COVID-19 medical devices and implications for Québec sellers and importers

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In light of the current global COVID-19 crisis, both federal and provincial governments have issued a call to manufacturers across Canada to manufacture medical equipment, including breathing apparatus. On March 18, 2020, the Minister of Health issued the *Interim Order Respecting the Importation and Sale of Medical Devices for Use in Relation to COVID-19* (Interim Order). The Interim Order expedites the review of applications for authorization to manufacture a medical device for use in relation to COVID-19 medical devices, as found in section 1. The expedited review is intended to respond to the country's current needs by issuing authorizations for medical devices related to the COVID-19 crisis, which will not be subject to the regulations under Part I of the *Medical Device Regulations* (MDR).

To assist manufacturers with their applications, Health Canada publicized the *Applications for medical devices under the Interim Order for use in relation to COVID-19 - Guidance document*. The targeted COVID-19 medical devices are:

- new COVID-19 medical devices not yet licensed either in Canada or other jurisdictions
- already existing and licensed medical devices that can now have COVID-19-related uses for existing devices that are either licensed under the Medical Device Regulations or under the Interim Order
- COVID-19 medical devices that leverage an authorization of a device from a trusted foreign regulatory authority, whereby the Minister would maintain the ability to request additional information on a case-by-case basis

This bulletin summarizes the Interim Order's implications and considerations in terms of risk mitigation for manufacturers selling and importing COVID-19 medical devices in Québec.

Impact on manufacturers selling and distributing COVID-19 medical devices in Québec

On March 13, 2020, the Québec government issued its first order declaring a state of public health emergency pursuant to section 118 of the Québec *Public Health Act*

(PHA). By virtue of this order, the Ministère de la Santé et des Services sociaux is allowed to proceed, without further delay, to purchase certain medical equipment and sign necessary contracts to protect the population during the current crisis. On March 20, 2020, the Québec government also made a call to all Québec companies to proceed with manufacturing COVID-19 medical devices and equipment.

Takeaways for manufacturers wishing to sell and distribute COVID-19 medical devices in Québec

The liability of manufacturers who sell and distribute products in Québec is subject to the rules of the Civil Code of Québec (CCQ). While the current sanitary crisis has been declared only under the PHA, it must be noted that no specific additional protection seems to exist for manufacturers contracting with the government under the PHA.

As of the date of this bulletin, the Québec provincial government has not yet declared a state of emergency by virtue of the Québec *Civil Protection Act* (CPA). Therefore, it is important to keep in mind that the potential available protection under the CPA (detailed in the section below) is not currently applicable.

It is worth noting that a national emergency declared by virtue of the CPA could give rise to certain protections available to manufacturers who are contracting with and under the direction of the government or any other governmental authority, namely an immunity and a right to indemnification. The CPA allows the government to grant authorizations and exemptions as provided under the state of emergency, through section 93 CPA. The persons or manufacturers that are invited to participate by virtue of section 93 CPA can benefit from immunity, to the exclusion of intentional fault or gross negligence, by virtue of section 125 CPA. The CPA triggers the obligation on the part of the government, or the authority issuing the grant, to indemnify the manufacturer requested to act under the CPA. Again, in case of intentional fault or gross negligence, the government or the assigned authority is not bound to take up the defence of the manufacturer.

As no additional protection is available under the PHA, manufacturers seeking to sell and distribute COVID-19 medical devices should consider mitigating their risks by looking at the CPA language, with regards to the immunity and right to indemnity, when contracting with a governmental agent in the current context. Nonetheless, manufacturers should remember that the CCQ provisions remain applicable and that the CPA is not currently triggered, and, thus, there is no additional protection guaranteed by legislation. It is also important to note that the Courts have not yet interpreted the applicable CPA provisions regarding immunity and indemnity for manufacturers contracting with the Québec government during a pandemic, war or any other major disaster.

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