NOTIFICATION

The following notification is being circulated in accordance with Article 10.6

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| **1.** | **Notifying Member:** Canada **If applicable, name of local government involved (Article 3.2 and 7.2):**  |
| **2.** | **Agency responsible:** Department of Health**Name and address (including telephone and fax numbers, email and website addresses, if available) of agency or authority designated to handle comments regarding the notification shall be indicated if different from above:** Canada's Notification Authority and Enquiry PointGlobal Affairs CanadaTechnical Barriers and Regulations Division 111 Sussex DriveOttawa, ON K1A 0G2CanadaTelephone: (343)203-4273Fax: (613)943-0346Email: enquirypoint@international.gc.ca  |
| **3.** | **Notified under Article 2.9.2 [****X],** **2.10.1 [****],** **5.6.2 [****],** **5.7.1 [****],** **other****:**  |
| **4.** | **Products covered (HS or CCCN where applicable, otherwise national tariff heading. ICS numbers may be provided in addition, where applicable):** Pharmaceutics (ICS 11.120) |
| **5.** | **Title, number of pages and language(s) of the notified document:** Notice of Proposal to expand lists of certain products for distribution as samples and a list of certain non-prescription drugs for which testing requirements do not apply (8 pages, available in English and French) |
| **6.** | **Description of content:** Health Canada intends to amend the lists for non-prescription drugs set out in the Canada-United States-Mexico Agreement (CUSMA) that meets the identified criteria, i.e., for topical use, localized and non-systemic effect, and meets the definition of a cosmetic. The product categories that meet these criteria include: toothpastes, mouthwashes, anti-septic skin cleansers, sunscreens, anti-dandruff products, diaper-rash products, medicated skin care products, acne therapy products and antiperspirants, as well as athlete's foot products and throat lozenges.Health Canada is proposing that within those products categories, all lists for non-prescription drugs will be expanded to include all approved ingredients, all approved quantities and all approved uses or purposes with the exception of certain medicated skin care products. The CUSMA does include some exclusions related to medicated skin care products (i.e., antifungals, antivirals, antibiotics, corticosteroids, counterirritants, and analgesics), and these exclusions will be maintained for the current proposal.Health Canada's proposal also includes updates and revisions to the list of certain non-prescription drugs for which additional (i.e., identity and confirmatory) testing is not required upon importation and that may be directly shipped to retailers or wholesalers. Health Canada intends to expand the list of certain non-prescription drugs for which testing requirements do not apply.  Thus expanding the list toinclude all approved ingredients, all approved quantities and all approved uses or purposes with the exception of certain medicated skin care products. |
| **7.** | **Objective and rationale, including the nature of urgent problems where applicable:** Health Canada wishes to advise interested stakeholders of a proposal posted for a 60 day consultation period to seek feedback, and make potential additions, to the products that will be added to the Amended List(s).; Other |
| **8.** | **Relevant documents:** Health Canada website: Notice of Proposal (available in English and French) [List D: List of Certain Non-prescription Drugs for Distribution as Samples](https://www.canada.ca/en/health-canada/services/self-care-regulation-non-prescription-drugs/list-d-non-prescription-drugs-distribution-samples.html)[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](https://www.canada.ca/en/health-canada/services/drugs-health-products/compliance-enforcement/legislation-regulatory-amendments/incorporation-by-reference/list-non-prescription-drugs.html) [Guidance document: Distributing samples of prescription drugs, non-prescription drugs and natural health products](https://www.canada.ca/en/health-canada/services/drugs-health-products/natural-non-prescription/legislation-guidelines/guidance-documents/distribution-drugs-samples-summary.html)  |
| **9.** | **Proposed date of adoption:** A final posting of the list of products that can distribute those drugs as samples or directly import to distributors or wholesalers will be posted this Fall/Winter 2020 **Proposed date of entry into force:** Fall/Winter 2020 |
| **10.** | **Final date for comments:** 10 October 2020 |
| **11.** | **Texts available from: National enquiry point [****X]** **or address, telephone and fax numbers and email and website addresses, if available, of other body:** The electronic versions of the regulatory text can be downloaded at:Canada's Notification Authority and Enquiry PointGlobal Affairs CanadaTechnical Barriers and Regulations Division 111 Sussex DriveOttawa, ON K1A 0G2CanadaTelephone: (343)203-4273Fax: (613)943-0346Email: enquirypoint@international.gc.ca <https://www.canada.ca/en/health-canada/services/drugs-health-products/natural-non-prescription/notice-consultation-expand-lists-samples-imports-without-retesting.html> (English)<https://www.canada.ca/fr/sante-canada/services/medicaments-produits-sante/naturels-sans-ordonnance/avis-consultation-elarger-listes-echantillons-importations-sans-retester.html> |