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Information Session on the Notice of Proposal to expand lists of certain products for distribution as samples

July 23, 2020

Natural and Non-prescription Health Products Directorate
Health Products Food Branch
Health Canada

YOUR HEALTH AND SAFETY... OUR PRIORITY.

Overview

- Background and General Requirements

- Distributing products
  - Consumers/General Pubic Mechanism
  - Heath Care Practitioners Mechanism

- Mechanism to add products to either list
  - Incorporation by Reference
  - Regulatory Amendment

- Notice of Proposal
  - Proposed Lists
  - Compliance and Enforcement
  - Next Steps

Background

- On March 13, 2020, Bill C-4 (the *Canada–United States–Mexico Agreement Implementation Act*) received Royal Assent.

- *On July 1, 2020,* amendments to the *Food and Drugs Act,* the *Food and Drug Regulations* and *the Natural Health Products Regulations* allow:
  - The distribution of certain products to the general public under certain conditions and
  - The distribution of products to a larger subset of health care practitioners.

Regulatory Language

- Previously, Section 14 of the *Food and Drugs Act* prohibited the distribution of drugs as samples other than to physicians, dentists, veterinary surgeons or pharmacists, under prescribed conditions.

- Amendments to the *Food and Drug Regulations* (including C.01.048) have been made, to permit the distribution of drugs as samples to practitioners and pharmacists who are entitled to treat patients with a prescription under their respective provincial and territorial laws and are practising their profession in that province.

Requirements for all drugs distributed as samples

- The distribution of a drug as a sample is considered a “sale” under the *Food and Drugs Act* (FDA).

- Distributing drugs as samples and all associated activities must comply with all requirements related to the “sale” of a drug. This includes, but is not limited to:
  - reporting adverse reactions
  - getting a market authorization
  - complying with advertising requirements
  - complying with good manufacturing practices
  - keeping records and executing recalls as necessary
  - complying with packaging and labelling requirements
  - obtaining a site or an establishment licence, as required
  - amending and notifying post-market changes to the market authorization

Requirements for all drugs distributed as samples (con't)

- Drugs distributed as samples must **not** be distributed
  - Past their labelled expiry or expiration date or
  - 30 days or one month before their expiry date

- Distribution of some drugs as samples is **not** permitted. These drugs are:
  - narcotics
  - controlled substances
  - prescription drugs containing cannabis
  - prescription drugs outside a practitioner's or pharmacist's prescribing authority in the province or territory in which they practice.
  - Non-prescription drugs (NPDs) and natural health products (NHPs) outside a practitioner's or pharmacist's scope of practice in the province or territory in which they practice.

Other Information

- **Re-packaging and labelling for a sample size**
  - Market authorization holders must report changes to packaging to Health Canada.

- **Products packaged together**
  - There is a risk that the co-packaging may imply certain unapproved claims or pose a safety concern when products are packaged together.
    - market authorization holders may be required to file a submission to obtain authorization to distribute their co-packaged product.

- **Drugs with risk management plans**
  - If a drug has a risk management plan, the plan would apply to the drug when distributed as a sample.

How samples can be distributed

- An individual or organization may distribute drug samples by two pathways:
  - directly to adult consumers (those 18 years of age or older)
  - to a practitioner or pharmacist, for further distribution to their patients, in accordance with their scope of practice

- The individual or representative of an organization who are distributing a drug as a sample should be:
  - at least 18 years of age
  - able to answer questions on the drug's:
    - risks
    - benefits
    - proper directions of use, etc.

Direct to Consumer sampling

- **Scope of products**: Only NPDs and NHPs on List A or List D may be directly distributed as samples
  - *List A: List of Certain Natural Health Products for Distribution as Samples* of the *Natural Health Products Regulations* (NHPR) or
  - *List D: List D: List of Certain Non-prescription Drugs for Distribution as Samples* of the *Food and Drug Regulations* (FDR)

- **Age**: Consumer must be at least 18 years old

- Practitioner and Pharmacists are not required to sample direct to consumer

Distributing drugs as samples to practitioners and pharmacists for further distribution to their patients

- Drugs that **are** on List A or List D do not require an order from a practitioner or pharmacist before they may be given to a practitioner or pharmacist for further distribution.
  - Practitioners and pharmacists are not required to sample directly to the consumer

- Drugs distributed as samples that are **not** on List A or on List D requires a signed order from the practitioner or pharmacist.
  - the samples can only be distributed in dosage form to the practitioner or pharmacist.

Incorporation by Reference

- **List A:** For NHPs under the NHPR, products able to be distributed as samples are contained on a static incorporation by reference (IbR) list, which would require a Governor-in-Council regulatory amendment to modify.
  - Ambulatory IbR authorities do not exist for NHPs under the FDA.

- **List D:** For NPDs under the FDR, products able to be distributed as samples are contained on an ambulatory incorporation by reference list

Static vs Ambulatory Incorporation by Reference

Static Incorporation by Reference:

- A static (or closed) reference refers to the incorporation of a document, as it exists at the time it is made part of the regulation. If the document is revised or amended after it is incorporated, the revision or amendment is not incorporated into the regulation and, therefore, the regulation continues to apply in reference to the original document. To incorporate the latest version of the document, the regulation would need to be amended to reference that version of the document through the regular regulatory process.

Ambulatory Incorporation by Reference:

- An ambulatory (or open or rolling) reference refers to the incorporation of a document in such a way as to include any future changes to that document without a need to remake the regulation. In the case of this type of incorporation by reference, the regulation incorporating the document would refer to a document "as amended from time to time".

Notice of Proposal

- Health Canada is undertaking steps to expand **all** the lists of products.

- Amend the following lists to include all currently authorized products in the product categories set out in the CUSMA and meeting the identified criteria, i.e., for topical use, localized and non-systemic effect, and meets the definition of a “cosmetic”:

  – List A: List of Certain Natural Health Products for Distribution as Samples

  – List D: List of Certain Non-prescription Drugs for Distribution as Samples

  – List of Non-prescription Drugs for Which the Testing Requirements Set Out in Subsections C.02.019 (1) and (2) of the *Food and Drug Regulations* Do Not Apply

Notice of Proposal (cont'd)

- For further clarity, the product categories covered across these three lists will include:
  - toothpastes, mouthwashes, antiseptic skin cleansers, sunscreens, anti-dandruff products, diaper rash products, medicated skin care products, acne products, antiperspirants, as well as athlete's foot products and throat lozenges.

- This means that, within those products categories, the three lists will be expanded to include all approved ingredients, dosages and indications (or claims) with the exception of medicated skin care products.

- The CUSMA does include some exclusions specific to medicated skin care products (e.g., antifungals, antivirals, antibiotics, corticosteroids, counterirritants, and analgesics), and these exclusions will be maintained for the current proposal.

Proposed List A: List of Certain Natural Health Products for Distribution as Samples

Column 1	Column 2	Column 3	Column 4	Column 5	Column 6
Class of Natural Health Products	Medicinal Ingredient (s)	Quantity of Medicinal Ingredient(s)	Qualifier (s)	Route(s) of Administration	Permissible Use(s) or Purpose(s)
Toothpastes	All approved ingredients	All approved quantities	For human use	Oral Cavity	All approved uses or purposes
Mouthwashes	All approved ingredients	All approved quantities	For human use	Oral Cavity	All approved uses or purposes
Antiseptic Skin Cleansers	All approved ingredients	All approved quantities	For human use	Topical	All approved uses or purposes
Sunscreens	All approved ingredients	All approved quantities	For human use	Topical	All approved uses or purposes
Anti-Dandruff Products	All approved ingredients	All approved quantities	For human use	Topical	All approved uses or purposes
Diaper Rash Products	All approved ingredients	All approved quantities	For human use	Topical	All approved uses or purposes
Medicated Skin Care Products	All approved ingredients	All approved quantities	For human use	Topical	All approved uses or purposes except antifungals, antivirals, antibiotics, corticosteroids, counterirritants, and analgesics
Acne Therapy Products	All approved ingredients	All approved quantities	For human use	Topical	All approved uses or purposes
Throat Lozenges	All approved ingredients	All approved quantities	For human use	Oral cavity	All approved uses or purposes
Athlete's Foot Treatments	All approved ingredients	All approved quantities	For human use	Topical	All approved uses or purposes
Antiperspirants	All approved ingredients	All approved quantities	For human use	Topical	All approved uses or purposes

Proposed List D: List of Certain Non-prescription Drugs for Distribution as Samples

Column 1	Column 2	Column 3	Column 4	Column 5	Column 6	Column 7
Class of Non-prescription Drugs	Medicinal Ingredient (s)	Quantity of Active Ingredient (s)	Qualifier (s)	Route(s) of Administration	Permissible Use(s) or Purpose(s)	Last Revised (YYYY-MM-DD)
Toothpastes	All approved ingredients	All approved quantities	For human use	Oral cavity	All approved uses or purposes	
Mouthwashes	All approved ingredients	All approved quantities	For human use	Oral cavity	All approved uses or purposes	2020-03-13
Antiseptic Skin Cleansers	All approved ingredients	All approved quantities	For human use	Topical	All approved uses or purposes	2020-03-13
Sunscreens	All approved ingredients	All approved quantities	For human use	Topical	All approved uses or purposes	2020-03-13
Anti-Dandruff Products	All approved ingredients	All approved quantities	For human use	Topical	All approved uses or purposes	2020-03-13
Diaper Rash Products	All approved ingredients	All approved quantities	For human use	Topical	All approved uses or purposes	2020-03-13
Medicated Skin Care Products	All approved ingredients	All approved quantities	For human use	Topical	All approved uses or purposes except antifungals, antivirals, antibiotics, corticosteroids, counterirritants, and analgesics	2020-03-13
Acne Therapy Products	All approved ingredients	All approved quantities	For human use	Topical	All approved uses or purposes	2020-03-13
Throat Lozenges	All approved ingredients	All approved quantities	For human use	Oral cavity	All approved uses or purposes	2020-03-13
Athlete's Foot Treatments	All approved ingredients	All approved quantities	For human use	Topical	All approved uses or purposes	2020-03-13
Antiperspirants	All approved ingredients	All approved quantities	For human use	Topical	All approved uses or purposes	

Proposed List of Non-prescription Drugs for Which the Testing Requirements Set Out in Subsections C.02.019 (1) and (2) of the *Food and Drug Regulations* Do Not Apply

Column 1	Column 2	Column 3	Column 4	Column 5	Column 6	Column 7
Class of Non-prescription Drugs	Active Ingredient (s)	Quantity of Active Ingredient (s)	Qualifier (s)	Route(s) of Administration	Permissible Use(s) or Purpose(s)	Last Revised (YYYY-MM-DD)
Toothpastes	All approved ingredients	All approved quantities	For human use	Oral cavity	All approved uses or purposes	
Mouthwashes	All approved ingredients	All approved quantities	For human use	Oral cavity	All approved uses or purposes	2020-03-13
Antiseptic Skin Cleansers	All approved ingredients	All approved quantities	For human use	Topical	All approved uses or purposes	2020-03-13
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Throat Lozenges	All approved ingredients	All approved quantities	For human use	Oral cavity	All approved uses or purposes	2020-03-13
Athlete's Foot Treatments	All approved ingredients	All approved quantities	For human use	Topical	All approved uses or purposes	2020-03-13
Antiperspirants	All approved ingredients	All approved quantities	For human use	Topical	All approved uses or purposes	

In the Interim – Compliance and Enforcement

- While the work to expand the lists is underway,
  - Health Canada will use interim measures to ensure a wider range of products can avail of the regulatory flexibilities (i.e., sampling provisions and elimination of quarantine and retesting provisions).
  - All products listed in the proposed lists will be exempt from the sampling prohibitions in light of the impending changes, and enforcement actions will be de-prioritized.

- As communicated in DEL Bulletin No. 89 to all Drug Establishment Licence (DEL) holders, interim measures in light of the impending changes will also be adopted to eliminate identity and confirmatory testing requirements and allow direct shipping of all products listed in Appendix B sourced from recognized countries or regions.

- The above-noted interim measures will be in place until such time that the lists referenced in this presentation have been formally updated.

Next Steps

- As the two non-prescription drug lists were incorporated by reference on an ambulatory basis in the FDR, amendments to these lists can be implemented through the publication of a Notice of Proposal. Following a comment period, a Notice of Modification as well the revised lists will be published on Health Canada's website.

- For natural health products, the list has been incorporated on a static basis in the NHPR as the Department does not have the authority to incorporate lists on an ambulatory basis for NHPs. As such, a regulatory package will be needed to amend the NHP list, and work will begin on advancing this regulatory proposal following the consultation period. As this work advances, we will be able to provide more details on timing for the regulatory change.

- Health Canada intends to begin this process by publishing a Notice of Proposal for a 60-day consultation, to begin in early August 2020.

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