Regulated health products in 2021: Post-COVID enforcement trends in Canada

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With the approval of the first COVID-19 vaccine in Canada at the close of 2020 and with large-scale vaccination programs underway, in 2021, Canada transitions to a post COVID-19 reality.

In 2020, activity in the regulated health product sphere was largely focussed on ensuring that products necessary to combat COVID-19 were available in Canada as quickly as possible. At the start of the pandemic Health Canada issued a number of interim orders to facilitate the rapid coming to market of new and existing drugs, natural health products and medical devices. These interim measures relaxed regulatory requirements allowing certain non-compliant products to be marketed in Canada (for example, those with a foreign product approval number rather than a Canadian product approval number).

In parallel, Canadians were flooded with messages encouraging individuals to sanitize their personal environments. This translated into a marketing opportunity for many businesses to supply products necessary to meet the demand, including hand sanitizers, disinfectant cleaners, face masks etc. For many businesses, this meant branching into new lines of business (distilleries manufacturing hand sanitizer is an example that comes to mind).

Taken together, 2020 saw an unprecedented volume of new health products (and general consumer products making health claims) coming to market in Canada from both old and new players in the arena.

A consequence of this race to market is a growing number of recalls for product non-compliance. The two most common reasons for recall include:

- Health products, such as drugs, natural health products and medical devices, that are not approved and/or do not comply with labelling requirements; or
- Health products or general consumer products making non-compliant health claims, such as claims to be “effective against COVID-19” or general consumer products claiming to have disinfecting properties.

The increased volume of recalls and post-market surveillance of packaging/labelling and advertising of health products and general consumer products may be short-lived compliance initiatives taken by Health Canada in response to COVID-19 related products. On the other hand, increased enforcement measures in the regulated health product sphere may be here to stay. As 2021 unfolds, we can expect to see the lessons learned from COVID-19 regulatory landscape to have a lasting impact on the manner in which compliance of health products and general consumer products making health claims is monitored and enforced.

Businesses selling health products or other consumer products making heath claims should expect heightened enforcement of applicable regulations, particularly as interim measures begin to expire or are modified to become more stringent. Already in the first quarter of 2021, Health Canada has moved to reinstate applicable regulations for health products:

- **New COVID-19 Interim Order (IO2) came into force on March 1, 2021:** *Interim Order No. 2 Respecting Drugs, Medical Devices and Foods for a Special Dietary Purpose in Relation to COVID-19* repeals and replaces *the Interim Order Respecting Drugs, Medical Devices and Foods for a Special Dietary Purpose in relation to COVID-19* made by the Minister on March 30, 2020 (IO1). Under IO2, flexibilities provided under IO1 for certain product categories are beginning to be rolled back. Businesses will have 6 months to come into compliance after which it is expected that Health Canada will strictly enforce regulatory requirements for health products that no longer benefit from regulatory exemptions. For example, IO2 reintroduces the requirement for companies to have a drug establishment license to conduct regulated activities related to drug-based hand sanitizer.
- **Amendments to the post-market surveillance requirements under the *Medical Device Regulations* coming into force beginning on June 23, 2021:** The post-market surveillance regulations amending the *Medical Devices Regulations* will provide Health Canada more powers to improve post-market surveillance of medical devices. Examples include:
- Expanded incident reporting obligations;
- Mandatory foreign risk notification;
- Mandatory annual summary reporting and issue-related analyses of safety and effectiveness; and
- Power to require assessments and power to require tests and studies.

- **Continued enforcement regarding non-compliant health claims:** The public's increased focus on a clean and sanitized personal environment and more broadly, general health and wellness, is a new way of thinking that is likely here to stay. It follows that businesses will continue to innovate and market products responsive to this mind-set. "Hot" products include UV lamps and air filtration devices marketed for sterilizing household goods and indoor environments. These products are already on Health Canada's radar for making unacceptable health claims in relation to COVID-19.

As businesses innovate they must continue to exercise caution in representing general consumer products for medical purposes, as such health claims may be prohibited outright or may push products into the regulated product sphere, for which a host of additional regulatory requirements must be met prior to coming to market.

While Health Canada has expanded compliance and enforcement initiatives to match the rate at which new health products are reaching Canadians under COVID-19 interim measures, there is no reason to expect these enforcement measures will stop once vaccination reaches critical numbers and "COVID-19" recedes from the day's headlines. The pandemic has taught of the value in maintaining a clean environment and Health Canada will continue to be vigilant in seeking to protect Canadians from products that may mislead the public with respect to their uses.

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