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Fall Regulatory Round Up â€“ The Shifting Shape of the Canadian Landscape

Fall Regulatory Round Up

Activity abounds on the regulatory landscape from modernization and transparency initiatives to consultations, collaborations, and even potential implementations. Our Fall Regulatory Round Up highlights significant developments for drug products and patents that are of interest to those in the life sciences and biotech spaces. We will be following these important regulatory initiatives as they continue to unfold and will provide updates of interest.

Health Canada's Forward Regulatory Plan – Updates for 2024-2026

Health Canada's Forward Regulatory Plan has been updated for 2024 to 2026. The plan sets out the regulatory initiatives to be proposed or finalized by Health Canada during this period, including several under the *Food and Drugs Act*. Selected drug-related initiatives are summarized below.

- ***Modernizing the Drug (Prescription and Over-the-Counter) Regulatory Regime Through "Agile Licensing"*:** Health Canada plans to introduce "agile licensing" amendments aimed at providing the drug regulatory system with sufficient flexibility and responsiveness to keep pace with innovation – thereby facilitating access to new and promising treatments and therapies – while continuing to ensure the safety and effectiveness of approved products.

  Proposed amendments, published for public comment late in 2022, included: allowing for rolling reviews of certain drug submissions, including those intended to address public health emergencies; clarifying expectations as to drug quality throughout fabrication, packaging, testing, storage and transportation; modernizing the regulatory requirements for biologics; requiring manufacturers to submit disaggregated clinical trial data (*i.e.*, data broken down by population subgroups such as women, racial minorities, children, the elderly);

and expanding the use of terms and conditions upon approval. Final amendments are expected to be published later this year.

- ***Modernizing the Regulation of Clinical Trials in Canada*:** As previously announced, the first phase of this modernization effort will deal with regulatory amendments relating to drug trials. Proposed amendments are intended to better accommodate innovative, non-conventional clinical trial designs; introduce a risk-based approach that will reduce regulatory burden for some trials; enhance predictability and transparency for stakeholders; improve safety monitoring for trial participants; and increase public access to information about clinical trials, including results. Some public consultations have already taken place. Publication of the proposed amendments for public comment is expected to take place in the spring of 2025.
- ***Modernizing Drug Establishment Licensing (DEL)*:** Health Canada plans to amend the DEL framework in two phases. Phase 1 amendments, published for public comment earlier this year, included drug recall reporting obligations, and provided for conditional exemptions from finished product testing for gene and cell therapies as well as radiopharmaceuticals. Final amendments were published on June 17, 2024. Phase 2 proposed amendments are expected to be published for public comment in the winter/spring of 2025.
- ***Addressing Therapeutic Product Shortages in Canada*:** Later this fall, Health Canada intends to publish for public comment various amendments to the *Food and Drug Regulations* (and *Medical Device Regulations*) to address the risk of therapeutic product shortages. Under the proposed amendments, market authorization holders will be required to implement protocols to help identify drugs at risk of shortage and, for critical drugs vulnerable to shortage, to ensure that safety stocks are maintained. Proposed amendments will also aim to improve the reporting of shortages and provide new regulatory flexibility to deal with shortages (*e.g.*, by extending drug expiry dates).
- ***Fees Increases*:** Health Canada plans to increase fees in respect of drugs and medical devices. Stakeholder consultations are planned for 2024, with publication of an amended *Fees in Respect of Drugs and Medical Devices Order* expected in the spring of 2026.

Other notable new or ongoing initiatives in the 2024-2026 Forward Regulatory Plan include agile licensing and modernizing the establishment licencing framework for medical devices, aligning the regulation of non-prescription drugs and natural health products, and consolidating the regulations covering controlled substances.

Final Patent Rules for the Patent Term Adjustment (PTA) Framework Expected Soon

Pursuant to its obligations under the Canada-US-Mexico Agreement, Canada is required to adopt a system for granting patent term adjustments by January 1, 2025. The system will allow term adjustments to be made to patents filed on or after December 1, 2020 to offset unreasonable pre-grant delays.

As a first step towards implementation of a PTA framework, amendments to Canada's *Patent Act*, enacted June 22, 2023, specify that a patent may be eligible for an additional term if the patent is granted more than five years from the "applicable day" (*i.e.*, the filing date, or a date to be prescribed for divisionals and national phase entry applications) or three years from the date of the request for examination, whichever is later. The amendments also provide that in fixing the length of any additional term, the Commissioner shall subtract from the days to patent grant beyond the five- or three-year benchmark (*i.e.*, total delay), additional days in accordance with forthcoming amendments to the Patent Rules.

The proposed amended Patent Rules (along with other regulatory amendments to facilitate the PTA framework) were published for public comment on May 18, 2024. The proposed amendments identify a broad range of activities giving rise to days to be subtracted from the total delay. These include the time to respond to examiner reports (running from the date of the report); periods of deferred or continued examination; any period in which the patent application is in abandonment; the time from issuance of the Notice of Allowance to payment of the final fee; and the time associated with appeals (including those that are successful) to the Patent Appeal Board or the courts, running from the date of the decision appealed from.

Under the proposed amendments, an application for an additional patent term must be submitted within three months of patent issuance. The proposed fee for seeking a term adjustment is $2500 (less for small entities). Upon receipt of an application, the Commissioner will notify the patentee of the Commissioner's preliminary determination of the duration of the additional term (if any). The notice will apparently be publicly available, as observations can be made by the patentee or any other person within a specified period. Thereafter, the

Commissioner will issue a certificate of additional term or dismiss the application. Various industry associations provided feedback on the proposed amendments prior to closure of the public comment period in early July.

With January 1, 2025 fast approaching, the final regulations are awaited with interest although no publication date has been announced. Regardless, if the new Patent Rules remain unchanged – particularly in respect of the categories of subtractable days – it seems likely that few patents will qualify for a term adjustment.

New Guidelines for the Patented Medicines Prices Review Board (PMPRB)

Following amendments to the *Patented Medicines Regulations* in July 2022, the PMPRB has been in the process of updating its Guidelines to reflect recent case law and to increase efficiency. To this end, the PMPRB began a three-phase consultation process, briefly outlined below. That process – currently in Phase 2 – is anticipated to conclude with the implementation of new Guidelines in 2025.

- ***Phase 1 – Scoping Paper and Policy Roundtable*****:** The PMPRB released a Scoping Paper in November 2023, seeking stakeholder views on various themes relating to the development of final PMPRB Guidelines. This phase concluded with the publication of the "What we learned" Report in January 2024, summarizing discussions from a Policy Roundtable held in December 2023.
- ***Phase 2 – Discussion Guide*****:** In June 2024, the PMPRB released "Shaping the Future: A Discussion Guide for PMPRB Phase 2 Consultations on New Guidelines". The Discussion Guide provides a framework, divided into four main sections, for the PMPRB's proposed new price review process:
    - Section A – Initial Price Review: Pursuant to the *Patented Medicines Regulations*, Rights Holders are required to report price and sales data to the PMPRB within 30 days after the medicine is first sold in Canada and on a semi-annual basis thereafter. Under the PMPRB's proposed price review process, a medicine's first semi-annual filing will be used to conduct an initial review based on the International Price Comparison (**IPC**) criteria to identify medicines that may need a more in-depth review. List prices which are at a low risk of excessive pricing will receive initial review from the PMPRB within 60 days and will require no further

consideration until Post-Initial Price Review (Section B) or the receipt of a complaint (Section C).

- Section B – Post-Initial Price Review: On an annual basis, the PMPRB will conduct a post-initial price review of all patented medicines under its jurisdiction. In this review, the PMPRB will apply the same IPC criteria used during the initial price review, in addition to comparing price changes of medicines against changes in the Consumer Price Index (**CPI**), to identify medicines that may need an in-depth review.
- Section C – Special Provisions: The PMPRB is considering the receipt of a pricing complaint as an additional pathway to an in-depth review. Under this section, approved individuals or groups who believe the price of a medicine is excessive can submit a complaint to the PMPRB, which would trigger an in-depth review. The PMPRB is considering a number of options for defining who will be permitted to submit a triggering complaint, ranging from restricting such complaints to the Federal Minister of Health or their provincial and territorial counterparts to imposing no restrictions at all.
- Section D – In-depth Review: An in-depth review is a PMPRB staff-led analytical process that considers all factors outlined in subsection 85(1) of the *Patented Medicines Regulations*, including comparing prices to the IPC, changes in the CPI, and the domestic and international therapeutic class comparison. Following an in-depth review, staff will recommend to the Chair whether to close the in-depth review or proceed to a Notice of Hearing. If the latter, the Rights Holder will be notified of the recommendation and given an opportunity to respond. The Chair will make a final decision whether to issue the Notice or close the in-depth review.

Phase 2 activities are nearing completion, as the PMPRB holds virtual stakeholder meetings to receive additional feedback about the Discussion Guide. The meetings are set to conclude on October 2, 2024.

- ***Phase 3 – Draft Guidelines*****:** The PMPRB intends to publish new draft Guidelines before the end of 2024, followed by a comment period. The new Guidelines are expected to be finalized and implemented in 2025.

Pharmacare Act: **First Provincial-Federal Collaboration Announced**

Bill C-64, *An Act Respecting Pharmacare* (***Pharmacare Act***), is the Government of Canada's next step towards the first phase of a national universal pharmacare program. Tabled on February 29, 2023, the *Pharmacare Act* has been reviewed in the House of Commons and is currently being considered by the Senate.

The *Pharmacare Act* allows the Minister, provided the Minister has entered into an agreement with a province or territory, to make payments to a province or territory to provide universal, single-payer, first-dollar coverage for drugs and related products. In the first phase of implementation, agreements covering select contraception medications and devices and diabetes medications (identified in lists released by Health Canada) will be negotiated with those provinces and territories willing to collaborate.

On September 12, 2024, the Government of Canada and the Government of British Columbia announced, through a Memorandum of Understanding (**MOU**), their intention to enter into such a collaboration. The Governments of British Columbia and Canada will commence formal negotiations to implement the program for listed contraception and diabetes products once Bill C-64 receives Royal Assent.

According to the MOU, other prescription drugs and related products could be added to the current lists of contraception and diabetes medications and these will be discussed during the negotiations. The MOU also sets out British Columbia's intention to provide free treatment of menopausal symptoms with hormone replacement therapy.

Greater Transparency for the Generic Submissions Under Review (GSUR) List

The GSUR List has become a more transparent, and more useful, resource. The GSUR List is a database of abbreviated new drug submissions (ANDSs) currently under review by Health Canada. For submissions accepted into review on and after April 1, 2024, the GSUR List now provides the name of the company sponsoring the submission, and the year and month of acceptance into review. The medicinal ingredient(s) in the product and therapeutic area to which the product relates continue to be specified, as previously.