Regulatory Essentials – January 12, 2022

Health Updates

DEADLINE EXTENDED Health Canada Questionnaire on DEL and GMP flexibilities

Health Canada has extended the deadline to complete the questionnaire on DEL and GMP flexibilities.

You now have until **January 27, 2022,** to complete the questionnaire.

Questionnaire – EN/FR

Health Canada's Annual Adjustment of Fees for Drugs and Medical Devices

Each year Health Canada's fees for drugs and medical devices are subject to an annual fee adjustment. The fee adjustments will be coming into effect on April 1, 2022, to allow companies to plan accordingly.

As per the *Fees in Respect of Drugs and Medical Devices Order* (Fees Order), Health Canada will be adjusting its human and veterinary drugs and medical devices fees for the 2022-2023 fiscal year by the Consumer Price Index (3.4%). Most of these CPI-adjusted fees are currently being phased in over 4 to 7 years and will therefore be different than those stipulated in the Fees Order.

For the 2022-2023 fiscal year, fees for human and veterinary drugs and medical devices will be adjusted as follows:

Fee Line	Authority for Adjustment	Annual Adjustment
Human and Veterinary Drugs and Medical Devices Pre-Market Evaluation, Right to Sell, and Establishment Licence	*Fees in Respect of Drugs and Medical Devices Order*	CPI 3.4%

Veterinary Drug Dealer's Licences	*Service Fees Act* (Fees set as per *Licensed Dealers for Controlled Drugs and Narcotics (Veterinary Use) Fees Regulations* under *Financial Administration Act)*	CPI 3.4%
Drug Master File	Ministerial Authority	2%

Certificate of Pharmaceutical Product	Ministerial Authority	2%
Certificate of Supplementary Protection	*Certificate of Supplementary Protection Regulations*	2%
Human Drug Dealer's Licences	*Fees in Respect of Dealer Licences Regulations*	2%

Here is the *Canada Gazette*, Part I Notice from December 11, 2021: https://canadagazette.gc.ca/rp-pr/p1/2021/2021-12-11/html/index-eng.html.

Notice of intent — Consultation on Modernizing the Medical Device and Drug Establishment Licensing Frameworks (Phase I)

Health Canada will be modernizing elements of the *Medical Devices Regulations* (MDR) and the *Food and Drug Regulations* (FDR), related to compliance and enforcement oversight, as outlined in the Health and Biosciences Sector Regulatory Review Roadmap.

A phased approach is being taken to modernize the MDR and the FDR to address stakeholder feedback. This feedback notes that elements of the frameworks limit Health Canada's ability to foster an innovative and competitive business environment and are not aligned with other jurisdictions. More recently, stakeholders have also indicated an interest in continuing certain measures introduced as part of Health Canada's response to the COVID-19 pandemic.

Amendments to the MDR and the FDR are needed to strengthen Health Canada's ability to provide efficient, effective, and agile oversight of medical devices and drugs. Health Canada intends to use the feedback received from this notice and subsequent opportunities for stakeholder engagement to better inform outstanding proposed regulatory, policy, and program considerations.

What We Heard Report for Health Canada's Consultation on the Draft Issue Identification Paper: Drug-Device Combination Products

Health Canada is updating its policy on Drug-device combination products (DDCPs) to provide more detail and clarity on the classification and regulation of these products. In Spring 2021 an Issue Identification Paper was published for a 60-day comment period to ensure that stakeholder concerns with the existing Policy are considered as we proceed with designing an updated policy approach.

Attached is the What We Heard Report for Health Canada's Consultation on the draft Issue Identification Paper: Drug-device combination products. Health Canada will continue to engage with stakeholders as work on this file progresses.

Amended regulations relating to restricted drugs and the Special Access Program

On January 5, 2022, the following regulatory amendments were published in the *Canada Gazette*, Part II, and came into effect immediately:

- *Regulations Amending Certain Regulations Relating to Restricted Drugs (Special Access Program)*

These regulatory amendments restore the possibility for practitioners who are allowed to prescribe drugs to request access to restricted drugs through Health Canada's Special Access Program (SAP).

With the regulations now amended, practitioners who are allowed to prescribe drugs can, on behalf of patients with serious or life-threatening conditions, request access to restricted drugs through the SAP when other therapies have failed, are unsuitable, or are not available in Canada, and when there is sufficient data to support the safety and efficacy of the drug for the specific condition of the patient. All SAP requests will continue to be assessed on a case-by-case basis and there is no guarantee that access to restricted drugs will be granted through the SAP.

The regulatory amendments are not intended to promote or encourage the early use of unapproved drugs, or to circumvent the well-established clinical trial or drug review and approval processes.

Drug Submission Performance Quarterly Reports (July-September 2021): TPD, BRDD & NNHPD

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 (July -September 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:

Non-prescription Drug Submissions:

- 24 DINA submissions were received in Q2 2021-2022. This represents a 4% increase compared to Q1 2021-2022 (23), a 11% decrease compared to Q4 2020-2021 (27), and a 17% decrease compared to Q2 2020-2021 (29).
- 47 DINF submissions were received in Q2 2021-2022. This represents a 213% increase compared to Q1 2021-2022 (15), a 52% increase compared to Q4 2020-2021 (31), and a 40% decrease compared to Q2 2020-2021 (78).
- 52 PDC submissions were received in Q2 2021-2022. This represents a 32% decrease compared to Q1 2021-2022 (77), a 4% increase compared to Q4 2020-2021 (50), and a 58% decrease compared to Q2 2020-2021 (125).
- 0 NDS submissions were received in Q2 and Q1 2021-2022 while 1 NDS submission was received in Q4 2020-2021 and 0 were received in Q2 2020-2021.

- 6 SNDS submissions were received in Q2 2021-2022. This represents a 50% decrease compared to Q1 2021-2022 (12), a 50% increase compared to Q4 2020-2021 (4), and a 50% decrease compared to Q2 2020-2021 (12).
- 1 ANDS submission was received in Q2 2021-2022. This represents a 75% decrease compared to Q1 2021-2022 (4), a 100% increase compared to Q4 2020-2021 (2), and a 100% increase compared to Q2 2020-2021 (2).
- 13 SANDS submissions were received in Q2 2021-2022. This represents an 8% increase compared to Q1 2021-2022 (12), a 30% increase compared to Q4 2020-2021 (10), and a 41% decrease compared to Q2 2020-2021 (22).

Overall, the total non-prescription drug submissions received in Q2 2021-2022 (143) remained the same compared to Q1 2021-2022 (143), increased by 10% when compared to Q4 2020-2021 (130), and decreased by 47% when compared to Q2 2020-2021 (268).

TPD – EN/FR

NNHPD- EN/FR

BRDD – EN/FR

Announcing new MedEffect e-Notice system to customize subscriptions

Health Canada is upgrading the free MedEffect e-Notice subscription service effective Tuesday, January 18, 2022. Email notifications will be sent using a new and improved system. If you are a current subscriber, you will be transferred to the new system automatically.

Actions required:

1. Add **medeffect.notice-avis.medeffet@hc-sc.gc.ca** to your approved sender's list.

2. Customize your subscription preferences.

You will receive an email on Tuesday, January 18, with a link. The link will bring you to a page where you can select to receive safety information on 4 topics: drugs, medical devices, natural health products, and vaccines.

If you don't see the email in your inbox on that day, be sure to check your spam folder and mark the email as "safe". This will prevent future mailings from being filtered as spam.

If you choose not to update your subscription preferences, you will continue to receive information on all 4 topics.

Environmental Updates

Canada Gazette Part I – Publication of Single-use Plastic Prohibition Regulations

On December 25, 2021, the proposed *Single-Use Plastics Prohibition Regulations* were published in the *Canada Gazette*, Part I initiating a 70-day public comment period ending on March 5, 2022.

The proposed Regulations would prohibit the manufacture, import, and sale of six categories of single-use plastic items (checkout bags, cutlery, food service ware made from or containing problematic plastics, ring carriers, stir sticks, and straws), with certain exceptions for straws.

The feedback received on the proposed Integrated Management Approach to Plastic Products has been considered in the development of the proposed Regulations. A What We Heard Report summarizes this feedback.

The draft Guidance for Selecting Alternatives to the Single-Use Plastics in the Proposed Single-Use Plastics Prohibition Regulations has been developed to help businesses and other organizations make decisions on alternative products or systems that prevent pollution and help Canada transition to a circular economy.

Please review the proposed Regulations, the accompanying Regulatory Impact Analysis Statement, as well as the draft Guidance for Selecting Alternatives and provide your feedback, no later than March 5, 2022, to the following email address: plastiques-plastics@ec.gc.ca or to regulatory@cosmeticsalliance.ca. Cosmetics Alliance will be working with the membership to help shape our engagement on recycled content considerations. Environment and Climate Change Canada have already proactively outreached to CA to have a preliminary bilateral to discuss their proposed approach and initial thinking regarding recycled content moving forward.

In the interim, we ask that you share any initial thoughts/considerations and challenges regarding recycled content considerations. CA will start collating initial input/impressions from the committee to help us prepare for these discussions in 2022. The full report can be viewed here.

Feedback to Health Canada should include the following for each specific comment:

1. the section of the proposed Regulations, Regulatory Impact Analysis Statement, or draft Guidance for Selecting Alternatives to which the comment relates

   e.g., 5(1)(a)(i) of the regulatory text; “Select Canadian Market Characteristics” section of the Regulatory Impact Analysis Statement; “Considerations for Alternative Single-use Plastics” section of the draft Guidance for Selecting Alternatives;

2. the comment itself; and
3. any supporting information or rationale.

Final Volatile Organic Compound Concentration Limits for Certain Products Regulations Published

Environment and Climate Change Canada published the Volatile Organic Compound Concentration Limits for Certain Products Regulations (Regulations) in the Canada Gazette, Part II after 15+ years in the making today. We can confirm that consistent with the spirit of the multitude of consultations, these Regulations are intended to be aligned to the categorical definitions and corresponding limits as outlined in the California Air Resources Board (CARB)

2010 Regulations, although specific wording may not be identical, due to differences in how Canadian regulation is drafted, including considerations for translation (2 official languages).

Under the Description of the Regulation (which highlights the extensive procedural due process that was undertaken in support of these regulations), the following is stipulated – in relation to "modifications from the Proposed Regulations"

"The Department carefully reviewed all comments received on the proposed Regulations published in 2019 in the Canada Gazette, Part I. Key concerns from stakeholders related to the alignment of product category definitions with existing California regulations. The Department has completed a detailed analysis of the comments and consulted with CARB staff to ensure alignment. As a result, many definitions have been revised to ensure more precise alignment with CARB definitions."

The inclusion of this detail is important as it acknowledges the significant input that stakeholders had on ensuring alignment of definitions to CARB – which is a key tenet of the regulation. Furthermore, the preamble to the Final Regulation under the banner of "Regulatory Development" also includes the following wording, which reflects the commentary that we have pursued tirelessly, along with an acknowledgement as to why 'incorporation by reference' (as per our original request for consideration), although considered, was ultimately deemed not to be possible…

"… the wording of the product categories in the Regulations may not be the same as the wording used by California, the Department has taken great care to ensure that the definitions align in scope and application. The Department engaged with CARB to ensure alignment with the scope of the product categories. The Department has considered all comments received and has reviewed the definitions for all product categories and has added precisions to the majority of product categories to better align with CARB. The Department will also provide guidance materials that clarify the intent to align with CARB definitions."

Again, these details are highly relevant in that it confirms the spirit and intent behind definitional alignment with CARB 2010 and provide a means to contextualize any follow-up considerations should the need arise in the future as to potential interpretive misalignment in practice.

Below is a quick summary of key findings in the Regulations:

- Confirmed 2-year transition (for all categories except disinfectants) – which has a 3 year transition period.
- There is no specific provision for sell-thru (confirming that enforcement will be at manufacturer/import level) and that the prohibition starts after the transition grace period for manufacture/import activities. In effect, there will be no impact on products already in the supply chain – to allow for clearances from distribution channels without interruption
- For disinfectants, definitional consideration – 'designed solely for use' was regrettably not taken up, although we understand that despite acknowledgement in the differential wording to CARB (which leverages FIFRA definitions); ECCC interprets these definitional considerations to be aligned in practice. Cosmetics Alliance would be

pleased to work with the membership to seek out any corresponding amendments if this poses a challenge.

Thank you to all our members for the feedback provided to us over the past 15 years which have ultimately helped to shape the final regulations.

Cosmetics Alliance Updates

Cosmétiques 101- Introduction aux cosmétiques au Canada

Date: Thursday, January 20, 2022; Jeudi le 20 janvier 2022

Time: 2:00 p.m. - 4:30 p.m.; 14h00 à 16h30

Cost: 1-4 delegates Member: $250 each Non-member: $395 each

5-10 delegates Member: $225 each Non-member: $370 each

Over 10 delegates: $200 each Non-member: $345 each

Please note the training session is in French and is open only to Cosmetics Alliance member companies that have an officially declared office in the province of Quebec.

Designed for:

- New Employees
- New Cosmetics Alliance Members
- 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

Save the Date - In Person Spring Regulatory Workshop

Cosmetics Alliance Spring Regulatory Workshop is scheduled for Tuesday, May 17, 2022, at Centre Mont-Royal, Montreal. Stay tuned for more information in the coming weeks.