Regulatory Essentials – October 31, 2018

Cosmetics Alliance Update

Cosmetics Labelling 101 – Introduction to Cosmetic Labelling for Canada

Date: Tuesday, November 13, 2018

Time: 1:00 p.m. – 2:30 p.m.

Cost: Member: $225 Non-member: $395

Objectives:

- Learn the language of cosmetics in Canada
- Overview of the cosmetic labelling regulations
- Learn how other Canadian regulations apply to cosmetics
- Understand how these regulations interact with each other

Register

Health Update

DEL Bulletin – Pause-the-clock Proposal for Drug and Medical Device Establishment License Applications

Health Canada wants your feedback on the development and implementation of the Pause-the-Clock mechanism for Establishment License applications. The Pause-the-Clock Proposal for Drug and Medical Device Establishment License Applications will be posted online for a 30-day consultation in early November 2018. The proposal is being shared with you in advance of the web posting.

The purpose of the pause-the-clock is to allow applicants the opportunity to rectify application deficiencies during the review of the application, but that this time is not counted as Health Canada time.

Who this document is for:

We are seeking the views of:

- People who work with drugs as:
  - fabricators
  - packagers
  - labelers
  - testers
  - distributors
  - importers
  - wholesalers
- People who work with Medical Device
  - Class I manufacturers
  - Importers
  - Distributors
- Others who are interested

What:

Health Canada is interested in stakeholder feedback on the following questions:

- What are your thoughts on the proposed triggers listed? Please provide specific feedback on the proposed triggers.
- Can you think of a situation in the application process beyond those mentioned within our proposal where a trigger could be used?
- When would it be valuable from industry's point of view to be able to pause the clock? Please describe under what circumstances this would occur.
- Is the proposed maximum 20 business day (1 month) of paused clock before rejecting an application reasonable? Would you suggest a shorter or longer timeframe? Please describe situations where more or less time would be more appropriate.

When:

The Pause-the-Clock Proposal for Drug and Medical Device Establishment Licence Applications will be posted online for 30-day consultation in early November 2018. You can submit comments related to drugs and medical devices between the issuance of this bulletin and the end of the consultation period.

How to participate:

1. Read the attached proposal (below): Pause-the-Clock Proposal for Drug and Medical Device Establishment Licence Applications
2. Consider the four questions highlighted above.
3. Provide your comments related to **drugs** by email to hc.del.questions-leppp.sc@canada.ca with the subject line “Pause-the-clock Feedback”
4. Provide your comments related to **medical devices** by email to hc.mdel.questions.leim.sc@canada.ca with the subject line “Pause-the-clock feedback”

Pause the Clock Policy – EN

Pause the Clock Policy – FR

Regulatory Enrolment Process (REP) Pilot for Human Drugs (Division 1 & 8) Transactions

Health Canada requesting sponsor participation in the Regulatory Enrolment Process (REP) pilot for Division 1 and Division 8 (human drugs) regulatory activities in both eCTD and non-eCTD formats.

REP helps industry provide information related to company and dossier to Health Canada, in advance of the regulatory review process; this is currently being provided using the submission application forms. By using web-based templates to capture this data in a structured format, Health Canada can receive the information via the Common Electronic Submission Gateway (CESG), partially populate internal systems ahead of time, and automate certain procedures when a regulatory transaction is received.

The objective of REP is to implement a common intake approach which includes expanding the scope of the CESG to accept more regulatory transactions in various formats. Once fully implemented, REP will reengineer existing administrative processes to take advantage of the tools and capabilities of an electronic processing and review environment. It will introduce a

consistent approach to collecting high quality structured information across multiple regulatory activity types.

The CESG provides sponsors the ability to send regulatory transactions electronically to Health Canada in a secure manner, with reduced transmission times. It has been in operation at Health Canada since February 2014, for a subset of regulatory activities in eCTD format. The scope of regulatory activities accepted via the CESG will continue to expand to include more regulatory transactions in eCTD and non-eCTD electronic-only formats. Refer to the Frequently Asked Questions - Common Electronic Submission Gateway (CESG FAQ) document for further details.

As Health Canada moves closer towards a common submission intake process to harmonize and improve its business processes and tools, companies are encouraged to stay informed, provide feedback and participate in upcoming pilot projects.

REP Pilot for human pharmaceuticals and biologics

- Target duration: October 1st, 2018 to March 30th, 2019.
- Scope: All Regulatory Activities and Transactions in scope of eCTD and non-eCTD electronic-only formats pursuant to:
    - Part C, Division 1 of the Food and Drug Regulations (Application for Drug Identification Number (DINA), Application for Drug Identification Number - Biologic (DINB), Application for Drug Identification Number - Disinfectant Product (DIND), Application for Drug Identification Number - Category IV Product (DINF), Post-Authorization Division 1 Change (PDC), Post-Authorization Division 1 Change - Biologics (PDC-B)
    - Part C, Division 8 of the Food and Drug Regulations

Regulatory activities for medical devices, veterinary medicine, clinical trial applications and master files will not be eligible for this pilot.

1. How to request for participation in the REP Pilot

1. Sponsors must express their interest by providing:
    - A written request to participate in the pilot, via email to hc.eReview.sc@canada.ca, with the subject heading “REP Pilot human drugs”.
    - The request should include the following information:
        - sponsor name
        - contact information
        - number of new and/or existing dossier(s) planned
        - number of Regulatory Activities planned

Health Canada encourages sponsors to submit their requests for participation as soon as possible**.** All requests will be assessed, and participants will be selected based on the requirements below. Further instructions on how to use the REP will be provided to all participants.

2. Sponsors must commit to the following requirements, if selected, to participate in the REP Pilot:

- All participants without CESG accounts must obtain one as soon as possible.
- All REP XML files must be sent to, and received from, Health Canada via the CESG, as no other method of transmission will be accepted.
- Regulatory Transactions (< 10 GB), provided as part of the pilot must be sent via the CESG.
- Once a participant uses the REP for a dossier (drug product), they must continue to use the REP for all subsequent regulatory activities and transactions for that dossier.
- Health Canada may limit the number of dossiers enrolled per participant.
- The first transaction should be submitted before the end of the pilot.

Questions related to this notice should be directed via email to hc.eReview.sc@canada.ca.

Draft Form for Notifying Health Canada for Foreign Actions

Further to the publication of our draft guidance *Notifying Health Canada of Foreign Actions - Guidance Document for Industry*, and the new regulation C.01.050, that will be coming into force November 20, 2018, Health Canada is preparing an on-line reporting form to assist with compliance. The guidance and the form consider comments received from stakeholders during the consultation process.

The draft form (below) is designed to provide Health Canada with minimum information that would result in a meaningful report under the regulations. If you have comments or concerns please direct them to bruce.wozny@canada.ca before October 26, 2018, so as not to delay posting of the form on line in advance of the coming into force date. Please note - there were several corrections made to the links and the recent links have been attached for your reference.

Form for Notifying Health Canada of Foreign Regulatory Actions – EN

Form for Notifying Health Canada of Foreign Regulatory Actions - FR

Notice of Amendment for Prescription Drug List (PDL) – Phyto cannabinoids

Health Canada has added phytocannabinoids to the Human and Veterinary Prescription Drug Lists (PDL). These additions are effective immediately.

The following classification parameters will immediately apply to health products containing cannabis: Any product making a health claim that contains a phytocannabinoid produced by or found in the cannabis plant, but not including health products containing parts of the cannabis plant that fall outside the legal definition of cannabis or that are exempted from the Cannabis Act (i.e. permitted cannabis parts which contain ≤ 10 ppm of THC and no other phytocannabinoids), will be classified as a prescription drug. All phytocannabinoids have been pre-emptively added to the PDL, except for the latter exemption. The listing will read:

Drugs containing any of the following:	**Including (but not limited to)**	**Qualifier**	**Effective date (yyyy-mm-dd)**
Phytocannabinoids produced by, or found in, the cannabis plant		except:	2018-10-17

and substances that are duplicates of such phytocannabinoids		(a) derivatives of cannabis as defined in subsection 2(1) of the Cannabis Act that are exempt from the application of the Cannabis Act under the Industrial Hemp Regulations and that do not contain an isolated or concentrated phytocannabinoid or a synthetic duplicate of that phytocannabinoid, or (b) anything referred to in Schedule 2 to the Cannabis Act that contains no more than 10 µg/g delta-9-tetrahydrocannabinol and that does not contain an isolated or concentrated phytocannabinoid or a synthetic duplicate of that phytocannabinoid	

Rationale:

Clinical evidence supporting the safety and efficacy of cannabis and its constituents for therapeutic purposes is currently insufficient to set acceptable threshold dosages for non-prescription use. While Health Canada has previously authorized health products containing cannabis, there remains significant scientific uncertainty regarding the pharmacological actions, therapeutic effectiveness and safety of the majority of phytocannabinoids which naturally exist within cannabis. The cannabis-based drug products which have been authorized by Health Canada under the former legislative framework have been studied, authorized and used in specific conditions on a limited subset of the population. While these authorized products have contributed to the global body of knowledge concerning the safety and efficacy of cannabis-based therapies, the presence of scientific uncertainty and limited market experience gives rise to the need for a precautionary approach. Listing all phytocannabinoids on the PDL addresses this uncertainty by allowing healthcare practitioners to monitor and manage any unanticipated effects.

All phytocannabinoids will remain listed on the PDL until there is sufficient scientific evidence (e.g., as demonstrated through a submission to Health Canada) to change the prescription status of a particular phytocannabinoid when used in specific conditions. Pursuant to section C.01.040.3 of the Food and Drug Regulations, Health Canada considers several criteria when deciding whether a health product would be required to be sold as a prescription drug. Additional information on how Health Canada determines prescription status (or non-prescription status) is available in the Guidance Document: Determining Prescription Status for Human and Veterinary Drugs.

Should you have any questions on this amendment to the Prescription Drug List please contact:

Health Canada
Prescription Drug Status Committee
Address Locator 3102C3
Holland Cross, Tower B
1600 Scott Street
Ottawa, Ontario
K1A 0K9

E-mail: hc.hpfb_cannabis_dgpsa.sc@canada.ca

Invitation to Participate in a Government of Canada Teleconference Concerning the Anthraquinones Group

A draft screening assessment for the Anthraquinones group and a risk management scope for the solvent Violet 13, CAS 81-48-1 have been developed by Health Canada and Environment and Climate Change Canada. Official release of the draft screening assessment is planned for November 3, 2018, along with the risk management scope. These documents will be subject to a 60-day public comment period ending on January 2, 2019 and will all be available on the Canada.ca (Chemical Substances) website. Health Canada and Environment and Climate Change Canada officials would like to invite you to a teleconference hosted on November 1, 2018 at 11 am ET in order to briefly summarize the publication process and answer any questions you may have. See call-in information below.

Please respond to Program Liaison by October 31, 2018 by noon if you will be attending the teleconference.

Local Dial-in Number: 613-960-7513
Toll-free Dial-in Number: 1-877-413-4788
Conference ID: 5295340

Environmental Update

Prohibition of Asbestos and Products Containing Asbestos Regulations

In October 2018, the final Prohibition of Asbestos and Products Containing Asbestos Regulations were published in the Canada Gazette, Part II. These regulations prohibit the import, sale and use of asbestos, as well as the manufacture, import, sale and use of products containing asbestos, with some exceptions. These regulations are published under the authority of the Canadian Environmental Protection Act, 1999 (CEPA 1999), and come into force on December 30, 2018.

The proposed regulations were published in January 2018 in the Canada Gazette, Part I for a 75-day public comment period. Comments and information received during the comment period were considered in the development of the final regulations, and are summarized in the Regulatory Impact Analysis Statement .

Because these regulations are more stringent than existing regulatory controls under the Asbestos Products Regulations made under the Canada Consumer Product Safety Act, the Asbestos Products Regulations will be repealed when the Regulations Prohibiting Asbestos and Asbestos Products come into force.

In addition, the Export of Substances on the Export Control List Regulations have been amended to list all forms of asbestos on the Export Control List (Schedule 3 to CEPA 1999). An order amending Schedule 3 to CEPA 1999 was published in the Canada Gazette, Part II: Vol. 152, No. 21 – October 17, 2018 . These amendments support the Regulations Prohibiting Asbestos and Asbestos Products by adding new provisions to prohibit (with some exceptions) the export of asbestos and products containing asbestos. They also ensure that Canada is compliant with its export obligations under international conventions, including the Rotterdam

Convention. Asbestos is currently on the List of Toxic Substances found in Schedule 1 to CEPA 1999, and the listing covers all 6 types of asbestos.

Final Screening assessment for the Thiols Group

The Government of Canada conducted a screening assessment of 4 substances in the Thiols Group to address the potential for harm to Canadians and to the environment. The Government of Canada published the Final Screening Assessment for the Thiols Group on October 20, 2018. The ecological hazard and exposure potentials of these 4 substances were classified using the Ecological Risk Classification of Organic Substances Approach. The Ecological Risk Classification of Organic Substances Approach characterized these 4 substances as posing a low risk of harm to the environment, based on current low levels of exposure.

Although some of these substances are associated with human health and/or ecological effects, the risk to Canadians and the environment is low at current levels of exposure. Therefore, it is concluded that these substances are not harmful to human health or to the environment at current levels of exposure.

Based upon the consideration of international assessments, the risk to human health from dimethyl sulfide, benzyl disulfide, and grapefruit mercaptan is low.

Based upon a comparison of levels to which Canadians may be exposed and the levels associated with health effects, the risk to human health from tert-dodecyl mercaptan is low.

Approach to Disclose Confidential Information and Promote Transparency in Chemicals Management

The Government of Canada would like to inform you of the publication of the *Approach to disclose confidential information and promote transparency in chemicals management* (the Approach) on October 5, 2018 on the Government of Canada website. The Approach aims to achieve an appropriate balance between transparency and industry's right to protect confidential information. It also supports the Government of Canada's work in response to the recommendations from the House of Commons Standing Committee on Environment and Sustainable Development regarding transparency under the Canadian Environmental Protection Act, 1999. To inform this approach, Environment and Climate Change Canada examined transparency-related best practices in other domestic and international programs and has conducted a thorough analysis of data received and claimed as confidential. In addition, public comments were received on the draft proposal in 2017, which have been considered in the development of this approach. To help increase awareness of the substances in the Canadian market, confidentiality claims for substance identity will be reviewed after a period of 10 years. Submitters will be provided the opportunity to update their claim. The flowchart provides an overview of the process.

Post-Consumer Waste Update

ÉEQ Consultation on 2019 Schedule of Contributions

Éco Entreprises Québec (ÉEQ) is consulting on the 2019 Schedule of Contributions. A summary of the proposed 2019 Schedule of Contribution is now available. A recorded consultation webinar will be posted as of October 30, 2018. Obligated companies may provide questions or comments on the proposal up until November 15, 2018.

CSSA Annual Steward Meeting & Report to Stewards

The Canadian Stewardship Services Alliance (CSSA) Annual Steward Meeting took place via webcast on October 24, 2018. A webinar recording and all materials are posted here. This includes the Report to Stewards, which provides packaging and paper recycling program information along with 2019 budgets and fees for Recycle BC, MMSW, MMSM and Stewardship Ontario programs.