Rx IP - Feature Article

From regulatory flexibility to reimbursement changes, how Canadian regulators and payers are managing the COVID-19 crisis.

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Canadian regulators and payers across the country have been actively taking steps to manage the evolving COVID-19 crisis. In this article, we highlight some of the key regulatory changes and guidance put in place by both the federal and provincial regulators as well as payers, which spans the gamut from regulatory pathway developments to clinical trials to pharmacy scope of practice to reimbursement issues.

Federal Developments - Health Canada

As previously reported, Health Canada is showing tremendous flexibility in facilitating and even encouraging the supply of COVID-19 related products. COVID-19 Health Product Industry is a helpful page to access some of Health Canada's numerous guidance documents as well as product information updates. The page even links to the specific products and services the Canadian government wishes to procure from businesses to help with Canadian supply.

Many of Health Canada's guidance documents address regulatory pathway issues for in-demand products such as applicable standards, how to fast-track approval, simplified regulatory requirements and regulatory requirements (e.g. labelling) that are not being enforced.

The documents and information available cover a range of products, including diagnostic tests; vaccines and treatments; Personal Protective Equipment (PPE) such as masks (Guidance on Optimizing the use of masks and respirators during the COVID-19 outbreak), medical gowns (Important regulatory considerations for the supply of medical gowns) and medical gloves (Important regulatory considerations for the supply of medical gloves during the COVID-19 outbreak); hand sanitizers and disinfectants (Guide on Health Canada's interim expedited licensing approach for the production and distribution of alcohol-based hand sanitizers); and ventilators (Notice: Importation or sale of ventilators - use of US FDA guidance and Canadian requirements for authorization under the Interim Order).

The guidance extends beyond typical regulatory pathway information and also includes:

- 3D printing and other unconventional manufacturing of PPE in response to COVID-19: This communication provides information on recommended standards for the production of face shields and face masks, the available test laboratories for product testing and the relevant regulatory authorization pathways. Although this document is specific to PPE that are Class I, Health Canada acknowledges in this document that 3D printing may evolve to manufacturing Class II medical devices (e.g. medical exam gloves, breathing circuit components and Venturi oxygen masks).
- Notice – Important Regulatory Considerations for the Reprocessing of Single Use N95 Respirators during the COVID-19 Response: This notice contemplates two separate reprocessing strategies for single use N95 respirators: (1)

sterilization devices that are manufactured and sold to reprocess N95 respirators, and (2) companies who reprocess and distribute N95 respirators to healthcare facilities.

On March 30, 2020, pursuant to subsection 30.1(1) of the *Food and Drugs Act*, Health Canada made an *Interim Order Respecting Drugs, Medical Devices and Foods for a Special Dietary Purpose in Relation to COVID-19* (the March 30 *Interim Order*), which addresses the exceptional importation of drugs (including biocides, such as hard surface disinfectants and hand sanitizers), medical devices, and foods for a special dietary purpose (e.g. infant formula) in relation to COVID-19. The March 30 *Interim Order* allows certain drugs and devices that do not fully meet regulatory requirements to be imported and sold in Canada. Overviews are available at Exceptional importation and sale of drugs in relation to COVID-19: Overview and Exceptional importation and sale of medical devices in relation to COVID-19: Overview. Only drugs and medical devices on the *List of Drugs for Exceptional Importation and Sale* and *List of Medical Devices for Exceptional Importation and Sale* ("Designated Drugs" and "Designated Medical Devices", respectively) are eligible.

At this time, only drugs that meet the criteria for Tier 3 drug shortages, including certain drugs used for intubation (e.g. neuromuscular blockers, sedatives and narcotic analgesics), salbutamol metered dose inhaler and hydroxychloroquine, can be Designated Drugs. A Tier 3 shortage is a shortage that has the greatest potential impact on Canada's drug supply and health care system, in terms of low availability of alternative supplies, ingredients or therapies.

In contrast, for medical devices, there is no requirement to meet any shortage criteria in order for a product to be considered a Designated Medical Device.

Transparency

In line with the general trend towards transparency, Health Canada is also publishing in real-time COVID-19-related applications, approvals and shortages. Below is a snapshot of what is available:

- Vaccines and treatments for COVID-19: All authorized clinical trials and investigational testing in Canada for COVID-19 are listed. Although Health Canada already has a public database of clinical trials, this new site is specific for COVID-19 vaccines and treatments.
- As mentioned in our previous article, Health Canada made an *Interim order respecting the importation and sale of medical devices for use in relation to COVID-19* on March 18, 2020 (March 18 *Interim Order*) to permit some regulatory flexibility.

For non-diagnostic devices, Health Canada publishes a list of medical devices authorized pursuant to the March 18 *Interim Order* (Medical devices for use against coronavirus (COVID-19): List of products authorized under Interim Order).
In contrast, for diagnostic devices, both the devices authorized as well as the applications for authorization are published (Diagnostic devices for use against coronavirus (COVID-19).

- Medical device shortages: The March 30 *Interim Order* requires manufacturers and importers to report shortages of medical devices on the List of Medical Devices related to COVID-19. A medical device shortage occurs when a manufacturer is unable to meet Canadian market demand for the device or its components, accessories, parts or consumable materials. It does not include a situation in which a substitute is available. As of the date of this article (April 15, 2020), no actual or anticipated shortages are posted on the website. Since drug shortages are already required to be reported, this new requirement does not cover drugs.

Clinical Trials

To facilitate the conduct of clinical trials while allowing self-isolation of participants and deployment of healthcare personnel to other duties, Health Canada has also provided guidance on Management of clinical trials during the COVID-19 pandemic: Notice to clinical trial sponsors. This guidance, which contains a chart with key points, is essential reading for anyone involved with clinical trials. For ongoing clinical trials during the pandemic, sponsors are directed to, among various suggestions and requirements, discuss with local research ethics boards whether it is in the best interest of a participant for them to continue as per the study protocol or to halt their participation; consider risks and risk mitigation strategies related to the use of any immunosuppressive agent; properly document protocol deviations; prioritize critical activities to ensure participant safety; evaluate alternative methods for safety assessments (e.g. phone contact, virtual visits); consider shipping clinical trial investigational products directly to patients in appropriate circumstances; and consider suspending recruitment or placing the study on hold where necessary.

Provincial Developments

Regulators and payers in the provinces have likewise been actively trying to facilitate and manage health care supply and services for patients. Some examples are as follows.

Pharmacy Developments

Scope of Practice

Pharmacists have a broad scope regarding the type of controlled acts they can engage in. The specific scope varies by province but includes:

- initiating or renewing prescriptions;
- adapting prescriptions and dosages; and
- administering medications, including by injection, either for treatment or for demonstration or education purposes.

COVID-19 has accelerated the further expansion of the scope of practice of pharmacists in most provinces and loosened some existing requirements. Some recent changes relate to which medications pharmacists may administer, and in what manner, as well as the initiation, renewal and adjustment of prescriptions.

For example, Québec Bill 31, *An Act to amend mainly the Pharmacy Act to facilitate access to certain services*, assented to on March 17, 2020, allows Québec pharmacists to prescribe and administer vaccines and, in emergency situations, certain other medications. However, "emergency situation" is interpreted narrowly – this refers to life-threatening situations where drugs like salbutamol or epinephrine are required, as opposed to the pandemic generally. Additionally, the Collège des médecins and the Ordre des pharmaciens have relaxed conditions relating to the expanded scope of practice first implemented through Bill 41, *An Act to amend the Pharmacy Act* (in force since 2015), such that, as of March 16, 2020, and until further notice, Québec pharmacists may:

- extend prescriptions for periods beyond those provided by law;
- prescribe medication for minor conditions (within four years of the physician's initial diagnosis);
- extend, adjust or substitute a medication without communicating such information to the physician (unless specifically requested to do so by the physician); and
- in the event of a shortage of medicines, substitute a medication with that of another therapeutic subclass if necessary.

These amendments bring the scope of practice of Québec pharmacists more into alignment with that of pharmacists in other provinces, with the notable exception of Ontario. Ontario pharmacists have a more limited practice scope compared to their counterparts in other provinces. However, changes are being considered – see the Ontario College of Pharmacists' consultations on Expanding Scope of Practice and Expanding Scope of Practice: Pharmacist Prescribing for Minor Ailments.

Expanded scope of practice for pharmacists is especially important during the pandemic since many physicians no longer routinely see patients in-person.

E-mailing Prescriptions

In many provinces, a physician typically writes a prescription on paper, which the patient then brings to a pharmacy to obtain the prescription. The physician can also telephone or fax a prescription to a pharmacy. Though e-prescribing may be permitted legally, in practice, there are many barriers such that e-prescribing is not widely used (at the community pharmacy level) in most provinces.

Currently, however, regulators are showing flexibility, as the physical transfer of paper from person-to-person is not ideal, many patients are not seeing their physician in-person, and many physicians are working from home without a fax machine. The Ontario College of Pharmacists, for example, issued a policy on Emailed and Faxed Prescriptions -

Temporary Method for Transmitting Prescriptions via Unsecure Email During COVID-19 stating that, although phone, fax and secure e-prescribing should be used wherever possible, unsecure e-mail may be used on a temporary basis (but not for narcotics) if the physician has the patient's consent to use unsecure e-mail and certain other requirements are met.

This new COVID-19 policy is consistent with the Information and Privacy Commissioner of Ontario's Communicating Personal Health Information by Email (pre-COVID 19 guidance, dated September 2016), which allows health information custodians to use unencrypted e-mail during an emergency or urgent circumstance.

Temporary Exemptions for Controlled Substances

Activities involving controlled substances are typically regulated more strictly than activities involving drugs that are not controlled substances. For example, depending on the province, a pharmacist's scope of practice may permit the extension (i.e. renewal) of a prescription but, previously, such scope of practice would exclude the ability to extend a prescription for a controlled substance. Now, however, to enable Canadians to access controlled substances for medical treatments (e.g. treatment of substance use disorders and chronic pain) while adhering to social distancing or self-isolation guidance, Health Canada has issued certain temporary exemptions for prescriptions of controlled substances under subsection 56(1) of the federal *Controlled Drugs and Substances Act*.

Accordingly, if permitted by the applicable provincial scope of practice rules, there is temporarily no longer a restriction against the following activities with respect to controlled substances (narcotics, controlled drugs and targeted drugs):

- pharmacists extending prescriptions;
- pharmacists transferring prescriptions to other pharmacists;
- prescribers issuing verbal orders (i.e. over the phone) to extend or refill a prescription; and
- pharmacy employees delivering prescriptions to patients' homes or other locations where patients may be (i.e. self-isolating).

Reimbursement

Cancer Care Ontario Funding

Cancer Care Ontario (CCO), the public payer for injectable cancer treatments in Ontario, has developed interim funding measures in recognition that patients may have limited access to surgery, radiation, systemic therapy delivery, diagnostic imaging and interventional procedures during the pandemic. Below are just a few of the interim policies.

- *Extended treatment breaks* – CCO recognizes that the benefits of continuing treatment must be weighed against the risks of potential COVID-19 exposure such that extended treatment breaks of publicly funded cancer drugs may be required. For patients taking a treatment break during the pandemic, re-starts will be funded, even if disease progression occurs while on the break.
- *Flexible start dates for sequencing treatments* – Even though a systemic treatment is usually started within a certain time period from another intervention, CCO has determined that a delay in the start date of the systemic treatment will not affect a patient's eligibility for public drug funding coverage.
- *Extending dosing intervals* – Extended dosing intervals for certain regimes will be funded. For example, certain regimens normally administered every X weeks will also be funded if administered less frequently (e.g. every Y weeks). For some of the newly funded regimens, the administration intervals are off-label.

30-Day Supply of Prescription

To minimize the risk of drug shortages and prevent unnecessary stockpiling, the Ontario Ministry of Health issued Notice: Ontario Drug Benefit (ODB) Program Changes and Guidance for Dispensers during the COVID-19 Public Health Emergency, recommending pharmacists dispense no more than a 30-days' supply of medication, subject to their professional judgment in exceptional cases with appropriate documentation.

Temporary changes were also made to allow a dispensing fee for each 30-day supply to be claimed even if a greater quantity must typically be dispensed. For example, with certain chronic-use medications for patients with Ontario Drug Benefit (ODB) coverage, pharmacists are usually entitled to receive a maximum of five dispensing fees per 365-day period. In response to the pandemic, the list of chronic medications subject to this rule has been temporarily removed.

The 30-day supply limit has not been welcomed by some patients, in part, because they may incur increased costs as a result of more dispensing fees and co-payments. However, it is not just the public payer in Ontario recommending a 30-day supply – many other associations and regulators have also taken such positions, including the Canadian Pharmacists Association, which issued a statement on COVID-19 and the responsible allocation of medications to patients.

Amendments to the determination of Ontario's Brand Reference Price

Ontario's rules for brand reference prices (i.e. the price for the original reference drug, which is used to calculate the price of an interchangeable drug on the ODB Formulary) were not completely aligned with the rest of Canada. This misalignment sometimes acted as a barrier to the listing of some generic drugs on the ODB Formulary.

As a result of the recent surge in demand for drugs (the impetus for the 30-day supply limitation discussed above) and concerns about potential drug shortages, the Regulations to the *Ontario Drug Benefits Act* were amended (effective April 1, 2020) to minimize potential disadvantage to Ontario from a supply perspective compared to other provinces. Among other changes, the Executive Officer now has the authority to align Ontario's rules for determining brand reference prices with the national approach used by the pan-Canadian Pharmaceutical Alliance. See March 30, 2020 Executive Officer Notice: Proposed Regulatory Amendments on Rules for Determining Brand Reference Prices and April 7, 2020 Executive Officer Notice: Regulation Amendments to Private Label Products and Brand Reference Pricing Rules.

As the COVID-19 crisis unfolds, Canadian regulators, at both the federal and provincial levels, and payers are developing innovative strategies and relaxing existing regulatory requirements to address unforeseen issues and to assist patients, health care professionals and industry in dealing with this unprecedented situation. Some of these measures facilitate the allocation of resources to COVID-19-specific responses to ensure adequate medical supplies. Other measures are put in place to minimize disruption to the proper functioning of our healthcare system. Together, the changes and guidelines highlighted in this article provide an overview of the Canadian regulatory landscape in the face of the COVID-19 public health emergency.

The preceding is intended as a timely update on Canadian intellectual property and technology law. The content is informational only and does not constitute legal or professional advice. To obtain such advice, please communicate with our offices directly.

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