PIVOTING PRODUCTION TO ADDRESS COVID-19 SHORTAGES – WHAT MANUFACTURERS AND DISTRIBUTORS NEED TO KNOW

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Canadian industry has rallied to the Canadian and provincial governments' calls for innovation and manufacturing capacity to meet the critical lack of personal protective equipment ("**PPE**") and medical equipment as well as the search for therapeutic treatments and vaccines to meet the COVID-19 pandemic. Ontario Power Generation is now utilizing 3D-printing technology to make faceshields, Labbatt's has shifted production to hand sanitizer and Canada Goose has converted its manufacturing plant to make gowns and patient scrubs. Other manufacturers have tested existing food sanitization and processing products to sterilize and allow the safe reuse of PPE.

Faced with the unprecedented demand for medical devices to respond to the COVID-19 pandemic, the Minister of Health issued an interim order on March 18, 2020[1] ("**Interim Order**") for Health Canada to issue expedited authorizations for the sale of medical devices to address the risk posed by COVID-19 ("**COVID-19 medical devices**"[2]). The Department of Public Works and Government Services has published specifications for specific COVID-19 medical devices or products on its website.[3] The Federal Government has pledged $2 billion to purchase medical supplies and PPE and the Ontario Government has committed $50 million to Ontario companies to shift their manufacturing operations to COVID related products and supplies.

1. **Making Medical Devices - Health Canada's Role**

The definition of "medical device" is broad and includes any instrument or component used to treat, diagnose or prevent a disease or abnormal physical condition. Although it is not surprising that COVID-19 tests kits or ventilators are medical devices which require Health Canada approval, more innocuous equipment like hospital gowns, surgical masks and N95 face masks also require Health Canada approval. While consumers can purchase N95 facemasks at Home Depot, facemasks and gowns used in health care are Class I Medical Devices under the *Food and Drug Act* and *Medical Device Regulations*.

Health Canada has published guidance as well as set out a process to facilitate the expedited approval process for COVID-19 medical devices that accelerate the availability of substitute sources of PPE (whether repurposed from other applications or produced by manufacturers that have pivoted capacity to meet the current demand

for medical supplies) and imported COVID-19 medical devices.

Medical devices are licensed through (i) medical device establishment licenses ("**MDEL**") and medical device licenses ("**MDL**")

- MDEL's are issued to companies that import or distribute medical devices (Class I to Class IV) **or manufacture Class I medical devices**; and
- MDLs are issued for Class II, III and IV medical devices.

Most PPE and devices intended to disinfect and sterilise PPE to allow for its safe reuse are Class I and Class II medical devices respectively.

The Interim Order relieves MDEL license holders from certain obligations under Part 1 of the Medical Device Regulations, and will expedite approvals for

- New COVID-19 medical devices that are not yet license in Canada or anther jurisdiction;
- COVID-19-related uses for existing devices licensed under the Medical Device Regulations, or under the Interim Order; and
- COVID-19 medical devices that that already have an authorization from a "trusted foreign regulatory authority, whereby the Minister would maintain the ability to request additional information on a case-by-case basis."[4]

The Interim Order also provides for the expanded use of medical devices or COVID-19 medical devices if the device is included in Health Canada's *List of Medical Devices for Expanded Use* provided certain conditions are met. As of the date of this Bulletin, no devices have been approved for expanded use[5].

Health Canada has provided guidance on the information it requires on all applications for expedited approval to import or sell a COVID-19 medical device, including labelling requirements as well as record keeping and reporting obligations. There is also a narrow exemption for COVID-19 medical devices that are already authorized by a foreign regulatory authority (and have not been suspended).

While all subject to the Interim Order, Health Canada provides specific guidance[6] and pathways for expedited approval of diagnostic devices and tests,[7] hand sanitizers and disinfectants,[8] ventilators,[9] and for vaccines and treatments.[10]

2. **Manufacturer's Liability**

Pivoting production to manufacture COVID-19 medical devices may change the risk profile for some manufacturers given the context in which the products will be used. The potential for a higher standard of care is something every manufacturer must take into account in deciding whether it will pivot production and, if so,

what additional research, testing and quality assurance steps it must impose. This clearly will be a disincentive to some manufacturers. In the United States, Congress encouraged private industry participation by explicitly addressing the added litigation risk to manufacturers. The *Coronavirus Aid, Relief and Economic Security* (*CARES*) Act protects manufacturers and distributors of PPE and medical supplies from civil liability. The Canadian response to the COVID-19 related shortages of PPE and other medical equipment does not provide manufacturers and distributors similar legislated protection against liability.

Health Canada approval for any medical device, drug or vaccine does not discharge a manufacturer's duty of care. Regulatory approval, however, has been viewed as corroboration when presented with expert evidence that a manufacturer conducted appropriate and sufficient testing that met industry and regulatory standards.

a. *Negligence Law – Standard of Care in Pandemics*

There is limited case law considering the impact of a pandemic emergency on the standard of care required of a manufacturer or distributors of medical devices, therapeutic treatments or vaccines. The Interim Order, however, contemplates that the approval process for COVID-19 medical devices will potentially include an abbreviated review process, or will be leveraged off the approval of a foreign regulatory authority, such as the United States Food and Drug Agency.

Responding to a pandemic will not lower the requisite standard of care, although it will undoubtedly affect the hind-sight risk-benefit analysis that lies at the heart of any standard of care analysis in product liability. In *Adam v GlaxoSmithKlein*[11], the Ontario Superior Court took into account Health Canada's authorization of a vaccine manufactured by GlaxoSmithKlein ("**GSK**") to respond to the H1N1 global pandemic as part of its analysis regarding the standard of care imposed on the vaccine manufacturer. Health Canada approved GSK's H1N1 vaccine based on animal studies and human studies, but before the completion of clinical trials. Noting that the vaccine had been adapted from an approved vaccine developed for H5N1, the Court concluded that the distribution and use of the H1N1 vaccine before the completion of clinical trials was "done for public health concerns and with government approval, not by virtue of carelessness."[12] GSK's disclosure of relevant information to Health Canada and physicians and its implementation of safety and surveillance indicated that GSK had acted responsibly and met its standard of care.[13]

The standard of care required of manufacturers and distributors of Class I COVID-19 medical devices will depend on the nature of the medical device. PPE manufacturers have a less exacting than that imposed on manufacturers and distributors of Class III and Class IV COVID-19 medical devices because of the nature of these products and intended use. The benefits of COVID-19 medical devices may outweigh inherent risks posed by these products given the current urgency and casualty rate of COVID-19. For example, the current shortage and pending gap available COVID-19 medical products may justify less exacting pre-market testing so

long as there is:

- sufficient, other reliable evidence to establish the efficacy of particular COVID-10 medical device,
- evidence that the equipment is safe and that takes into account the heightened risk posed by novel coronavirus-2 to users in contracting COVID-19 if product fails to perform as intended; and
- appropriate (and perhaps enhanced) post-market surveillance and reporting system to monitor and address product performance, safety or adverse events.

Whether manufactures of COVID-19 medical devices meet the requisite standard of care will depend on the circumstances of each case and an analysis of the benefits and risks associated with the ordinary use of the product. The evidence to establish the efficacy of PPE may be less than what is necessary to establish the efficacy and safety of devices intended to sterilize single-use PPE so that it can be safely reused. In the context of treating serious illness or disease, the balancing of risks and benefits associated with the ordinary and intended use of a medical device, therapeutic treatment or even PPE may be acceptable in the absence of any other reasonable, safer, alternatives. For example, the nearly always-fatal course of rabies in humans if left untreated outweighs the risk of serious but rare side effects associated treatment of the disease. In contrast, a manufacturer may not meet its standard of care if it produces and sells an influenza vaccine with common, serious side effects if the particular strain of influenza is one that does not carry a high casualty or mortality rate.

b. *Contractual Protections*

In certain circumstances, a manufacturer or distributor of a COVID-19 medical device may be able to negotiate contractual indemnity provisions to mitigate litigation risk in supply agreements with the Canadian government or provincial governments.

c. *Business Structure*

A manufacturer or distributor who is looking to enter the COVID-19 medical device market should consider whether it should conduct such operations within its current corporate structure or whether modifications to that corporate structure, including establishing a new affiliate or subsidiary to conduct such operations, should be made in order to mitigate risk to the rest of the enterprise. If an organization is looking to develop a COVID-19 medical device together with another organization through a joint venture, the structure of that joint venture and agreements between them should clearly reflect the responsibilities of each party and allocate risk between them appropriately.

d. *Insurance*

Finally, all manufacturers should review their existing insurance coverage to ensure that any products

approved by Health Canada under the Interim Order falls within current insurance coverage. If there is any doubt whether these COVID-19 medical devices fall within coverage, it may be necessary to obtain additional riders from insurers.

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[1] Interim order respecting the importation and sale of medical devices for use in relation to COVID-19.
[2] Defined in the Interim Order as "a medical device that is manufactured, sold or represented for use in relation to severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2).
[3] Specifications for COVID-19 Products.
[4] Interim Order.
[5] List of medical devices for expanded use in relation to the COVID-19 pandemic.
[6] Health Canada Applications for medical devices under the Interim Order for use in relation to COVID-19 - Guidance Document.
[7] Diagnostic devices for use against coronavirus (COVID-19).
[8] Hard surface disinfectants and hand sanitizers (COVID-19).
[9] Notice: Importation or sale of ventilators - use of US FDA guidance and Canadian requirements for authorization under the Interim Order.
[10] Vaccines and treatments for COVID-19.
[11] 2019 ONSC 7066.
[12] *Ibid*., para. 57.
[13] *Ibid*., para 59.

A Cautionary Note

The foregoing provides only an overview and does not constitute legal advice. Readers are cautioned against making any decisions based on this material alone. Rather, specific legal advice should be obtained.