Regulatory Essentials – April 3, 2019

Cosmetics Alliance Updates

A Perfect Storm for Cosmetic Product Claims on the Horizon Webinar

Engage with product claims management expert John Cooper about how current and emerging trends such as personalization, wellness, globalization, fast-beauty, digital enablement, and accompanying supply chain challenges are combining to exponentially complicate the process of managing claims. John will explore the impact of trends like these on claims management and provide an action plan to help your team weather the storm.

Date: Thursday, April 11, 2019
Time: 1:00 pm - 2:00 pm ET
Cost: Member: $50; Non-Member: $150

Register

Register for the Spring Regulatory Workshop

Cosmetic Alliance Canada's Regulatory Workshops provide members with the opportunity to stay up-to-date and informed on "everything regulatory". You will not want to miss this opportunity to hear from government officials and Cosmetics Alliance staff first-hand on issues that will directly affect your business. Cosmetics Alliance will be hosting a Member Engagement Session at the end of the Workshop followed by a reception so be sure to attend for the whole day.

Key Updates from:

- Consumer Product Safety Directorate (CPSD)
- Natural and Non-prescription Health Products Directorate (NNHPD)
- Regulatory Operations and Enforcement Branch (ROEB)
- Self-Care Framework Team
- Cost Recovery

Preliminary agenda

Register

Health Updates

Health Canada Highlights Best Practices for Submitting Drug Establishment Licence (DEL) Applications

Since 2011 Health Canada has been issuing decisions for DEL applications whenever a portion of an application is ready. This allowed applicants to obtain decisions on components of applications in a timely manner. However, Health Canada's performance is monitored based on the number of applications completed, which is when a decision is issued for all the portions of the application.

Reporting by Application Type

Health Canada has repeatedly received feedback from applicants requesting that performance standards and performance reporting be modified to be based on application type rather than using a performance standard of 250 days for all types of applications. These changes have been requested to improve predictability of approvals and assist companies in the planning of the introduction of new products to the Canadian market. However, such reporting is not possible if applicants continue to submit applications that pertain to multiple buildings in a single application.

As such, Health Canada is requesting that when submitting amendment applications, applicants submit applications on a per building basis; that is, they include only a single component in a single application rather than multiple components. More information is provided below on best practices for separating applications. This approach will not be applied to applications for a new DEL.

Change to Process - Issuing Decisions on Applications Received

Health Canada requires the collaboration of every applicant to submit their amendment applications following the attached guidance to support optimal performance reporting. Applications that are not separated cause challenges in realizing the objective of reporting performance on application types.

To that effect, Health Canada will change its issuance practices to discontinue the issuance of decisions on portions of applications as they are ready for licensing. Health Canada will issue a decision per application, as it is submitted to Health Canada. If an application contains amendments for several buildings, the decision will be issued only once a decision for all buildings is ready to be rendered.

Guidance on How to Split Applications

Application for a New DEL

Please continue to submit applications for new DELs by including in the application every Canadian and foreign building for which the license is requested. These applications should not be separated and will not be subject to the new issuance practices at this time.

Amendment Application for Existing DEL

Administrative changes:

Administrative changes to an existing DEL should always be submitted separately from other types of requests (e.g. separate from requests to add activities, drug categories, dosage form…). Administrative changes include changes to:

- Mailing or billing address,
- Name, telephone number, fax number and email address
- Warehouse information.

Foreign Building Applications

Applications to add, renew or amend a foreign building should be submitted with only one foreign building per application. Multiple changes can be requested for the foreign building in the same application; however, each application should only be for a single foreign building.

As an exception, when GMP evidence covers multiple buildings, every foreign building covered by the evidence can be grouped into a single application.

Additionally, when applying to add or amend a foreign building to your DEL, all drug categories, activities, sterility status and dosage forms requested for the foreign building must be authorized at the domestic building level. When this is not the case, the application must also include a request to amend the associated domestic building to add the missing drug category, sterility status or dosage form under the activity of import.

Canadian Building Change:

Applications to amend or add a Canadian building to the DEL should be submitted individually. Multiple changes can be requested for the same building in one application. However, the application should only be for a single Canadian building.

Note about importation:

> When submitting an amendment to add the activity of import to an existing DEL, whether adding a new building or adding import to an existing building, the application must include a request to add at least one foreign building. When the applicant wishes to apply for the addition of multiple foreign buildings, the application should include all the foreign buildings requested in the application. This is only applicable when the application is to add the activity of import to a DEL.

Next steps

- If you require further guidance on how to split your application or have comments or questions, please email hc.del.questions-leppp.sc@canada.ca.

Updated Drug Submission Application Fee Form for Human and Disinfectant Drugs Published

Fees for regulatory activities related to human drugs (pharmaceutical and biological) are currently charged as per the Fees in Respect of Drugs and Medical Devices Regulations

As per the existing *Fees in Respect of Drugs and Medical Devices Regulations,* Health Canada will be implementing the established annual 2% increase in human drug and medical device fees for fiscal year 2019 - 2020, taking effect April 1, 2019. In addition, as stipulated under Section 17.1 of the *Service Fees Act,* current veterinary drug fees will increase by the Consumer Price Index (2.2%).

A notice of fee changes to this effect will be published in the *Canada Gazette*, Part I before April 1, 2019. Related guidance documents and application forms will be updated to reflect the adjusted fees and will be published on the Health Canada website.

Health Canada appreciates industry engagement over the past year on the *Fee Proposal for Drugs and Medical Devices* and the *Revised Fee Proposal for Drugs and Medical Devices*. Health Canada will keep you apprised of developments on the revised fees.

Filing Submissions Electronically – Health Canada Creates Webpage Containing all Required Documents

This page lists all the guidance documents and other related documents to provide companies with information on how to file their submissions electronically in eCTD and non-eCTD formats. This page also includes information on current consultations and pilots, and additional information related to the Regulatory Enrolment Process and the Common Electronic Submission Gateway.

Government of Ontario – Industrial Electricity Prices Consultation and CME Industrial Electricity Pricing Study

The Government of Ontario has publicly announced this afternoon that they will be beginning consultations on industrial electricity pricing on April 1st. Electronic submissions will be accepted for 60 days. Consultation questions will be posted at www.ontario.ca/page/consultations-directory.

The press release of the announcement can be found here: https://news.ontario.ca/mndmf/en/2019/03/ford-government-to-launch-consultations-on-industrial-electricity-prices.html

Consistent with a commitment by Premier Ford during the 2018 election campaign to stabilize industrial hydro rates through a package of aggressive reforms, the launch of this consultation follows last week's tabling of Bill 87 - Fixing the Hydro Mess Act, 2019 and a recent staff report to the Ontario Energy Board (OEB) entitled Rate Design for Commercial and Industrial Electricity Customers.

As the Independent Electricity System Operator (IESO) disclosed at the 2018 Technical Planning Conference, much of Ontario's current demand projections are predicated on certain assumptions respecting the future impact of current pricing structures and programs. This consultation therefore has significant relevance for the manufacturing sector.

We have already taken a leadership role in this consultation and is advocating on your behalf. We have already begun an industrial electricity rate study in conjunction with London Economics International (LEI) to demonstrate practical, implementable options to achieve a competitive, predictable manufacturing electricity rate and to look at options for Class A and Class B ratepayers. The study will be assessing the resulting economic benefits from each option and analyzing how to effectively lower electricity costs for all manufacturers and how the recommendations could be implemented. This study is a data-driven, economic and evidence-based approach that will offer perspective on the viability of different options on this.

Extensive stakeholder outreach is already underway and will be conducted throughout the study to take in feedback from CMC members and other stakeholders in Ontario. The outreach will include us working with the Government of Ontario directly during in-person consultation sessions within every region of the province, including participating in a manufacturing sector specific consultation.

A complete overview of the study can be found below. The draft findings of the study completed by mid-May and a final report completed by the end of May in time for the conclusion of the consultation.

To help ensure a successful study and consultation, the government needs your help and support. Please provide your input on the following questions below to help assist us in the consultation process:

1. What aspects of electricity rate design do you believe are most inconsistent with your impact on the system?
2. If you operate across multiple LDC service territories in Ontario, are these differences in the way similar load is treated in the territories in which you operate?
3. If you operate outside of Ontario, what (if any) attributes of rate design in those external jurisdictions do you think should be adopted in Ontario?
4. Do you take advantage of onsite generation or load shifting programs?
5. Would you be willing to accept lower service quality in return for a discount, or conversely, pay more for higher than targeted service quality?
6. Do you have any other observations regarding rate design?

The Government also welcomes any data and information from your company that you can share with respect to your electricity costs. The information you send will be kept in strict confidence and will not be shared nor attributed to any one company.

Please send all input directly to Alex Greco at alex.greco@cme-mec.ca and Adam Hariri at adam@londoneconomics.com.

Certificate of Pharmaceutical Product and Good Manufacturing Practice Certificate Annual Fee Increase

Please note the fees for Certificates of Pharmaceutical Products (CPP) and Good Manufacturing Practice (GMP) Certificates increase 2% annually every April 1st. The fees for the 2019-2020 fiscal year will be $ 90.00 + applicable taxes.

The fee form is updated accordingly and will be available shortly on Health Canada's website at: https://www.canada.ca/en/health-canada/services/drugs-health-products/compliance-enforcement/establishment-licences/directives-guidance-documents-policies/guidance-application-certificate-pharmaceutical-product-0024.html

Environment Updates

Environment and Climate Change Canada Released Microbeads Toiletries Factsheet for Industry

The Microbeads in Toiletries Regulations contains a retail ban on certain toiletry products containing plastic microbeads, which can include bath and body products, toothpastes and exfoliants. Attached is a factsheet to help retailers understand their new obligations.

We ask you to review this factsheet which contains information that can help you comply with the Microbeads in Toiletries Regulations and avoid the application of potential enforcement measures.

Microbeads Toiletries Factsheet – EN

Microbeads Toiletries Factsheet – FR