerous ways. First, with modern point of sale (POS) technology, it is no longer necessary to physically isolate products from consumers in order to ensure that a pharmacist intervenes in each sale. The current “no-public-access” approach to Schedule II disrupts the product selection process and leaves many consumers to choose a consumer health product without necessarily being aware of all their self-care options. Modern POS technology would permit Schedule II and Schedule III products to displayed together, thus ensuring that consumers are aware of all their self-care product options, while still preventing the purchase of a Schedule II product without pharmacist intervention.

The availability of pharmacist supervision and/or the need for pharmacist intervention will always constitute vital conditions-of-sale options for the regulator. But a modern system also needs to recognize that changes in information technology and the retail environment have created the possibility of new tools to manage and regulate the conditions of sale for consumer health products. We have previously alluded to the rapidly evolving work around the role of electronic apps as potential enablers of self-care with consumer health products. These and other web-based approaches also have the potential to help resolve many of the challenges associated with providing all of the information necessary to permit safe and effective use of consumer health products on the physical labels of these products, in formats that are legible, readable and suitable for an increasingly diverse population with varying levels of literacy. Thus, CHP Canada would like to see a modernized regulatory regime for consumer health products that recognizes and manages the continuum of information sources that can drive informed self-care with these products, including labelling, advertising, electronic apps and web-based information tools.
4.0 Conclusion

CHP Canada strongly supports the Advisory Council on Economic Growth’s report and recommendation to evolve the regulatory system so that it can better fit an innovative economy. We agree that the regulatory environment should act as a catalyst for new health products and that regulation should be predictable, efficient and consistent. The intent of Health Canada’s Self-Care Framework, if properly implemented, is designed to achieve this outcome of developing consistent, risk-based regulatory framework for non-prescription drugs, natural health products and cosmetics. We look forward to continue to engage along side other stakeholders to ensure this intent is met that we believe will create the type of regulatory agility the Advisory Council has envisioned.
Annex 1: Professional Sampling and Direct-to-Consumer Sampling of consumer health products

- Non-prescription drugs, natural health products, cosmetic-like drugs and disinfectants can be donated to support international disaster relief initiatives, but they cannot be distributed domestically due to restriction against direct-to-consumer sampling in Canadian legislation. This legislation also prevents certain healthcare practitioners from distributing prescription drug samples to their patients who need them and cannot otherwise obtain access.
- An amendment to the *Food and Drugs Act* is needed to enable direct-to-consumer sampling of non-prescription drugs, natural health products, low-risk ‘cosmetic-like’ products classified as drugs and disinfectants and to expand prescription drug sampling to a wider scope of health care practitioners.
- Such an amendment, with enabling regulations would positively impact health care delivery and health outcomes for Canadians.

**Background**

- Section 14 (1) of the *Food and Drugs Act* prohibits sampling. However, the exception in Section 14 (2) states that “Subsection (1) does not apply to the distribution, under prescribed conditions, of samples of drugs to physicians, dentists, veterinary surgeons or pharmacists.” The conditions where health professionals may distribute drugs as samples are found in Sections C.01.048 and C.01.049 of the *Food and Drug Regulations*.
- Natural health products are considered a subset of drugs under the Act. However, there are no conditions for the sampling of natural health products to health care practitioners in the *Natural Health Products Regulations*.
- In 2014, Health Canada published a consultation document on a Framework for Consumer Health Products that proposes to permit direct-to-consumer sampling of non-prescription drugs. Specifically, the document stated:
  - “The regulations would propose sampling rules that allow the distribution of samples of any authorized non-prescription drugs to any person (ie. exempt non-prescription drugs from the prohibitions in Section 14 of the *Food and Drugs Act*).”
- Throughout 2016, Consumer Health Products Canada (CHP Canada), Cosmetics Alliance Canada (CAC), Canadian Health Food Association (CHFA) and the Canadian Consumer Speciality Products Association (CCSPA) worked jointly with NNHPD and RORB to develop a detailed policy proposal to enable direct-to-consumer sampling of non-prescription drugs, natural health products, cosmetic-like drugs and disinfectants in advance of the framework.

**Current Status**

- As a result of industry discussions with the Regulatory Operations and Regions Branch of Health Canada (RORB), it was recently determined that an amendment to the Act is required to enable direct-to-consumer sampling.
  - Enabling regulations may also be required.
- Health Canada is currently consulting on the Self-care Framework, to create a consistent, risk-based regulatory regime for self-care products (non-prescription drugs, natural health products and cosmetics) as well as design a separate parallel approach for disinfectants. Direct-to-consumer sampling delivers on the objectives of the Framework and creates the ideal opportunity to develop enabling regulations to facilitate direct-to-consumer sampling, if required.
Considerations

- The current Prohibition in the Act against sampling was enacted in 1962 in response to concerns that the large number of samples being distributed at that time were contributing to the high cost of drugs. The regulatory environment, health care delivery and the industry has evolved since this Prohibition was enacted, mitigating the need for this measure to influence drug pricing, and resulting in unintended consequences as it unduly restricts the distribution of consumer health products that are otherwise accessed directly by consumers without a prescription.
- Enabling direct-to-consumer sampling of consumer health products is supported by CHP Canada, CCSPA, Cosmetics Alliance, CHFA and the Organization for Health Action (HEAL).
- Enabling direct-to-consumer sampling aligns with government initiatives to reduce regulatory red tape, and align regulatory approaches with the US as a part of the Regulatory Cooperation Council.
- RORB frequently receives questions from industry to seek clarity on the distribution of consumer health product samples. Although consumer sampling of non-prescription drugs, natural health products, cosmetic-like drugs and disinfectants are a low enforcement priority for the Department, a clear, policy position will decrease Departmental resource burden and make enforcement activities more efficient and risk-based in this area.
- Healthcare practitioners and the health of consumers would directly benefit from the ability to sample prescription drugs to Canadians.
  - Specifically, a broader scope of practitioners that can sample prescription drugs would directly benefit the delivery of health care and access to medicines in remote communities with limited access to physicians.
- Industry seeks to contribute non-prescription drugs, natural health products, ‘cosmetic-like’ drugs and disinfectants to humanitarian and public health initiatives such as:
  - Distributing sunscreens at outdoor events
  - Making vitamins more accessible to lower socio-economic groups
  - Distributing hand sanitizers at public events
  - Distributing first aid kits and products respond to disaster relief initiatives
    - Organizations like Vitamin Angels and Health Partners International of Canada already perform these activities to those in need internationally, however the current Canadian legislation prevents industry from responding to the needs of Canadians, posing a significant irritant for industry.
- Canadian consumers would directly benefit from the ability to obtain samples of non-prescription drugs, natural health products, cosmetic-like drugs and disinfectants. Enabling greater access to safe and effective self-care options will help Canadians maintain and improve their health.

Recommendations and Rationale

- Amend the Food and Drugs Act to:
  - Broaden the scope of health care practitioners that can sample prescription drugs to any provincially regulated prescribing health care practitioners according to the prescribed conditions set out in C.01.048 of the Food and Drug Regulations. This would expand the scope of health practitioner sampling to include nurse practitioners, and pharmacists in certain provinces and naturopathic doctors in certain provinces for certain drugs
  - Permit direct-to-consumer sampling of non-prescription drugs, natural health products, cosmetic-like drugs and disinfectants to any person by any person.
- Make consequential amendments to the Food and Drug Regulations and Natural Health Product Regulations (as proposed in Appendix 1) to enable direct-to-consumer sampling of non-prescription drugs, natural health products, cosmetic-like drugs and disinfectants in accordance with supporting guidance and policy (as proposed in Appendix 2)
Annex 1: Appendix 1: Proposed legislative and regulatory amendments

Amendments to the Food and Drugs Act

Samples

14 (1) No person shall distribute or cause to be distributed any drug as a sample.

Exception

(2) Subsection (1) does not apply to the distribution, under prescribed conditions, of samples of prescription drugs to a person who is entitled under the laws of a province to provide health services in the province and is entitled to prescribe drugs, including physicians, dentists, veterinary surgeons or pharmacists.

(3) Subsection (1) does not apply to the distribution, under prescribed conditions, of samples of drugs that are permitted to be sold without a prescription, including a natural health product within the meaning of the Natural Health Product Regulations.

Amendments to the Food and Drugs Regulations

C.01.048 (1) Where a person referred to in Section 14(1) of the Food and Drugs Act who is a physician, dentist, veterinary surgeon or pharmacist registered and entitled to practice that person’s profession in a province has signed an order specifying the brand name, proper name or common name and the quantity of a drug, other than

(a) a narcotic as defined in the Narcotic Control Regulations,
(b) a controlled drug as defined in subsection G.01.001(1), or
(c) a new drug in respect of which a notice of compliance has not been issued under section C.08.004,

the person who receives the order may distribute the drug to the person referred to in Section 14(1) of the Food and Drugs Act physician, dentist, veterinary surgeon or pharmacist as a sample if the drug is labelled in accordance with these Regulations.

(2) An order referred to in subsection (1) may provide that the order be repeated at specified intervals during any period not exceeding six months.

2 Health care professional definition: Schedule A and Section 3 to the FDA Guidance
3 We are not proposing to amend Section 30 of the Food and Drugs Act (Regulations) as this section requires the Governor in Council to may make regulations. Such an approach would be lengthy and unnecessary given the powers that exist to Incorporate by Reference a document into the Food and Drug Regulations.
**C.01.049 (1)** A person who, under section C.01.048, distributes a drug as a sample shall

(a) maintain records showing

(i) the name, address and description of each person to whom the drug is distributed,

(ii) the brand name, quantity and form of the drug distributed, and

(iii) the date upon which each such distribution was made; and

(b) keep those records and all orders received for drugs in accordance with section C.01.048 for a period of not less than two years from the date upon which the distribution referred to in the records was made.

**C.01.49 (2)** No person shall distribute a drug that is permitted to be sold without a prescription as a sample unless the distribution is in accordance with the requirements set out in the Policy and Guidance for Direct-to-Consumer sampling, as published by the Department of Health and as amended from time to time.4

**Amendments to the Natural Health Product Regulations**

**Prohibition**

4 (1) Subject to subsections (2) and (3), no person shall sell a natural health product unless a product licence is issued in respect of the natural health product.

(2) No product licence holder, manufacturer, importer or distributor of a natural health product for which a product licence is issued shall sell the natural health product during any period that the sale of that natural health product is directed to be stopped under section 17.

(3) No person shall sell a natural health product for which a product licence is issued

(a) during the period of any suspension of the licence under section 18 or 19; or

(b) after cancellation of the licence under paragraph 20(b).

**Section 4 (4)** Subject to sections (1), (2) and (3), no person shall distribute a natural health product as a sample unless

a) a product license is issued in respect to the natural health product and it is labelled and packaged in accordance with these Regulations

b) the natural health product is manufactured, packaged, labelled, imported, distributed or stored in compliance with the requirements set out in Part 3

c) the natural health product is distributed in a manner that is consistent with its recommended sub-population, if applicable

d) the natural health product is distributed to the attention of adults 18 and over.
Annex 1: Appendix 2: Policy and guidance for direct-to-consumer sampling

Purpose

Health Canada is considering legislative and regulatory measures to align and enable their current thinking that some forms of sampling activities related to non-prescription drugs, disinfectants and natural health products and cosmetic-like drugs to be a lower enforcement priority provided certain conditions are met. This guidance is intended to provide the supporting policy direction to Health Canada to guide legislative and regulatory development that would enable sampling of non-prescription drugs, disinfectants and natural health products to any party.

Definitions

For the purposes of this policy, the following definitions are applied:

“health professional” includes a person who

(a) falls with the definition of “practitioner” in the Food and Drug Regulations;

(b) is entitled under the laws of a province to treat patients in any field of physical or mental health, and is practicing their profession in that province, including but not limited to physicians, dentists, veterinarians, pharmacists, nurses, dietitians, chiropractors, occupational and physical therapists, optometrists, midwives and psychologists, naturopathic doctors and homeopathic doctors; or

(c) treats patients using traditional medicine, complementary medicinal or alternative medicine for the maintenance of health as well as in the prevention, diagnosis, improvement or treatment of physical and mental illness, including but not limited to homeopathic practitioners, traditional Chinese medicine practitioners, and ayurvedic medicine practitioners.

"sample" is a package of a non-prescription drug, disinfectant or natural health product that is provided free of charge to a consumer or a health professional (intended for subsequent distribution to a consulting patient) without any accompanying product or service for which consideration is given.

"sell" includes offer for sale, expose for sale, have in possession for sale and distribute, whether or not the distribution is made for consideration (Food and Drugs Act).

"party" includes but is not limited to a manufacturer, retailer, e-retailer, distributor, sales representatives, sales consultant, wholesaler, or broker.

Scope

Inclusions:

- This policy applies to any party (including a health professional) that is distributing non-prescription drugs, disinfectants and natural health products as a sample direct-to-consumers.
• This guideline does not apply to prescription drugs, medical devices, cosmetics or food. For clarity, sampling of prescription drugs to healthcare practitioners is permitted under prescribed conditions set out in Sections C.01.048 and C.01.049 of the Food and Drug Regulations.

Policy Statement

Sampling of non-prescription drugs, disinfectants, cosmetic-like drugs and natural health products that meet the criteria below are permitted, unless a safety concern has been identified and communicated to the market authorization holder or distributor by Health Canada with respect to sampling of the product.

Criteria for direct-to-consumer sampling

1. The sample must have a valid Health Canada authorization and be compliant with the Food and Drug Regulations or the Natural Health Product Regulations, as applicable.
2. Samples should be distributed in a manner that is consistent with its recommended sub-population, if applicable
3. The sample must be manufactured in accordance with Good Manufacturing Practices and be compliant with the Food and Drug Regulations or the Natural Health Product Regulations, as applicable.
4. The sample must be distributed to the attention of adults 18 and over.

For greater clarity, the following direct-to-consumer sampling activities are prohibited:

1. Distribution of samples of unauthorized products
2. Distribution of samples to subpopulations that the product is contraindicated for
3. Distribution of samples that do not comply with quality requirements
4. Distribution of samples directly to those under the age of 18

Guidelines

The following guidelines are developed to provide clarity about how to meet the criteria for direct-to-consumer sampling of non-prescription drugs, natural health products, cosmetic-like drugs and disinfectants.

Considerations for meeting Criterion #1

Criterion # 1 is: The sample must have a valid Health Canada authorization and be compliant with the Food and Drug Regulations or the Natural Health Product Regulations, as applicable. In order to meet this criterion the product must:

• Have a valid DIN, NPN or DIN-HM
• Be labelled in accordance with the regulatory requirements (i.e., brand name, manufacturers contact information, listing of medicinal ingredients and their amounts, listing of non-medicinal ingredients, conditions of use including dosage instructions, warnings and contraindications) including labelling requirements and policies that apply to small package labels or special labels, as applicable.
• Be packaged in accordance with regulatory requirements, including regulatory and policy requirements for security packaging, special packaging or child resistant packaging, as applicable.
• **Note:** Provincial/territorial governments can establish different requirements, such as drug schedules, which may affect sampling of certain authorized products within a province/territory.

**Considerations for the non-application of Criterion #2**

Criterion #2 for prohibiting sampling is: Samples should be distributed in a manner that is consistent with its recommended sub-population, if applicable. In order to meet this criterion the distribution activity must be designed to exclude certain sub-populations that the product is contraindicated for. This criterion would create a situation that would make it cost-prohibitive to sample products with specific contraindicated populations. For example, sunscreens do not have any contraindications or designated doses for specific sub-populations, and such this criterion would not limit the sampling of lower risk products such as sunscreens. However, for products that do have contraindications, the following are considerations for how industry could ensure this criterion is met when designing sampling activities:

• **Sampling in person:** Require the person requesting the sample to complete a survey question to identify whether the contraindication applies, prior to deciding to distribute the product. Those who identify a contraindication will not be eligible to obtain the sample.

• **Sampling by direct mail:** Require the person requesting the sample to complete a survey question to identify whether the contraindication applies, prior to mailing the product to the attention of the individual. Those who identify a contraindication will not be eligible to obtain the sample.

• **Sampling by indirect mail:** Outer packaging could include labelling to state “*This product may not be right for you. Always read and follow the label directions.*”

• **No representative present sampling:** Sampling in a retail environment may consider including additional labelling on the product or on the shelf (i.e. Shelf-talker) that states “*This product may not be right for you. Always read and follow the label directions.*” Sampling with no representative present may consider including on outer packaging “*This product may not be right for you. Always read and follow the label directions.*”

**Considerations for the non-application of Criterion #3**

Criterion #3 is: The sample must been manufactured in accordance with Good Manufacturing Practices and be compliant with the Food and Drug Regulations or the Natural Health Product Regulations, as applicable. In order to ensure this criterion is met the product must:

• Be manufactured in, or imported to, a facility with a valid Site License or Establishment License (with the exception of disinfectants which are not subject to this regulatory requirement)

• Ensuring products are sampled in accordance with specified storage conditions (i.e., ensuring products that require refrigeration are not sampled in a manner without temperature controls).

**Considerations for the non-application of Criterion #4**
Criterion # 4 is: The sample must be distributed to the attention of adults 18 and over. In order to meet this criterion, the distribution activity must be designed to account for age verification. The following are considerations for how industry could ensure this criterion is not met when designing sampling activities:

- **Sampling in person:** Age verification can be informally assessed by a representative of the distributor of the sample by ensuring that samples are not directed to those appearing to be under the age of 18.

- **Sampling by direct mail:** Age verification can be integrated into process for collecting information on the person requesting the sample, whereby they would self-identify that they are over 18 years of age.

- **Sampling by indirect mail:** Outer packaging could include labelling to state “This package contains a sample of a health product that is directed to adults 18 and over. This product may not be right for you. Always read and follow the label directions.” Outer packaging could also be plain and designed to be challenging for children to open.

- **No representative present sampling:** Sampling in a retail environment may consider including additional labelling on the product or on the shelf (ie. Shelf-talker) that states “This package contains a sample of a health product that is directed to adults 18 and over. This product may not be right for you. Always read and follow the label directions”. Samples that are made available without a representative present may consider including on outer packaging state “This package contains a sample of a health product that is directed to adults 18 and over. This product may not be right for you. Always read and follow the label directions.” Outer packaging could also be plain and designed to be challenging for children to open.

**Enforcement Expectations**

Consistent with the Natural Health Products Compliance and Enforcement Policy (POL-0044) and the Compliance and Enforcement Policy (POL-001), Health Canada’s Regulatory Operations and Regions Branch uses compliance monitoring activities to ensure compliance with the Act and Regulations. Situations of non-compliance are then triaged based on risk and other factors such as compliance history. Triage determines compliance verification priorities in cases where compliance has not yet been confirmed as well as risk mitigation priorities for confirmed non-compliance. Health Canada records information gathered via compliance monitoring and risk mitigation activities, and uses trending and analysis to identify proactive compliance monitoring and compliance generation priorities. Health Canada will enforce against sampling that is not performed in accordance with this guide.
Annex 2: Policy for two-stage switch

- The current Health Canada (the “Department) process for switching ingredients from prescription status to over-the-counter (OTC) status causes unnecessary delays in the market entry for innovative new OTC products.
- CHP Canada is recommending that the Department adopt a new policy that would retain the current process for switching ingredients, without unnecessarily subjecting the innovator’s product with the delay, by implementing a “two-stage” switch process.
- The policy proposal is supported by industry, aligned with WTO TBT obligations and would reduce red tape. It would also be consistent with international regulatory processes.

Issue

Canada’s process of switching ingredients vs. products has resulted in a six-month delay to market for innovative new OTC products. In the absence of any form of data protection, this delay, combined with the delays associated with drug scheduling, the shorter federal approval time and absence of a drug scheduling process for second entry products, means that competing products often hit store shelves before the innovator’s product has had time to establish itself. Sometimes “second entry” products even get there first.

Background

In 2013, Schedule F of the Food and Drugs Act was repealed and replaced with the Ministerial Prescription Drug List in order to eliminate red tape and reduce the time required to bring a new prescription or nonprescription drug to market. This change eliminated the Canada Gazette public consultation process that was previously required to add or amend an ingredient to Schedule F, which could take over 18 months. The rationale was that, by establishing a Ministerial List the largely administrative process could be complete in just over three months. However, Canada’s system for switching prescription drugs to OTC status is ingredient based rather than product based, meaning that the “switch” applies to all competing products with the same formulation at the same time. Consequently, the act of switching an ingredient is considered a technical regulation as per the World Trade Organization's (WTO) Technical Barriers to Trade Agreement. This requires that Canada must notify the WTO and its member countries and delay the finalization of the switch for at least 6 months in order to give enough time for competitors who also use this ingredient in their products to adapt to the change.

Recommendations and Rationale
CHP Canada recommends that the Department adopt a policy to allow for a two-stage switch process, whereby products could be switched first, followed by ingredient switches, in accordance with the following process:

**Step 1: Public posting & Notice of Consultation:** Health Canada would consult on proposal to revise the listing of an ingredient on the Prescription Drug List in accordance with specific conditions in accordance with the normal procedure.

For example, if a submission to switch 5% diclofenac for “ProductX” (DIN ############) was approved, then the consultation would be on the following revision to the Prescription Drug List (See Table 1 example):

- **Diclofenac or its salts (diclofenac diethylamine, diclofenac sodium, diclofenac potassium),**
  - (a) except when sold as a single medicinal ingredient for topical use on the skin in a concentration equivalent to 2% or less of diclofenac for not more than 7 days; or
  - (b) except when sold as “ProductX” (DIN ############)

**Table 1: Example of a Prescription Drug Listing before a switch**

<table>
<thead>
<tr>
<th>Drugs containing any of the following</th>
<th>Including (but not limited to)</th>
<th>Qualifier</th>
<th>Effective date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Diclofenac</td>
<td>Diclofenac diethylamine, diclofenac sodium, diclofenac potassium</td>
<td>except when sold as a single medicinal ingredient for topical use on the skin in a concentration equivalent to 2% or less of diclofenac for not more than 7 days.</td>
<td>2014-08-21</td>
</tr>
</tbody>
</table>

**Step 2: Public posting & Notice of Intent to Amend:** Health Canada would publish the outcome of the consultation and notify that, as a result of the consultation,

(1) Health Canada will switch certain uses of the ingredient, including the proposed wording to the Prescription Drug List in the “qualifier” section and the effective date six months from the date of the notice (as per the normal procedure); and

(2) Health Canada has amended the Prescription Drug List to switch the product, and what the listing now reads (see below example in Table 2)

**Table 2: Example of a Prescription Drug Listing Product Switch**

<table>
<thead>
<tr>
<th>Drugs containing any of the following</th>
<th>Including (but not limited to)</th>
<th>Qualifier</th>
<th>Effective date</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
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</tr>
</tbody>
</table>
Step 3: Public posting & Notice of Amendment: Health Canada would publish that Health Canada will revise the Prescription Drug Listing to switch the ingredient and remove the product qualifier and what the listing now reads (see below example in Table 3).

Table 2: Example of a Prescription Drug Listing Product Switch

<table>
<thead>
<tr>
<th>Drugs containing any of the following</th>
<th>Including (but not limited to)</th>
<th>Qualifier</th>
<th>Effective date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Diclofenac</td>
<td>Diclofenac diethylamine, diclofenac sodium, diclofenac potassium</td>
<td>(1) except when sold as a single medicinal ingredient for topical use on the skin in a concentration equivalent to 2% or less of diclofenac for not more than 7 days. (2) Except when sold as “Product X” DIN # #######</td>
<td>(1) 2014-08-21</td>
</tr>
</tbody>
</table>

Considerations

CHP Canada’s proposal:

- Meets Health Canada’s obligations under the WTO TBT agreement without delaying product approval.
- Delivers on the proposed Self-Care Framework objectives to eliminate unnecessary burden on industry and maintain and increase access to safe and effective self-care products for Canadians
- Reduces administrative red-tape for innovators.
Would not add additional steps into the existing Prescription Drug List consultation process.
Would not require any legislative or regulatory change on the part of the Department.
Aligns regulatory systems with the product-based switch in the U.S. in accordance with the Regulatory Cooperation Council objectives.
Delivers on the Advisory Council on Economic Growth’s recommendations to establish an agile regulatory system designed for the new economy by fostering innovation and promote efficient and predictable regulation.
Would give consumers access to innovative rx-to-OTC switches 6 months earlier, resulting in savings and benefits to Canadians, private drug plan sponsors, employers, governments\(^5\)

\(^5\) Conference Board of Canada, Value of Consumer Health Products: Impact of Switching Prescription medications to Over-the-counter (March 2017)
https://www.chpcanada.ca/sites/default/files/files/8681_EcoImpactsRxTtoOTC_RPT.pdf