Regulatory Essentials – May 13, 2020

Cosmetics Alliance Updates

Update from the Hand Sanitizers Manufacturing Exchange Program

We understand that the federal government is currently assessing the volume of hand-sanitizers required to meet Canada's domestic needs and should be providing a preliminary estimate shortly. This estimate is critical in assessing progress as well as estimating the expected demand for various ingredients and components to ensure adequate supplies moving forward.

At the current time, the Exchange can offer the following summary of progress in the five areas that are critical in meeting Canada's domestic requirements for hand-sanitizers:

Supplier List from the Exchange Program

Cosmetics Alliance Exchange Program is now publishing a list of all registered suppliers that contains the ingredients, components or services they have available, as well as their location and contact information.

The Suppliers List is Now Available on the Exchange which can be found here and will be updated daily. We encourage manufacturers to contact suppliers that may have what they require.

Health Updates

Updated Guidance Document: Questions & Answers: Plain Language Labelling Regulations for Non-prescription Drugs

Health Canada has recently updated the Question & Answer: Plain Language Labelling for Non-prescription Drugs. Below are the following changes:

- The title has been changed from Questions and Answers: Plain Language Labelling Regulations for Non-prescription Drugs and Contact Lens Disinfectants to Questions and Answers: Plain Language Labelling Regulations for Non-prescription Drugs
- Revisions to Section 5: Mock-up Requirements – References to Notifiable Changes was removed and is effective 2018.04.01

Please review the updated guidance document and let your CA Regulatory Team know if you have any questions.

MedEffect e-Notice – Protect Yourself and Your Family from Poisonings

On May 5, 2020, Health Canada released a MedEffect Notice on improperly using hand sanitizers, disinfectants, household cleaning products and bleaches. This MedEffect Notice was in response to the CBC story released yesterday on Canadians accidently poisoning themselves while cleaning to prevent COVID-19. The article can be found here. The article focuses on the jump in the number of cleaner and disinfectant-related accidental poisoning since the COVID-19 pandemic, provides some precautionary measures, common cleaning mistakes and accidental consumption.

It is our priority to ensure that products on the marketplace are safe and effective. Thus, we have been working with Health Canada to provide guidelines to stakeholders on producing safe and effective disinfectants such as the few listed below:

- HC's Interim Expedited Licensing Approach for Alcohol-Based Hand Sanitizers
- HC's interim guide on the production of Ethanol for use in Hand Sanitizers
- Hard-surface Disinfectants and Hand Sanitizers (COVID-19) : Information for Manufacturers

For complete list of all the guidelines please visit Cosmetics Alliance Website – Hand Sanitizer Tools.

CUSMA Enters into Force on July 1, 2020 – Resulting in Regulatory Amendments for Low-Risk Drugs/NHPs

On April 24, the United States notified Canada of the completion of its domestic process for the Canada-United States-Mexico Agreement (CUSMA). On the same day, USTR sent written notice to Congress informing its members that Canada and Mexico have taken measures necessary to comply with their commitments under CUSMA, and that the Agreement will enter into force on July 1, 2020.

RESULTING REGULATORY AMENDMENTS FOR LOW-RISK DRUGS & NHPs

CA is pleased to announce that on April 29 Health Canada published Regulatory Amendments in Canada Gazette Part 2 to:

1. Eliminate the quarantine & re-testing requirement for certain low-risk non-prescription drugs,
2. Permit the distribution of certain low risk non-prescription drugs and natural health products under specified conditions.

These Canada Gazette Part 2 postings are the result of *Bill C-4 An Act to implement the Agreement between Canada, the United States of America and the United Mexican States* which received Royal Assent on March 13, 2020.

The products listed in the amendments for both sampling and quarantine/re-testing are not yet fully in alignment with CUSMA and appear to be based on products with well-established safety and efficacy profiles (i.e. monographed products) and not based on the product consideration aspects as outlined in 12 Sectoral Annexes Chapter – 12B Cosmetics. Cosmetics Alliance has reached out to officials to understand how exactly these regulatory amendments deliver on the requirements under CUSMA and next steps to rectify discrepancies.

CUSMA provided an opportunity to advance these reforms, however, separate from the implementation of CUSMA, Health Canada is also modernizing its approach to regulating all self-care products under the Self-Care Framework Initiative. These reforms under CUSMA are an important step in advancing the Self-Care Framework.

For details as summarized by your CA Regulatory Team, please see below.

If you have any questions, please don't hesitate to reach out to your Regulatory Team.

1. FINISHED PRODUCT TESTING

Regulations Amending the Food and Drug Regulations (Finished Product Testing) SOR/2020-73 April 7, 2020 – SOR/2020-73 April 7, 2020 – PDF HERE

Further to DEL Bulletin LEPP No 77 and as mentioned on our March 22nd Webinar on the *Elimination of Drug Quarantine & Re-Testing for Low-Risk Non-Prescription Drugs*, Health Canada published on April 29, the Regulatory Amendments respecting finished product testing in Canada Gazette Part 2.

The regulations come into effect on July 1st, 2020. Until that time, DEL Bulletin No. 77 is in effect as an interim measure. The regulations reference two documents which are incorporated by reference into the regulations:

List of Foreign Countries or Regions and Their Regulatory Authorities for the Application of Subsection C.02.019 (5) of the Food and Drug Regulations

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

These lists allow Health Canada to respond swiftly to any changing circumstances which may affect each list, without a need for regulatory amendments.

Separate from the implementation of CUSMA, as you know, Health Canada is modernizing its approach to regulating self-care products under the Self-Care Framework Initiative. This is an important step in advancing the Self-Care Framework.

Summary

New Flexibilities:

- Importers of the listed products from the listed countries are:
  - no longer required to re-test for identity after receipt in Canada,
  - no longer required to have a full confirmatory re-testing program.
  - given the option to ship directly to retail from the foreign site

Previous Requirements:

- RE-DO chemical identity testing after receipt in Canada
- RE-DO all testing again according to a schedule after receipt in Canada (full confirmatory testing)
- SHIP to a warehouse in Canada prior to distribution.

What has not changed:

- Importers are still required to release product destined for Canada: prior to shipment to Canada, or prior to distribution in Canada.

Countries:

The list of countries is not about MRA agreements or product classification in those jurisdictions, it is about your foreign supplier(s) and the country in which it is located.

All activities (i.e. fabrication, packaging, labelling and testing) must occur in Canada or in a recognized country or region in order to be subject to the reduced testing / direct ship options.

2. SAMPLING – DRUGS AND NHPs

Regulations Amending the Food and Drug Regulations (Distribution of Drugs as Samples) SOR/2020-74 April 7, 2020 – Published April 29, 2020 – PDF HERE

Regulations Amending the Natural Health Products Regulations (Distribution of Natural Health Products as Samples) SOR/2020-75 April 7, 2020 – SOR/2020-73 April 7, 2020 – PDF HERE

The Food and Drug Regulations (FDR) and the Natural Health Product Regulations (NHPR) are now amended to meet Canada's CUSMA commitment to permit the distribution of certain low risk non-prescription drugs (NPDs) and natural health products (NHPs) under certain conditions.

This amendment to the Food and Drugs act allowed amendments to Regulations which now permit the distribution of specific low risk non-prescription drugs and natural health products as samples under certain conditions. Section 14 of the Food and Drugs Act previously prohibited the distribution of drugs as samples other than to physicians, dentists, veterinary surgeons or pharmacists, under prescribed conditions. This has been eliminated from the act and these conditions are now included under the respective FDR and NHPR.

Amendment to Section 14 of the Food and Drugs Act – Bill C-4

14 ~~(1)~~ No person shall distribute or cause to be distributed any drug as a sample except in accordance with the regulations.

~~(2) Subsection (1) does not apply to the distribution, under prescribed conditions, of samples of drugs to physicians, dentists, veterinary surgeons or pharmacists.~~

These two sets of regulations are specifically amended to permit the distribution of NPDs and NHPs as samples through lists that are incorporated by reference. The NPD list may be amended on an ambulatory basis which will allow for the addition and removal of NPDs and introduce product/class-specific qualifiers for drugs. The NHP List is a static list and is required to be amended via changes to the NHPR.

These regulations come into effect on July 1st, 2020 to allow industry to distribute certain NPDs and NHPs as samples as a strategy to encourage their use on a trial basis. This may provide benefits to Canadians, practitioners and pharmacists, by increasing their knowledge of available health product options to meet their needs.

Health Canada has developed a guidance document entitled EN_Guidance – Distribution of Drugs as Samples 2020.

These changes apply to:

- Industry stakeholders distributing drugs/NHPs as samples
- Practitioners and pharmacists receiving drugs/ NHPs distributed as samples
- Canadian consumers receiving drugs/NHPs distributed as samples

Summary and Comparison Table

	Drugs	NHPs
Distribution of samples to the general public (i.e. a consumer)		
General	A person may distribute or cause to be distributed a drug, in dosage form, as a sample to any consumer if that drug is not a prescription drug and is part of a class of drugs that is set out in List D if certain conditions are met. Incorporated by reference	A person may distribute of cause to be distributed a natural health product, in dosage form, as a sample to any consumer if that natural health product has a localized effect and is for administration either in the oral cavity or on the skin, or is a throat lozenge if certain conditions are met.
Scope of products for distribution to the general public	Low risk NPDs as set out in the *List of Certain Non-prescription Drugs for Distribution as Samples* (List D) under the FDR	Low risk NHPs as set out in the *List of Certain Natural Health Products for Distribution as Samples* under the NHPR.
Conditions of distribution	Variable List · Limits distribution to individuals who are 18 years of age or more. · The distribution of a sample to the general public cannot occur during the 30 days prior to its expiry date.	Static List
Distribution of drugs as samples to practitioners and pharmacists for further distribution to their patients		
Scope of practitioners and the conditions of distribution	· The term “practitioner” replaces the terms physician, veterinary surgeon and dentist. · The term “pharmacist” remains. Pharmacist are individuals in a province who are entitled to practise pharmacy in that province Practitioners are individuals who are entitled to treat patients with a prescription drug in that province. Health Canada does not consider practitioners and pharmacists to be consumers and they are not subject to the specific regulatory provisions permitting the distribution of drugs as samples to a consumer. Health Canada does not consider the further distribution of a drug as a sample from a practitioner or a pharmacist to their patient to be a distribution to a consumer. Practitioners and pharmacists engage in this type of distribution in accordance with their provincial or territorial scope of practice, therefore the age restriction f 18 years or more does not apply in respect of their patients in a healthcare setting.	Same as Drugs – References the definitions in the FDR C.01.048(1).
	Change permits the distribution of samples of prescription and non-prescription drugs to practitioners or pharmacists. Drugs distributed as samples that are not on List D or on List A may only be distributed in dosage form to a practitioner or pharmacist if you have a signed order from that practitioner or pharmacist.	Change permits the distribution of NHPs as samples to practitioners and pharmacists.

In addition, a person will only be able to distribute a prescription drug to a practitioner who is able to prescribe that drug in accordance within their provincial or territorial law.	
Record keeping provisions	Record keeping provisions

Update – Health Canada Interim Policy for Household Consumer Cleaning Products, Hand Soaps and Body Soaps (COVID-19)

Health Canada has updated its interim policy for certain household consumer cleaning products, hand soaps and body soaps. The updates are:

- Importers are required to provide sellers with a means to inform consumers, at the time of sale, of the website where bilingual label text is posted. This could be made available through a sticker applied directly to the products, posters, or signage with take-away pamphlets at the point of sale. Effective immediately, all new importers of these products through the interim policy must meet this requirement; importers who have previously submitted a form are to meet this requirement no later than June 8, 2020.
- Health Canada will lift the interim policy when the regular supply stabilizes.

It is expected that these updates will help further ensure that consumers have access to the necessary label text in both official languages before they use the products imported under this policy.

The updated policy is available online at: https://www.canada.ca/en/health-canada/services/home-safety/household-chemical-safety/covid19-cleaning-products-hand-body-soaps.html

The updated form is also available here: https://www.canada.ca/content/dam/hc-sc/documents/services/home-safety/household-chemical-safety/covid19-cleaning-products-hand-body-soaps/form-importation-non-compliant-cleaning-products.docx

Forms and questions regarding this policy should continue to be sent to hc.ccpsa-lcspc.sc@canada.ca.

Regulatory Amendments Respecting Finished Product Testing

Further to DEL Bulletin No. 77 and as mentioned on our March 22nd Webinar on the Elimination of Drug Quarantine & Re-Testing for Low-Risk Non-Prescription Drugs, Health Canada published on April 29, the Regulatory Amendments respecting finished product testing in Canada Gazette Part 2.

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TECHNICAL SUMMARY

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Post-Consumer Waste Updates

Minister Directs Amendments to MHSW Wind Up Plan

In response to new Ministerial direction, Stewardship Ontario will be consulting on amendments to the management of surplus funds during the wind up of the MHSW program. These proposed amendments to the Wind Up Plan will be of interest to all MHSW stakeholders given the potential financial implications for the program and individual stewards.

The Minister of the Environment, Conservation and Parks recently sent Stewardship Ontario a letter directing the organization to develop amendments to the approved MHSW Wind Up Plan which would return 100% of material-specific surplus funds to Industry Stewardship Organizations (ISOs) in one lump sum transfer.

In a second letter received this week, the Minister granted an extension for submitting the amendments to the Resource Productivity and Recovery Authority (RPRA) to June 5, 2020 in order to allow sufficient meaningful consultation with stakeholders given the current situation with the COVID-19 pandemic.

Consultation on Amendments for All MHSW Stakeholders

We will be holding two consultation webinars during which Stewardship Ontario will review its proposal for disbursing existing surplus funds to ISOs pursuant to surplus fund transfer agreements that:

- Outline how ISOs are to return surplus funds to Industry Stewardship Plan (ISP) stewards "*in the form of fee reductions for the maximum benefit of consumers*" and;
- In the case that there is a delay in the transition of the MHSW program under the *Resource Recovery and Circular Economy Act, 2016*, allow Stewardship Ontario to recover "*reasonable unexpected costs related to the materials managed by the ISOs*."

The content will be the same for both webinars. Please register for the date and time that works best for you using the links below:

Tuesday, May 12, 2020

8:30 - 10:30 a.m.

Register here

Wednesday, May 13, 2020

2:30 - 4:30 p.m.

Register here

Feedback

We invite stakeholders to submit feedback on the content discussed during the consultation webinars up until Friday, May 22, 2020.

We will then finalize the proposed amendments and submit to RPRA by the June 5, 2020 deadline for approval. The Minister expects RPRA will approve the amendments no later than June 25, 2020.

If you have any questions, please contact us at mhswwindup@stewardshipontario.ca

Deadline for Stewardship Ontario to Submit Proposed Blue Box Program Wind-up Plan to the Authority has been Extended

The Minister of the Environment, Conservation and Parks has extended the deadline for Stewardship Ontario (SO) to submit its proposed Blue Box Program Wind-up Plan to the Authority to August 31, 2020, instead of June 30, 2020.The extension was requested by SO due to the COVID-19 pandemic to ensure meaningful consultation with stakeholders. The timelines for the wind up of the Blue Box Program and transition to the individual producer responsibility framework remains the same. Learn more.