Regulatory Essentials – August 19, 2020

Health Updates

Health Canada Compliance & Enforcement Plan for OTC Plain Language Labelling

BACKGROUND

The regulatory deadline for OTC plain language labelling is June 30, 2021 whereby all non-prescription drug products must be in full compliance with the regulatory requirements, which include the presence of a Canadian Drug Facts Table (CDFT) on the outer label, at the retail level.

Health Canada has processed label changes or received compliance plans for close to 75% of the affected OTC DIN-holders. Submission continue to be received for labelling conversions where submissions are required.

WHAT DO YOU NEED TO DO?

- If you have not submitted a PLL compliance plan, you are encouraged to do so.
- If you have submitted a PLL compliance plan, and your plan has changed, you are encouraged to submit an updated compliance plan.
- If you are unsure whether or not your company has submitted a compliance plan, reach out to Jason diMuzio (jason.dimuzio@canada.ca) for assistance.

WHY IS THIS IMPORTANT?

Health Canada seeks fairness in the approach to addressing challenges with meeting the retail compliance deadline, given the current environment, and expects that non-compliant OTCs may continue to be on shelves past June 2021. Health Canada has recognized the effort that most companies (75%) have already made in meeting the deadline, such as submitting compliance plans to Health Canada.

Cosmetics Alliance previously outlined the details and importance of compliance plans in our May 21st, 2019 communication in which we informed members of Health Canada's intention to utilize these compliance plans to inform their compliance and enforcement (C&E) approach come July 2021.

Health Canada has proactively reached out to many companies who have not submitted these plans, relying on their contact lists from their Drug Product Database. Follow-up has included formal letters, multiple emails and telephone follow-ups. In some cases, no contact has been made or no response has been received from the stakeholder.

WHAT WILL THE COMPLIANCE & ENFORCEMENT APPROACH LOOK LIKE?

After June 30, 2021, the C&E approach will consider factors such as risks to health, compliance history and willingness to comply as outlined in the Compliance & Enforcement Policy (POL-0001). It will be implemented in 2 phases each with proactive (such as market surveys or sampling) and reactive (complaint-based) elements. Reactive elements use an established triage process to evaluate and prioritize complaints according to the level of risk.

Phase 1 (July 1, 2021 – December 31, 2021): Health Canada will proactively focus department resources on the most serious cases of non-compliance, such as manufacturers who have not

submitted compliance plans or label revisions to HC since June 2017. This would encompass willful non-compliance.

Phase 2 (January 1, 2022 onward): Health Canada will continue to apply a risk-based approach to address any cases of non-compliance, with proactive elements expanded to all regulated parties (i.e. no longer limited to the most serious cases). C&E efforts will focus on companies that have submitted a compliance plan but are experiencing some delays in implementation.

Health Canada will work directly with manufacturers (DIN owners) with PLL non-compliance issues.

WHAT RETAILERS SHOULD EXPECT

- Expect that some manufacturers will continue to ship non-PLL compliant products to your Distribution Centres beyond June 2021
- Expect to stock store shelves with non-PLL compliant products beyond June 2021
- Expect to answer consumer questions regarding the different appearance of labels, particularly if individual stores carry large volumes of overstock
- Expect to work closely with manufacturers if Health Canada identifies risks beyond PLL (such as product quality issues or safety concerns) that require action at the retail level

WHAT IS THE ROLE OF RETAILERS IN PLL COMPLIANCE?

- Health Canada does not expect retailers to discard previously authorized products that are not yet aligned with PLL
- Health Canada does not expect retailers to refuse shipments of non-PLL products to Distribution Centres or stores
- Retailers do not need to request evidence from a manufacturer regarding the status of their PLL compliance
- In cases where non-compliance with PLL is identified, Health Canada will work directly with manufacturers to address the issue. Only when other non-compliances arise (quality or safety concerns) would a retailer be expected to participate in mitigation measures

DEL Bulletin LEPP NO.91 – Nitrosamines Extension

The Director General of the Natural and Non-prescription Health Products Directorate (NNHPD) notified CA of the notice to associations from the Therapeutic Products Directorate (TPD) on the extension of the Step 1 of the Nitrosamines Impurities Risk Assessment. Below is the notice CA received from the TPD.

Please take the time to review the notice and let us know if you have any questions.

Nitrosamines Extension – EN

Nitrosamines Extension - FR

https://www.cosmeticsalliance.ca/del-bulletin-lepp-no-91-nitrosamines-extension/

DEL Bulletin No. 92 - New Guidance: Importing and Exporting Health Products for Commercial Use

Attached is the new guidance document, Importing and Exporting Health Products for Commercial Use (GUI-0117) which has an implemented on August 14, 2020. This guide replaces GUI-0084, Import Requirements for Health Products under the Food and Drugs Act and its Regulations; POL-0060, Import and Export Policy for Health Products under the Food and Drugs Act and its Regulations; POL-0059, Border Integrity Approach; and POL-0018, Policy for the Importation or Sale of Active Pharmaceutical Ingredients for Veterinary Use.

At this time, GUI-0117 is available in English only. A French version will be available in future and sent to you by DEL Bulletin. In the meantime, should you have questions in either official language, please contact Health Canada's Border Integrity Program in writing at **hc.hpbcp-pcpsf.sc@canada.ca.**

GUI-0117

DEL Bulletin No. 93 – Webinar: Changes to the Guidelines for Environmental Control of Drugs During Storage and Transportation (GUI-0069)

Health Canada is hosting a webinar to review changes to the *Guidelines for environmental control of drugs during storage and transportation (GUI-0069).* GUI-0069 will be posted on the Health Canada website for final publication over the next few weeks.

The ENGLISH session is full and we suggest members to email hc.gmp.conditions-bpf.sc@canada.ca to request for an additional English Session. Cosmetics Alliance has also requested for another English Session as well. We will notify members once an English session is available.

To register for the FRENCH session on August 28, 2020 at 11am go to **Register.**

Public Comment Period – Notice of Proposal for Products to be Distributed as Samples

Further to recent information sent to you on next steps on the implementation of the Canada-United States-Mexico Agreement (CUSMA), Health Canada is pleased to inform you that the public comment period on the 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 is **now open**.

The Notice of Proposal, along with information on how you can provide your comments, is available here. Proposal is open till October 10, 2020.

Health Canada understand there will be interest in expanding these lists further (e.g., beyond topical products). It was always the intention that, in consultation with stakeholders, these lists would be expanded over time, and there will continue to be opportunities moving forward to consider further expansion of these lists.

The current guidance document, "Distributing samples of prescription drugs, non-prescription drugs and natural health products" will be updated following the comment period. If you have specific comments with respect to the guidance, please submit these during this public comment period as part of your feedback on the proposal.

We will be holding a meeting on this in the coming weeks with our Product Compliance & Market Access Committee and our Facility Compliance & Manufacturing Committee. If you are

not part of the committee and would like to take part in the discussion please email regualtory@cosmeticsalliance.ca.

CUSMA Webinar Notice of Proposal Presentation – EN

CUSMA Webinar Notice of Proposal Presentation – FR

Consultation on Policy for Packaging and Labelling of Alcohol Based Hand Sanitizers in Drinking Containers

Given the current demand for hand sanitizer in Canada, existing and new hand sanitizers manufactures have either quickly increased their production or have adapted their existing production lines to manufacture hand sanitizers to address the increasing needs. The increased production and demand have led to shortfalls in standard packaging, resulting in the use of other unconventional types of containers such as beverage or drinking containers (e.g., water bottles, wine bottles, etc.).

Based on data from Canadian Poison Control Centres (PCCs), the number of reported exposure incidents related to hand sanitizer has been increasing steadily since January 2020, and a noticeable increase has been seen from incidents in 2020 compared to the same time period in 2019. The use of beverage containers for alcohol-based hand sanitizers may contribute to the increase in the risk of accidental ingestion.

Health Canada has developed the attached policy to provide direction to licence holders, manufacturers, packagers and labellers of alcohol based hand sanitizers on additional labelling and packaging requirements to minimize risks of accidental ingestion of alcohol-based hand sanitizers, packaged and sold in beverage or drinking containers. This policy is intended to complement the existing labelling requirements for natural health products under the Natural Health Product Regulations (NHPR).

This policy is a draft document, we are sharing today to provide affected stakeholders an opportunity to provide comments and feedback on the proposed document. Please keep the distribution within your memberships.

Please consider the following questions when reviewing the attached policy document.

- Are the additional labelling and packaging requirements clear and easy to follow?
- Are there any barriers you would see to implementing these changes? (e.g. continued shortages of pumps, caps, or containers)
- If so, to what extent do these barriers extend?
- Would a more prescriptive alternative approach to the labelling be easier for implementation? For example, Health Canada could supply a standard graphic of the statement corresponding to different sizes of containers. i.e.:
  - < 500 mL containers (beer/soda cans and water bottles)
  - 500- 750 mL containers (water bottles and drinking containers)
  - 750 -1L containers (wine and spirit bottles)
  - 1L and greater (sprits and other beverage containers)
- Do you have other suggestions or considerations for Health Canada to help mitigate the risk of accidental ingestion given the current use of beverage or drinking containers for hand sanitizers?

Please provide your comments and feedback by **Wednesday September 2, 2020**. by sending your comments to: hc.nnhpd.consultation-dpsnso.sc@canada.ca with the subject line: **Consultation response regarding packaging and labelling of alcohol based hand sanitizers in beverage containers.**

Health Canada is targeting mid-September for the implementation of the additional labelling and packaging requirements; products on the shelf will be expected to comply within 8 weeks. The policy will be available on our website when finalized, and we will notify you once available.

Cosmetics Alliance will be submitting comments. If you have any comments please send them to regulatory@cosmeticsalliance.ca

Draft Policy – EN

Draft Policy - FR

Quarterly Consumer Products and Cosmetic Reports Received for Q1 2020-2021

The Consumer and Hazardous Products Safety Directorate regularly receives reports on human health or safety concerns related to consumer products and cosmetics. Consumer products are regulated under the *Canada Consumer Product Safety Act,* while cosmetics are covered under the *Food and Drugs Act*. 447: Number of reports received by the Consumer and Hazardous Products Safety Directorate

Industry is required to submit reports to the Consumer and Hazardous Products Safety Directorate when they become aware of an incident related to their consumer product. Consumers report concerns about consumer products and cosmetics on a voluntary basis. Percentage of industry reports and consumer reports: 55% and 45%, respectively

Percentage of reports received by product category
Appliances: 23%; Housewares: 20%; Electronics: 13%; Children's Products: 12%; Outdoor Living: 9%; Home and Automobile Maintenance: 7%; Grooming Products and Accessories: 6%; Sports, Recreation, and Hobby: 3%; and Clothing, Textiles, and Accessories: 3%.
Note: Total does not always add up to 100 due to rounding.

Top 5 product types based on number of reports received
Telephones or Accessories: 21; Cosmetics: 21; Electric Ranges or Ovens: 18; Computers: 15; and Laundry Soaps or Detergents: 14.

Not every report the Consumer and Hazardous Products Safety Directorate receives involves an injury. Over the time period, injuries, including deaths, were reported in 40% of reports received.
178: Number of reports including an injury

Top 3 Injury Types
Irritations: 43; Burns: 31; Cuts: 26.

https://www.canada.ca/en/health-canada/services/consumer-product-safety/reports-publications/industry-professionals/consumer-product-cosmetics-reports-received/quarterly-data-april-1-june-30-2020.html

Environmental Updates

Various Publications Under the Chemicals Management Plan

Final Screening Assessment and Significant New Activity for Epoxides and Glycidyl Ethers Group

The final Screening Assessment and Significant New Activity Notice of Intent for the Epioxides and Glycidyl Group was published on August 7. The Final Screening assessment concludes that none of the five substances are concluded to be harmful to human health or the environment at levels of exposure considered in the assessment.

Draft Screening Assessment for Sliver and its Compounds

The Chemicals Management Plan released the Draft Screening Assessment of Silver and its compounds on August 14 with a 60-day consultation period ending on October 14. The Government is proposing that silver and its compounds are not harmful to human health at levels of exposure considered in the assessment. The Government is also proposing that the seven substances in the Silver and its Compounds Group are not harmful to the environment. Although silver and its compounds may have an environmental effect of concern, it was determined that the risk posed by these substances to the environment is not of concern at levels of exposure considered in the assessment. As a result the seven substances in the Silver and is compounds will be monitored. CA will be monitoring any developments and will inform committee accordingly.

Please take the time to review the draft screening assessment and let us know if you have any questions or concerns.