Dear Stakeholders/ Chers intervenants,

Please see below an advanced copy of an email that will be sent to all NPN and DIN holders over the coming days and by COB July 3rd at the latest, to provide an update on the implementation of the Canada-United States-Mexico Agreement.

Veuillez voir ci-dessous une copie avancée d'un courriel qui sera envoyé à tous les détenteurs de NPN et de DIN au cours des prochains jours et d'ici l'heure de fermeture des bureaux le 3 juillet au plus tard, pour faire le point sur la mise en œuvre de l'accord Canada-États-Unis-Mexique.

Dear Stakeholders,

As you may know, on March 13, 2020, Bill C-4 (the Canada–United States–Mexico Agreement Implementation Act (CUSMA)) received Royal Assent. CUSMA included regulatory commitments specific to products recognized as being at the interface of cosmetics and drugs (as outlined in Appendix I to Annex 12-B of the agreement).

To implement these commitments, regulatory amendments were made to the *Food and Drug Regulations* (FDR) and the *Natural Health Products Regulations* (NHPR), which come into force on July 1, 2020. These amendments will allow for:

- The distribution of specific low risk non-prescription drugs and natural health products as samples directly to consumers (the general public), under certain conditions; and
- The release of certain non-prescription drugs to the Canadian market without quarantine and additional testing upon importation and direct shipment of such products to retailers and wholesalers.

As part of the CUSMA implementation, Health Canada established a guidance document on the distribution of drugs as samples, as well as lists of the specific non-prescription drugs and natural health products that can be distributed as samples directly to consumers. Health Canada also established a list of the non-prescription drugs for which additional (i.e., identity and confirmatory) testing is not required upon importation and may be directly shipped to retailers or wholesalers.

Additional Amendments

Further to this guidance document, Health Canada wishes to advise interested stakeholders of the steps that are being undertaken to expand the lists of products described above, as follows:

1. Amend List A: List of Certain Natural Health Products for Distribution as Samples 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".

2. Amend List D: List of Certain Non-prescription Drugs for Distribution as Samples 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".

3. Amend the 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 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".

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.

For details on the product scope expansion proposed for all three lists, please refer to Appendix A for the proposed revisions to the list of natural health products that could be distributed as samples directly to consumers. Please refer to Appendix B for the list of proposed revisions to the list of non-prescription drugs that could be distributed as samples directly to consumers, as well as for which additional (i.e., identity and confirmatory) testing is not required upon importation and may be directly shipped to retailers or wholesalers.

Process and Timing for Amendments

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 a 60-day 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 in July 2020.

In the Interim

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).

This means that, while Health Canada works towards implementing the expanded lists, all products listed in Appendices A (NHPs) and B (OTCs) will be exempt from the sampling prohibitions in light of the impending changes, and enforcement actions will be de-prioritized.

Also, 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. A PDF copy of this bulletin is attached for your reference.

The above-noted interim measures will be in place until such time that the lists referenced in Appendices A and B have been formally updated.

Should you have any questions or require clarification related to the elimination of duplicative testing requirements upon importation and allowance of direct shipment to retailers or wholesalers, please contact the Good Manufacturing Practices Unit at: hc.gmp.conditions-bpf.sc@canada.ca.

For any questions relating to the distribution of non-prescription drugs or natural health products as samples, please contact the Natural and Non-prescription Health Products Directorate at: hc.nnhpd.consultation-dpsnso.sc@canada.ca. Please note that an information session on the distribution of products as samples is being planned for interested stakeholders later in July. Further details will be shared as soon as available.

We look forward to your continued collaboration and engagement.

Manon Bombardier
Director General, Natural and Non-Prescription Health Products Directorate
Health Products and Food Branch | Health Canada

APPENDIX A: Proposed Updates to the 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

APPENDIX B: Proposed Updates to the List of Certain Non-prescription Drugs for Distribution as Samples, and the List of Non-prescription Drugs for which identity and confirmatory testing are not required upon importation

Column 1	Column 2	Column 3	Column 4	Column 5	Column 6
Class of Non-prescription Drugs	**Active[1] Ingredient (s)**	**Quantity of Active 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

[1] Column 2 in List D will be maintained as "Medicinal Ingredient(s)".

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