Regulatory Essentials – May 22, 2019

Cosmetics Alliance Update

CA's Executive Briefing & Networking Event at Veeva Systems Inc.

June 4, 2019
4:30 to 7:30 pm
Veeva Systems Inc.
20 Toronto Street, Suite 1000
Toronto

Join us for this CA complimentary event intended for leaders or their representatives. Learn about fast moving issues that can affect your business and the opportunities they create.
The Speaker - John Cooper, Director of Strategy, Veeva Claims
The Topic – Navigating the Increasing Complexity of Cosmetics Product Claims
The competitive landscape in the cosmetics category has changed dramatically over the past several years as natural and sustainable trends have taken center stage and a wave of new indie and influencer led brands have rushed to capitalize. These and other factors have added challenges to the already complex task of managing cosmetic product claims. Compounding this is the fact that most companies are using manual, disparate systems for claims management.

Given current trends and the pace of change in cosmetics, it's likely that claims management will get considerably more complex in the not too distant future. Companies without the proper systems and processes in place could be in for a rude awakening.
Hear from product claims management expert John Cooper about how the latest cosmetics trends such as personalization, the rise of influencers, wellness, and accompanying supply chain challenges are merging to further complicate claims management in the cosmetics category. John will also present findings from recent third-party research on claims management challenges, and offer recommendations to help your team prepare for what lies ahead.

To register please email Michele Davis (mdavis@cosmeticsalliance.ca).

Health Updates

Revised Fees for Drugs and Medical Devices

The revised fees for drugs and medical devices will be implemented on April 1, 2020. The revised fees will be published in Canada Gazette, Part II on May 29, 2019. A Final Fee Report: Fees for Drugs and Medical Devices which summarizes the consultation and evolution of the revised fees will also be published on Health Canada's website. For your reference, an advanced copy is attached. the revised fees include a comprehensive small business strategy, fee waivers for publically funded health care institutions and staggered implementation of fees to minimize impact to industry. Health Canada remains committed to meeting its performance standards. All existing public accountability and transparency measures will continue with annual reporting. Furthermore, Health Canada will meet with stakeholders on an annual basis to discuss topics such as performance, costs and business improvements.

The revised fees enable Health Canada to continue to deliver its regulatory services in order to meet the needs of Canadians and the healthcare system, and to remain competitive with other international regulators.

Health Canada will be engaging with stakeholders at various intervals beginning June 4, 2019, to present the revised fee regulations and respond to questions, details of which will be provided in a separate email to all stakeholders.
Please take the time to review the Revised Fee Proposal below and let your CA regulatory team know if you have any questions or concerns.

Final Fee Report – EN

Final Fee Report – FR

NNHPD Technical Issues Resolved

Earlier this month Health Canada's Natural and Non-Prescription Health Products Directorate (NNHPD) experienced technical issues which caused their various databases and license applications to be down for a few days. CA reached out to the NNHPD to understand the nature of this outage and plans to prevent similar ones in the future. We have been told that the outage was government-wide and related to the strengthening of security and firewalls and unfortunately could not be prevented. Moreover, Information Request Notice (IRN) response times during the outage were extended. CA will continue to notify members of any outages experienced by Health Canada.

Stakeholder Information Session Presentation Now Available: Proposed Approach to Regularizing Sunscreen Pilot

Please find below the presentation deck for the Stakeholder Information Session for the Proposed Approach to Regularizing Sunscreen Pilot that was presented by the Regulatory, Operations and Enforcement Branch (ROEB).

Info Session – EN

Info Session – FR

NHP MAP Final Guidance Document and Webinar Presentation

NNHPD has posted the final Natural and Non-prescription Health Management of Applications Policy (NHP MAP). Below are the final versions for your reference. Also, below for your reference is the NHP MAP webinar presentation deck from the April 25, 2019 webinar. Please take the time to review both documents and please let your CA Regulatory Team know if you have any questions.

NHP MAP Guidance Document – EN

NHP MAP Guidance Document - FR

MAP Webinar

Adverse Reaction Reporting Notice

Please find enclosed a notice that clarifies section 4.3 (Regulatory Authority Sources) of the "Reporting Adverse Reactions to Marketed Health Products – Guidance Document for Industry", which will be published online in late May 2019 at the following link: https://www.canada.ca/en/health-canada/services/drugs-health-products/reports-publications/medeffect-canada/reporting-adverse-reactions-marketed-health-products-guidance-industry.html.

The purpose of this notice is to clarify Health Canada's expectations with respect to the re-reporting of cases identified from the Canada Vigilance Adverse Reaction Online Database by Market Authorization Holders (MAHs).

In light of the extent of the issue around duplicates, Health Canada has determined that MAHs will now be required to report cases associated with their marketed health products when identified from the Canada Vigilance database, only if new information, other than what is available online, can be provided with the report.

In addition, starting May 2019, please note that the Canada Vigilance Adverse Reaction Online Database extract files will contain four additional data fields, when available, to aid in the identification of potential duplicate reports. The new fields are:

- Authority Number
- Company Number
- E2B Safety Report Number
- Literature Reference

For more information about these fields, please visit the Glossary of Fields in the Canada Vigilance Adverse Reaction Online Database.

If you have any questions or concerns regarding this notice and/or the *Guidance Document for Industry on Reporting Adverse Reactions to Marketed Health Products*, please email your CA Regulatory Team or to the Canada Vigilance Program (hc.canada.vigilance.sc@canada.ca).

Notice – EN

Notice - FR

Plain Language Labelling Compliance Plans – Request from NNHPD

Further to the compliance plans the NNHPD sent to stakeholders from December 2018. The NNHPD is sending out a second set of DIN specific Plain Language Labelling Compliance plans. There are two types of compliance plans being sent:

1. a follow-up compliance plan to stakeholders who responded to the first compliance plan

2. a compliance to stakeholder who did not respond to the first compliance plan

The objective of the compliance plans is to assist the NNHPD in managing the flow of submission to have more predictability on when to expect submission from sponsors. It will also help to inform the Compliance and Enforcement Policy for the June 30, 2021 on-shelf deadline. The new compliance plans will be focused on when the submissions will be submitted (with the

number of SKUs) and the type of submission and details on the products you will not be required to submit applications to meet the PLL regulations (i.e. Self-Care Category 1 products and those using the full standard drug facts table format). Receiving 30 PDC, 30 DINF and 30 SNDS simultaneously would have different impacts on submission review management. The NNHPD is also interested in knowing more about the number of products that will not be submitted to NNHPD that are using full Products Facts Table or Category 1 flexibilities.

NNHPD understand that some sponsors may be working on various solutions for their labels and may not be in a position to complete the compliance plans however they request sponsors to share all the information available at this time (and indicate the plan is not complete). The NNHPD also acknowledges that these plans can evolve and invites sponsors to send updated plans at anytime.

Please ensure you submit the compliance plan and if you have not received a compliance please reach out to your CA Regulatory Team at regulatory@cosmeticsalliance.ca and we send your information to NNHPD.

Environmental Updates

Multi-Stakeholder Workshops under the Chemicals Management Plan

Since 2014, Environment and Climate Change Canada (ECCC) and Health Canada (HC) have been hosting a series of Multi-Stakeholder workshops (MSW) under the Chemicals Management Plan (CMP) with the objective of providing stakeholders with an opportunity to engage, follow and contribute to CMP activities.

In the spirit of maintaining an open dialogue with stakeholders, ECCC and HC would like to invite you to the next workshop, which will be held in Ottawa at the Delta Ottawa City Center on May 24th, 2019 from 8:30am-4:00pm. An agenda will be circulated in the coming weeks.

The meeting will also be available by Webcast and a Web link will be circulated in advance of the meeting to those who have registered.

Please RSVP by May 16th, 2019 and indicate whether you plan to attend in person or for Webcast to ec.liaison-pgpc-cmo-liaison.ec@canada.ca)

Draft Screening Assessment for Copper and its Compounds

The draft screening assessment of Copper and its Compounds has been posted with a 60-day comment period ending on July 17, 2019. The Minister of the Environment and the Minister of Health have conducted a screening assessment of copper and its compounds. Twenty-six of these substances were identified as priorities for assessment, as they met the categorization criteria under subsection 73(1) of CEPA or were considered a priority based on other human health concerns. Eleven additional substances were identified for further consideration following prioritization of the Revised In Commerce List. This draft screening assessment focuses on the copper moiety; therefore, it considers copper in its elemental form; copper-containing substances; and copper released in dissolved, solid, or particulate form. This screening assessment therefore considers copper-containing substances beyond those identified as priorities for assessment. Please take the time review the draft screening assessment and let your CA Regulatory Team know if you have any concerns. CA will be commenting on the DSAR if members have any concerns or interest.

Final Screening Assessment for Seven Hydrocarbon-based substances

The Final Screening Assessment for Seven Hydrocarbons-based substances was published on May 17, 2019 on the Canada Gazette Part 1. The seven hydrocarbons can be found here. The Government of Canada conducted a science-based evaluation, called a screening assessment, to address the potential for harm to Canadians and to the environment from 7 hydrocarbon-based substances.

- Under the *Canadian Environmental Protection Act, 1999* (CEPA 1999), the risk posed by a substance is determined by considering both its hazardous properties (its potential to cause adverse human health or ecological effects) and the amount of exposure there is to people or the environment. A substance may have hazardous properties; however, the risk to human health or to the environment may be low depending upon the level of exposure.
    - More information on assessing risk can be found in the Overview of Risk Assessment and related fact sheets, particularly on Types of Risk Assessment Documents and the Risk Assessment Toolbox.
- As a result of this screening assessment, the 7 hydrocarbon-based substances are considered to have a low potential for risk to human health and the environment.

Please take the time to review the final screening assessment. CA did not provide comments for the Draft Screening Assessment as membership did not have any concerns or comments.

Post-Consumer Waste Updates

RPRA Annual General Meeting – Register by May 31, 2019

The Resource Productivity and Recovery Authority (RPRA) invites you to its Annual General Meeting on **Thursday, June 27, 2019** at St. James Cathedral Centre, or via webcast, from 10 a.m. to 12 p.m. The AGM is a chance for RPRA to engage with stakeholders and share an update on key activities and milestones from the past year. Learn more and RSVP

Ontario consultation on proposed regulations – Electronics and Batteries

The new regulations under the *Resource Recovery and Circular Economy Act,* 2016 will affect participants of the current Waste Electrical and Electronic Equipment Program operated by Ontario Electronic Stewardship (OES). To view the proposed Ontario regulations, visit the Environmental Registry of Ontario. Comments are due by **June 23, 2019**. Review the draft regulations and register for a consultation webinar. The Resource Productivity and Recovery Authority will be the regulator mandated by the Government of Ontario to enforce the requirements of the new EEE and batteries regulations once they take effect. Learn more at rpra.ca/programs/electronics/. Ontario Electronic Stewardship will continue to operate the current program without disruption until the proposed regulations take effect. Continue to contact them directly for any operational inquiries.