

Regulatory Essentials – October 13, 2021

Health Updates

Drug Submission Performance Quarterly Reports (April-June 2021)

Please find below the Therapeutic Products Directorate (TPD), Biologic & Radiopharmaceutical Drugs Directorate (BRDD) and Natural & Non-prescription Health Products Directorate (NNHPD) Drug Submission Performance Quarterly Reports (April-June 2021).

The Drug Submission Review Performance Reports provides detailed metrics about the timeliness of the pre-market drug review process against performance service standards. The quarterly report compares five consecutive quarters from April-June 2020 to April-June 2021. The reports are broken down by operational areas. Of relevance to our industry is the NNHPD. Below are some key highlights of the NNHPD performance report:

- 23 DINA submissions were received in Q1 2021-2022. This represents a 15% decrease compared to Q4 2020-2021 (27) and a 60% decrease compared to Q1 2020-2021 (58).
- 15 DINF submissions were received in Q1 2021-2022. This represents a 52% decrease compared to Q4 2020-2021 (31) and a 81% decrease compared to Q1 2020-2021 (78).
- the total non-prescription drug submissions received increased by 10% in Q1 2021-2022 (143) when compared to Q4 2020-2021 (130) and decreased by 48% when compared to Q1 2020-2021 (276).
- The non-prescription drug submission workload is following the expected trajectory of a post-pandemic setting. The volume of COVID-19 hand sanitizers has returned to pre-pandemic volumes.
- In response to recent outreach to sponsors for plain language labelling (PLL), there was an increase of PDC submissions to update the labels of non-prescription drugs in advance of the retail-level PLL deadline (June 30, 2021).

TPD – [EN/FR](#)

BRDD – [EN/FR](#)

NNHPD – [EN/FR](#)

Mid-Year Update from Health Canada: Health Products Approved in 2021

Health Canada released an update on October 6, 2021, on the drugs, medical devices, over the counter (non-prescription) drugs and natural health products approved by Health Canada between January and June 2021. This is an [informative update](#) on what has been done for the first 6 months of 2021 and work that will be continuing for the rest of year including Self-Care Framework. Phase I NHP Improved Labelling consultation has formally closed, and CA will be submitting comments and we are in process of pursuing Interim Measures while the SCF is developed.

Environmental Updates

Update on Homosalate Draft Screening Assessment

Homosalate is still under review under the Chemicals Management Plan under the Salicylates grouping. The release of the Final Screening Assessment of the Salicylates group is still to be determined. The [European's Commission's Scientific Committee on Consumer Safety \(SCCS\) recently published their most recent opinion on Homosalate](#) in June 2021. Since the publication of this opinion this summer, the SCCS received a [new mandate](#) from the European Commission to further investigate the safety of Homosalate in certain sunscreen products, based on follow-up considerations as submitted by industry in Europe.

On the home front, Cosmetics Alliance is continuing its scientific dialogue with Health Canada officials, as they look to finalize their assessment of Homosalate under the Canadian Chemicals Management Plan (CMP). In this regard, CA Canada is looking to ensure that the Government of Canada takes into account this most recent mandate prior to finalization of this assessment. To support these efforts, CA is in the process of setting up a follow-up science meeting with the CMP assessment group in charge of this review to further discuss the developments in the European Union, in addition to activities in the United States.

Post-Consumer Waste Updates

Full Producer Responsibility for Post Consumer Waste is Coming to Ontario

You Will Need to Know Your Choices! Get to Know Your PROs in Ontario

[Full Producer Responsibility](#) is now being implemented for products sold in Ontario. Your company will need to:

- Register your tonnage with RPRA (Deadline to Register – October 1st).
- And eventually join a Producer Responsibility Organization (PROs).

Companies signing on with a PRO before November 1st, 2021, will be represented by that PRO in the rule setting process.

CA is featuring the three PROs you can currently register with to represent you or to manage your waste.

Additionally, we are including our Associate member Covanta Environmental Solutions who provides services for waste management that can divert some of your waste from the collection system as allowed under the regulations.

[Webinar schedule to register](#)

Government consulting on proposed Administrative Penalties Regulation

Under the Resource Recovery and Circular Economy Act (RRCEA), the Authority is responsible for compliance and enforcement of the RRCEA and its associated regulations, including oversight of the producer responsibility framework. The [proposed Administrative Penalties Regulation](#) will support and strengthen the Authority's enforcement tools to allow them to issue monetary penalties to entities that do not comply with the law.

The government is seeking feedback on the proposed regulation from September 17, 2021, to November 1, 2021. To provide feedback, visit the [Environmental Registry of Ontario. Learn more here.](#)

Cosmetics Alliance Updates

Cosmetics 101 - Introduction to Cosmetics in Canada

NOW OFFERING TWO DATES TO CHOOSE FROM

Dates: November 16, 2021, or November 23, 2021

Time: 1:00 pm - 3:00 pm EST

Cost: Member: \$250; Non-Member: \$395

This popular program is designed for individuals who are: New to the Industry

- New Employees
- New Cosmetics Alliance Members
- or as a Refresher Course

Objectives:

- Learn the language of cosmetics in Canada
- Understand the set-up of Canadian Law
- Overview of the Cosmetic Regulations
- Enable attendees to access the Canadian market

Training will include exercises, a quiz, and a training certificate for your training file.

Only those electronically registered will be able to take the quiz and receive a training certificate

Register – [November 16, 2021](#); [November 23, 2021](#)