Spotlight on medical devices in the age of COVID-19

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The global pandemic has created a need for medical devices including diagnostic tests, personal protective equipment, and ventilators. While these much-needed products are subject to regulatory oversight by Health Canada, the Canadian regulator has announced interim measures to facilitate expedited access to them.

We highlight some of the measures Health Canada has introduced through the federal Minister of Health's Interim Order of March 18, 2020 (the IO) and related communications, as well as some important considerations that manufacturers, importers and distributors should keep in mind in the coming months.

- **Expedited Access** : The IO allows for expedited authorization for the importation or sale of medical devices used in the diagnosis, treatment, mitigation, or prevention of COVID-19. Specifically, this mechanism allows the Minister to use her discretion to balance the benefits and risks of COVID-19 related devices and to fast-track authorizations where appropriate to meet the urgent public health need resulting from the pandemic. The IO provides a new application and authorization process for COVID-19 medical devices that a) are not yet licensed in Canada or elsewhere; b) are authorized by a trusted foreign regulatory authority; or c) are currently licensed under the *Medical Devices Regulations* for another purpose.
- **Application Approval Process:** Within the auspices of the IO, Health Canada has provided guidance on the required contents of an application for the authorization of importation or sale of COVID-19 medical devices. Health Canada has also outlined the labelling requirements for such devices. With respect to ventilators, Health Canada has referred the industry to the US Federal Drug Administration's enforcement policy to assist with informing application submissions to the Canadian regulator.
- **Relaxed Regulatory Requirements:** COVID-19 medical devices for which an IO authorization has been issued will also be exempted from most of the regulatory requirements set out in Part 1 of the *Medical Devices Regulations.* The IO, however, still mandates incident reporting and requires applicants to have documented procedures for distribution record-keeping and recalls.

While those wishing to import or sell Class I medical devices would typically require a Medical Device Establishment Licence (MDEL), it would no longer be required if Health

Canada issues an IO authorization because of an urgent public health need for the importation or sale of the device. Notably, however, for N95 respirators and other surgical, procedure and medical masks – which are considered Class I medical devices – Health Canada is endeavouring to complete the MDEL approval process within 24 hours of receiving a completed application from a company wishing to manufacture, import or distribute these products. Health Canada has also recently clarified that those wishing to manufacture Class I medical devices via 3D printing or other unconventional means for distribution or sale must hold either an IO authorization or a valid MDEL, subject to certain exceptions.

While the recent regulatory changes will assist in meeting the demand for COVID-19 medical devices, it is important to remember, despite the urgent need for such devices, regulatory requirements for approval must be carefully observed to ensure compliance and to mitigate the risks associated with any device-related issues down the road. Manufacturers, importers and distributors should avoid selling or otherwise transferring products that may be classified as medical devices before the necessary approvals are in place. Companies who have the capacity to manufacture or supply medical devices, but who do not have experience navigating the complex regulatory scheme for such devices, may wish to partner with companies who have an established history in the industry and/or engage legal counsel to ensure compliance. It is also important to keep abreast of new directions and guidance from Health Canada in this rapidly-evolving landscape.

BLG has created a COVID-19 Resource Centre to assist businesses on a variety of topics, including investment management, labour and employment, contractual risks, public disclosure requirements, education and criminal law.

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