The Federal Government Demonstrates Nimbleness in Responding to the COVID-19 Health and Economic Crisis

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Health Canada Fast Tracks Authorization of the Importation and Sale of Masks and Respirators amid the COVID-19 Pandemic

By Jennifer McKenzie and Anastassia Trifonova

Medical devices cover a wide range of health or medical instruments used in the treatment, mitigation, diagnosis or prevention of a disease or abnormal physical condition. They range from toothbrushes and thermometers to diagnostic tests to pacemakers and breast implants. Medical devices are classified based on the level of potential risk related to their use. There are four classes: I, II, III and IV with Class I being the lowest potential risk.

Masks, including both surgical masks and N95 respirators (or particulate filtering face-piece respirators), which are designed to reduce the risk of inhaling hazardous airborne particles and aerosols, are categorized as Class I devices. COVID-19 test kits would be classified as Class III devices.

One or two types of licences are needed from Health Canada to manufacture, import or distribute medical devices in Canada:

1. a Medical Device Establishment Licence, which is issued by the Medical Devices Bureau to the "establishment" or business who is engaged in activities relating to devices namely, their manufacture, importation or distribution ("MDEL"); and
2. a Medical Device Licence, which is issued by the Medical Devices Bureau for the device itself upon a review of evidence of their safety and efficacy ("MDL").

Whether you need one or both of the above depends on the Class of device and the intended activity relating to the device.

A MDEL is issued to "establishments" or businesses upon certification that they adhere to good manufacturing practices, and quality protocols related to aftermarket oversight such as adverse event reporting and procedures for recall, if necessary. Holders of MDEL are subject to audits and investigation to ensure that the protocols to which they certified exist are actually in place. A MDEL is required to manufacture, import or distribute a device in Canada. However, certain entities are exempt from the need to hold a MDEL. For example, a manufacturer of a Class I medical device need not hold a MDEL if it imports or sells in Canada through an entity that does.

A MDL is required for Class II, III or IV medical devices and is issued upon review of evidence provided by the applicant concerning the safety and efficacy of the device. A Class I device does not need a MDL, however, it must be fit for its intended purpose.

Applying for licences can be time consuming. Under normal circumstances, an application for a MDEL can take months. In this current health crisis that lead time is not tenable given the current shortages of personal protective equipment or PPE, which includes masks.

To help alleviate the shortages of medical devices for use in relation to COVID-19, Health Canada issued an *Interim Order*, which allows Health Canada to fast-track the necessary authorizations. Companies wishing to import or distribute Class I masks can submit the MDEL Application Form and state that their request is urgent pursuant to the COVID-19 outbreak. A MDEL is granted on the basis of the importer or distributor certifying it meets all the protocols, including aftermarket

oversight. Health Canada's guidance regarding the application process can be found here.

There are many companies who through various connections to manufacturers outside Canada are able to import medical devices but that is not the mainstay of their business. For such businesses, it may not be possible for them to certify that they meet all of the MDEL protocols required on the fast track application form. However, there are some holders of MDEL who will amend their MDEL to import and distribute on behalf of these businesses.

For inquiries about the regulation of COVID-19 related devices, please contact us at jmckenzie@bereskinparr.com.

Competition Bureau releases guidance about competitor collaborations during COVID-19 pandemic

By Amanda Branch

On April 8, 2020, the Competition Bureau (the "**Bureau**") released a statement on competitor collaborations during the COVID-19 pandemic. Recognizing the exceptional circumstances surrounding the COVID-19 pandemic may call for rapid short-term business collaborations, the Bureau stated:

> The Bureau therefore wishes to signal that in circumstances where there is a clear imperative for companies to be collaborating in the short-term to respond to the crisis, where those collaborations are undertaken and executed in good faith and do not go further than what is needed, it will generally refrain from exercising scrutiny.

The Bureau made it clear that it would have "zero tolerance for any attempts to abuse this flexibility". To help organizations which may need further clarity, the Bureau has created a team to assess the proposed collaborations and to provide informal guidance. At the time of making such a request for guidance, businesses are asked to provide the following information on any proposed collaboration:

- The firms involved and the parameters of the collaboration including its proposed scope and duration;
- A detailed description of how the collaboration is intended to achieve a clearly identified COVID-19 related objective in the public interest;
- An explanation of why the collaboration is necessary to meet this objective; and
- A description of any guidance sought from relevant authorities on whether the collaboration contemplated will actually further Canada's response to COVID-19.

The Bureau noted that any information guidance would be time limited and would be reviewed again should the parties request the guidance be extended. Additionally, the Bureau may seek input from other parts of government, stakeholders and market contacts and the Commissioner may make the guidance public. Finally, the Bureau noted that its guidance does not insulate conduct from the possibility of private lawsuits.