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# Health Canada facilitates availability of COVID-19 health products.

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Health Canada has instituted various approaches to facilitate the review and availability of health products which will help diagnose, treat, prevent or mitigate COVID-19 diseases. Below are just a few highlights from each.

The *Interim order respecting the importation and sale of medical devices for use in relation to COVID-19* (Interim Order) allows manufacturers of Class II, III and IV devices (e.g., ventilators, surgical gloves) to be exempt from most of the requirements under Part I of the *Medical Devices Regulations*, including Medical Device Licence and Medical Device Establishment Licence (MDEL) requirements, as long as the manufacturer has received an authorization for the importation or sale of such product. Health Canada may grant such authorization if it determines there is an urgent public health need and certain other requirements are met. Safety, efficacy and quality information must normally be included with a Class II, III or IV medical device licence application, but such information is not necessarily required under this Interim Order route if the product has already received market approval by a "foreign regulatory authority" (which includes approvals at the state level). To further minimize barriers, Health Canada is waiving any application fees associated with the Interim Order (see *Applications for Medical Devices under the Interim Order for Use in Relation to COVID-19 - Guidance Document*).

The Guidance on *Optimizing the use of masks and respirators during the COVID-19 outbreak* describes various types and grades of masks and respirators (personal respiratory protective devices). As a Class I device, no Medical Device Licence is required for their sale but an MDEL may be. This Guidance states Health Canada will aim to complete the review of an MDEL application within 24 hours (normally it is 120 days) for applicants seeking to manufacture, import or distribute masks and respirators. The Guidance also contemplates permitting products that are not compliant with Canadian laws (i.e., product is past its expiry date; is non-medical grade; and/or may not have a bilingual label).

The Guidance on *Expedited access to disinfectants, hand sanitizers and personal protective equipment to help limit the spread of COVID-19, as well as swabs for testing* similarly facilitates the importation and distribution of certain non-prescription drugs or natural health products (e.g., disinfectants, hand sanitizers), as well as medical devices (e.g., gowns, swabs, in addition to masks) which may not fully meet current regulatory requirements, as an interim measure.

Finally, the *Notice: Expedited Review of Health Product Submissions and Applications to address COVID-19* says, "In an effort to facilitate earlier access to a vaccine, or therapeutic product for COVID-19, the Department will expedite the review of any COVID-19 related health product submissions and applications". The Notice explicitly mentions clinical trials as well as the Special Access Programme.

Health Canada has also reached out to various sectors, including in the cannabis industry, to identify if any lab capacity exists which can support COVID-19 testing.

*The preceding is intended as a timely update on Canadian intellectual property and technology law. The content is informational only and does not constitute legal or professional advice. To obtain such advice, please communicate with our offices directly.*

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