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2023 year in review: Canada's top 10 drug and medical device regulatory/legal issues

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Canada has made a number of updates to its drug and medical device regulations and guidelines as part of the ongoing work to modernize the regulatory framework in the face of a changing industry, from AI-driven advancements and health product advertising to pharmaceutical exports. Below is our list of the top 10 drug and medical device regulatory and legal issues in Canada from 2023 and the first quarter of 2024.

Concern about shortages due to U.S. export of Canadian-labelled prescription drugs

Changes to U.S. state and Federal laws that may permit the importation of "Canadian" drug products have prompted updates to the Canadian *Food and Drug Regulations* (FDR) and increased oversight by Health Canada of drug supply and shortage concerns.

In response to the Trump Administration's Import Plan[1], which came into effect in 2020, Health Canada first issued an Interim Order on November 27, 2020, prohibiting the sale of certain medicines from being distributed outside of Canada if the sale could cause a shortage[2]. The Interim Order was replaced by permanent amendments to the FDR, which came into force on November 27, 2021 (2021 Amendments)[3].

The export of a commercial shipment of drugs from Canada is considered a "sale" requiring the exporting entity to hold a Drug Establishment Licence (DEL) issued by Health Canada. Following the 2021 Amendments, if a DEL holder exports from Canada a drug intended for the Canadian market, it must immediately create and retain (for at least one year after the latest expiration date of the drug that was exported) a detailed record explaining why such export would not cause or exacerbate a shortage of the drug in Canada. The 2021 Amendments also expanded Health Canada's authority to compel information from DEL holders so that Health Canada can assess the reasons and impacts of shortages and take measures to prevent or alleviate shortages.

Recent announcements have re-focused attention on these FDR amendments. On January 5, 2024, the U.S. Food and Drug Administration (FDA) authorized Florida's plan to import prescription medicines from Canada. This was part of a bulk-buying initiative meant to reduce prescription drug costs for Florida residents. Health Canada issued a statement shortly thereafter, stating that "[r]egulations have been implemented under the Food and Drugs Act to prohibit certain drugs intended for the Canadian market from being sold for consumption outside of Canada if that sale could cause, or worsen, a drug shortage in Canada. This includes all drugs that are eligible for bulk importation to

the U.S., including those identified in Florida's bulk importation plan, or any other U.S. state's future importation programs"[4]. According to the statement, Health Canada issued a communication to DEL holders reminding them of their regulatory obligations and continues to communicate expectations to companies through the supply chain. We note that, in addition to the legislative restrictions, manufacturers commonly include commercial terms in their standard distribution agreements that restrict the export of drugs intended for distribution in Canada.

Industry associations in Canada, including Innovative Medicines Canada, have issued statements regarding their opposition to the FDA's most recent announcement[5]. Canadian drug manufacturers should continue to monitor the situation closely.

Canadian pharmacies dispensing drugs directly to U.S. patients

In addition to concerns about bulk export discussed above, Canada continues to deal with drug supply "leakage" from another pipeline—direct pharmacy sales of Canadian-labelled prescription drugs from Canada to U.S. patients. U.S. patients have long attempted to fill prescriptions from Canadian pharmacies, largely driven by the widespread adoption of internet-enabled mail-order pharmacies. The cross-border pharmacy sales have impacted the Canadian drug supply for decades. The Federal measures discussed above are focused on stopping bulk exports of medication by DEL holders but do not address pharmacy sales, which fall under provincial jurisdiction.

In Canada, pharmacy regulations vary between provinces. Some provinces prohibit cross-border pharmacy services to patients outside of Canada (with limited exceptions) while other provinces are more flexible, provided that a valid prescription is co-signed by a Canadian prescriber and other requirements are met.

In 2023, the province of British Columbia (BC) discovered a pattern of cross-border pharmacy sales of prescription semaglutide products (which includes drugs sold under the brand names Ozempic, Rybelsus, and Wegovy) that could result in shortages of semaglutide for diabetic patients in the province. Through an internal investigation, BC's Ministry of Health indicated that almost 13,000 U.S. residents had obtained prescription semaglutide drug products from BC pharmacies in January and February of 2023 alone, accounting for almost one-fifth of all semaglutide prescriptions in BC during that period[6].

To safeguard semaglutide supply for diabetic patients in BC, the Ministry enacted the *Drug Schedules (Limits On Sale) Regulation* on April 19, 2023, to restrict the purchase of semaglutide drug products by non-Canadian patients to only in-person purchases at a BC pharmacy[7]. The restrictions are intended to prevent online sales of Canadian semaglutide products to patients outside of Canada. The Ministry may add other classes of medications to the Regulation in the future to protect BC patients' access to medication.

In less than two months following the enactment of the Regulation, BC reported a more than 99% drop in the number of dispenses of semaglutide to U.S. residents, a sign that the new restrictions are having the intended effect[8].

Steps towards a universal pharmacare system

Canada's provinces and territories have historically established public drug plans to help certain subpopulations (such as seniors and low-income individuals) offset their prescription drug costs; however, there is presently no universal public drug coverage available to all Canadians, regardless of age, income, or other demographics. Outside of the hospital setting, many Canadians either pay out of pocket for their prescription drugs or are covered by private drug insurance plans, many of which are sponsored by their employers as workplace benefits.

In recent years, Canada's Federal government has publicly communicated its plan to establish a national, universal pharmacare system that would provide coverage for certain prescription drugs and related products to all Canadians.

In December 2023, the Federal government announced the creation of the Canadian Drug Agency to provide coordination of Canada's drug system[9]. Subsequently, in February 2024, Bill-C 64 *An Act respecting pharmacare* (Bill-C 64) was introduced[10]. If passed into law, Bill-C 64, as currently drafted, would provide for funding by the Federal government to the provinces and territories to increase existing public pharmacare coverage and to provide

universal, single-payer, first-dollar coverage for specific prescription drugs and related products to all Canadians.

Although the Canadian Drug Agency's role is still being determined, Bill-C 64, as currently drafted, would empower the Canadian Drug Agency to (1) establish the scope of prescription drugs and related products to which Canadians should have access under national universal pharmacare, and (2) develop a national bulk purchasing strategy for prescription drugs and related products.

Interestingly, Bill-C 64 specifically contemplates funding for certain drugs and related products intended for contraception and the treatment of diabetes. With almost 1 in 10 Canadians over the age of 20 having been diagnosed with diabetes[11], and more than 9 million Canadians currently in their reproductive years[12], the government is prioritizing these therapeutic areas for a potential first phase of coverage.

Bill-C 64 is very high level at this stage and has only been subject to a first reading at the House of Commons. Further work is needed, including support from the provinces and territories, to make the proposed national pharmacare system practicable. However, insurers, drug and device manufacturers, healthcare providers and Canadian citizens are watching to see how the proposed plan evolves.

Health Canada's approach to AI/machine learning-enabled medical devices

In recent years, medical device manufacturers have begun leveraging big data sets collected during the delivery of healthcare (e.g., medical imaging results, diagnostic blood and urine test results, genetic markers, patient demographics, patient outcomes, etc.) for innovative purposes. In particular, such data sets are being used to create Artificial Intelligence (AI) driven medical devices capable of learning from real-world experiences and outputting diagnoses and treatment plans based on patient-specific metrics.

Given the acceleration of medical technologies in recent years, Health Canada has begun developing a framework for the regulation of "advanced therapeutic products" meant to address drugs and/or devices that are so complex or distinct from their traditional counterparts that they are not contemplated by current regulations. As part of this mandate, Health Canada published in 2023 its "Pre-market guidance for machine learning-enabled medical devices" (Machine Learning Guidance)[13].

This guidance highlights Health Canada's need to balance emerging risks associated with AI-driven medical devices versus the impracticality of repeatedly re-evaluating such products for post-market modifications. This is driven, for example, by AI-based medical devices with "adaptive" rather than "static" algorithms, as the devices that Health Canada initially reviews and approves will continually change over time after market release through iterative software modifications.

Device manufacturers that leverage AI should familiarize themselves with the Machine Learning Guidance, including Health Canada's adoption of predetermined change control plans (PCCP), as a mechanism for the regulator to pre-authorize certain planned changes to machine learning systems to address known risks. The guidance also emphasizes the need for Good Machine Learning Practices (GMLP). Device manufacturers should continue to monitor Health Canada's position on this topic as the regulation of AI-driven medical devices, and Health Canada's approach to such regulation, continues to evolve.

Patented Medicine Pricing Review Board update

The Patented Medicines Prices Review Board (PMPRB) is a quasi-judicial body that regulates the prices of patented medicine in Canada. The PMPRB publishes and relies on a set of guidelines that set forth tests to determine if a medicine's price is excessive.

The *Patented Medicines Regulations* were amended on July 1, 2022, to create a new basket of 11 comparator countries to reference (referred to as the PMPRB11) when assessing whether a medicine's list price in Canada is excessive[14]. New patented medicines approved since then have not had their pricing reviewed, as the guidelines to address the amended regulations have not been adopted. This has created much uncertainty regarding compliance,

and a significant backlog of new products that have not had their price assessed[15].

PMPRB issued interim guidance (most recently amended September 27, 2023)[16] to provide manufacturers of new medicines with some predictability regarding the status of their list price review while the PMPRB continues to consult and develop full guidelines.

Under the interim guidance, new patented medicines that have Canadian list prices below the median international price (MIP) of the PMPRB11[17] are considered "reviewed". Reviewed means that such prices will not be subject to further price review during the interim guidance period. It does not mean that such prices are or will be regarded as non-excessive once final guidelines are adopted. New medicines with Canadian list prices that are above this threshold will continue to be considered as "under review" until new guidelines are in place.

The price of a patented medicine that was issued a marketing authorization before July 1, 2022 will not trigger an investigation if the price is at, or below, the non-excessive average price as communicated to patentees in 2021 and no price increase is taken[18].

Importantly, a reviewed price can be reassessed after the interim guidance period ends and new final guidelines are in place. The PMPRB has indicated that there will be no clawback of potential excess revenues for sales of new medicines, whose list prices are below the MIP of PMPRB11, during the interim period.

PMPRB is conducting consultations for a new set of binding guidelines, which should be published for comments by the end of 2024.

Private surgical/diagnostic Centres

Ontario's new legislation *Integrated Community Health Services Act, 2023* (ICHSA) came into force on September 25, 2023, and is intended to "expand access to publicly funded community-based health services" through the licensing of integrated community health services centres (the Centres)[19]. The Centres are private health facilities where surgical and diagnostic services paid for by the Ontario government (i.e., public pay) may be performed. Plans to expand the Centres were first announced to address the backlog of surgical procedures because of COVID-19.

The ICHSA replaced prior legislation governing the regulation of these Centres. Similar to the prior legislation, the ICHSCA provides for the licensing and regulation of the Centres. The Regulation enacted under the ICHSCA introduced some additional requirements for Centres—for example, a requirement to post a list of prices for all uninsured services that a patient may choose to purchase (i.e., for additional devices, treatments, or services) and the process for obtaining patient consent in connection with those services[20].

The ICHSA explicitly prohibits charging a publicly insured person a fee for preferential access to an insured service[21] at a Centre. The ICHSA also prohibits charging and receiving facility costs from anyone other than the Ontario government or Ontario Health as prescribed by the Regulation. The Regulation refers to Ontario's published Schedule of Benefits as facility costs that will be reimbursed to Centres for the delivery of publicly insured healthcare services.

Applications for licences under ICHSA are solicited through calls for application, which will specify the types of services for which facility applications are sought. The government recently announced in January 2024 that, beginning in the Spring of 2024, it would take the next steps in expanding the number of Centres licensed under the ICHSCA, including Centres providing MRI/CT scans, GI endoscopies and orthopedic surgeries.

The changes in Ontario have been subject to some controversy, with press reports suggesting that Centres receive more funding to perform certain insured surgeries than the government provides to public hospitals to perform the same operations[22]. Concerns have also been raised about the ability of public hospitals to retain healthcare professionals who may choose to work exclusively in the private Centres. For now, the government continues to move forward with the expansion, indicating that this "can reduce wait times by doing more surgeries in state-of-the-art, convenient and safe facilities, always paid for by your OHIP card, never your credit card"[23].

Health Canada's updated guidance on *Distinction between Advertising and Other Activities*

Health Canada's long-promised modernization of its guidance on the *Distinction Between Advertising and Other Activities for Health Products* (the Guidance) was finalized and published on July 31, 2023. The new Guidance replaced the decades-old guidance from 1996 (last updated in 2005).

Canada restricts advertising health products to healthcare professionals (HCPs) and the public. For example, a manufacturer cannot both name a prescription drug and describe its intended use in an ad directly targeting Canadian consumers. Also, when advertising to healthcare professionals, drugs cannot be promoted for off-label uses.

Nonetheless, Health Canada recognizes that there are legitimate instances where it is necessary and beneficial for the health product industry to share non-promotional information on human and animal health products to HCPs, limited audiences, or the general public. To this end, the Guidance is an administrative tool to help industry distinguish between the act of promoting a health product for sale (which is highly restricted and prohibited in certain scenarios) and the act of providing non-promotional information to applicable stakeholder audiences.

There are a few notable differences between the new Guidance and the previous guidance. While the previous guidance applied to drugs only, the new Guidance captures a broader scope of "health products": vaccines, biologics, medical devices, prescription drugs, controlled substances, non-prescription drugs, animal health products and natural health products. The new Guidance includes additional content and context factors to be considered when determining whether a message or activity is promotional and clarifies that any information linked in a message should be considered in the assessment. The examples provided in the new Guidance for non-promotional messaging and activities have also been updated to reflect technological advances (e.g., social media, websites, "sharing" features, etc.)[24].

The Guidance applies to any form of media (e.g., television, radio, print, online, digital platforms) or setting regardless of the target audience. The Guidance sets out 13 examples to illustrate the principles and factors used to determine whether a message or activity is promotional or non-promotional[25]. Several new categories are included as examples, including medical condition and treatment awareness materials, other learning activities, medical procedure and health service messages, and risk management plans.

Charter of the French Language updates affecting the use of trademarks on product labelling[26]

In 2022, the province of Québec updated its *Charter of the French Language*, introducing the most significant amendments to the legislation since its 1977 adoption[27]. While the changes affect all areas of Québec's society, drug and device manufacturers operating in Québec should pay particular attention to the requirements pertaining to the use of French language and trademarks on products, advertising and related materials[28].

Specifically, the amendments require that, as of June 1, 2025 in the province of Québec, only registered trademarks can appear exclusively in a language other than French on products, and only as long as no corresponding French version of the trademark appears on Canada's trademark register. In contrast, before these changes, trademarks "recognized" under the *Trademarks Act* (i.e., common law, applied-for trademarks and registered trademarks) could appear exclusively in English and languages other than French if a French version of the trademark had not been registered.

Trademark owners will no longer be able to rely on the inclusion of generic or descriptive English text in a registered trademark to avoid translating the text into French on a product sold in Québec. If a registered trademark appearing on a product includes a generic term or description of the product in a language other than French, the generic/descriptive phrase must also appear in French on the product or on a medium that is permanently attached

to the product.

Draft regulations published in January 2024 by the Québec government[29], aim to clarify that the definition of a "registered trademark" includes trademark applications pending at the Canadian Intellectual Property Office (CIPO), thus permitting trademarks subject to Canadian applications to appear on product packaging exclusively in a language other than French if no corresponding French version has been registered. Further, these draft regulations contemplate a two-year grace period (until June 1, 2027) to permit products manufactured before June 1, 2025, to continue to display trademarks on their product packaging exclusively in a language other than French if no corresponding French version has been registered.

Drug and device manufacturers marketing their products in Canada should familiarize themselves with these changes to assess requirements for product label revisions and trademark filing strategies in Canada.

Medical device launches in Canada

As in the U.S., medical device products and establishments in Canada are subject to Federal licensing by Health Canada (including Medical Device Licence and Medical Device Establishment Licence)[30].

U.S. companies often wonder whether Canadian medical device approval by Health Canada can be fast-tracked where U.S. market authorization has already been obtained for the same medical device (e.g., 510(k) or Premarket approval). Unfortunately, Health Canada currently has no formal system for expedited review or approval of medical devices simply as a result of prior U.S. market authorization; however, we are seeing some progress in respect of U.S. and Canadian coordination on this. (In certain circumstances, expedited or priority review[31] is available for certain medical devices, but not simply because of a prior U.S. market authorization.)

In 2023, Health Canada introduced two pilot programs for eSTAR, an interactive PDF form that guides an applicant through the process of preparing a medical device submission for regulatory approval before bringing the device to market[32]. One pilot is a joint program with the USFDA to test the feasibility of using eSTAR to prepare a single medical device submission to both Health Canada and the USFDA for premarket approval (the Joint Pilot). The other pilot is a Health Canada-only pilot program assessing the use of eSTAR for medical device submissions to Health Canada only (the Health Canada Pilot).

Both pilots are full and currently underway. A successful pilot could mean decreased regulatory burdens for sponsors and faster access to medical devices for Canadians.

Health Canada's Forward Regulatory Plan 2024

Health Canada updated its Forward Regulatory Plan: 2023-2025, which provides information on regulatory initiatives that Health Canada aims to propose or finalize in the next two years[33]. Below, we list some of the new and updated initiatives related to drugs and medical devices in the Forward Regulatory Plan:

- In March 2023, Health Canada proposed to amend the *Medical Devices Regulations* (MDR) to expand the regulatory framework for COVID-19 medical devices to address future public health emergencies, to enable accelerated access to medical devices that would diagnose, treat, mitigate, or prevent such future public health emergencies. The amendments came into force on January 3, 2024, substantially as proposed.

- Health Canada plans to modernize the regulatory system to permit agile licensing of drugs and medical devices. The proposed changes are intended to expand health product safety and reduce certain regulatory barriers, including earlier market access for drugs eligible for a rolling review, modernized requirements for biologic drugs, expanded use of terms and conditions on approvals, risk management plans, and disaggregated data to evaluate drug safety in diverse populations. Health Canada plans to publish the final amendments to the FDR and MDR in 2024.

- Health Canada plans to modernize the regulation of clinical trials. Potential impacts may include accommodating innovative, non-conventional clinical trial designs and permitting healthcare professionals to apply for investigational testing of medical devices (without going through a manufacturer). Health Canada has engaged in various consultations with stakeholders and plans to pre-publish the regulatory proposal for public comments in spring 2025.
- Health Canada plans to modernize the Medical Device Establishment Licensing (MDEL) and DEL frameworks. The proposed amendments include establishing a reporting framework for therapeutic product recalls ordered by Health Canada, changes to reporting requirements for voluntary recalls, record-keeping requirements for medical device recalls and conditional exemptions for certain stakeholders of radiopharmaceuticals or gene/cell therapies from finished product testing requirements. Health Canada plans to publish final amended regulations in 2024.

FOOTNOTES

To discuss these issues, please contact the author(s).