THE MDEL BULLETIN

PRODUCED BY THE MEDICAL DEVICES COMPLIANCE PROGRAM

This bulletin provides MDEL holders with information on upcoming updates from Health Canada.

APRIL **2020**

Health Canada is taking action to effectively and efficiently respond to actual and anticipated medical device shortages in the fight against COVID-19

On March 30, 2020, the Minister of Health signed the *Interim Order Respecting Drugs, Medical Devices and Foods for a Special Dietary Purpose in relation to COVID-19* (the Interim Order).

The Interim Order makes it **mandatory** for manufacturers and importers to report to Health Canada shortages of specified medical devices, their components, accessories, parts or consumable materials, related to COVID-19. The requirements are outlined in the Interim Order. The *List of Medical Devices – Notification of Shortages*, which is incorporated by reference (IBR) in the Interim Order, is maintained by Health Canada and is regularly updated.

What is a medical device shortage?
A medical device shortage occurs when a manufacturer is unable to meet Canadian market demand for the device or for its components, accessories, parts or consumable materials. It does not include a situation in which a substitute device, component, accessory, or part is available.

There are two types of shortages:

1. Actual, when the current supply can't meet current demand
2. Anticipated, when the future supply can't meet projected demand

Who needs to report a medical device shortage?
Manufacturers and importers must report shortages that are on the *List of Medical Devices – Notification of Shortages*, located on Health Canada's website, by completing the electronic reporting form.

To avoid duplicate reporting, a manufacturer may permit a designated importer of a medical device to prepare and submit a shortage report on its behalf. This is permitted only when the information that would have been reported to Health Canada by the manufacturer and importer is identical. Under these circumstances, the manufacturer must submit an authorization form to Health Canada, via email to hc.meddev-matmed.sc@canada.ca.

When does a medical device shortage need to be reported?
Information about a medical device shortage is listed on the *List of Medical Devices – Notification of Shortages* and must be reported to Health Canada when:

- a manufacturer or importer first becomes aware of a shortage (within 5 calendar days)
- a manufacturer or importer anticipates a shortage (within 5 calendar days)
- updated information about a particular shortage needs to be submitted (within 2 calendar days)
- the manufacturer has determined that the end of the shortage can be reported, as they are able to meet market demand (within 2 calendar days)

Posting of medical device shortages
Health Canada posts information concerning all shortages that meet the criteria outlined in the Interim Order on Health Canada's website page, Medical device shortages: List of shortages. More information on medical device shortage reporting may be found on Health Canada's website.

Summary of Important Contacts:
For inquiries or to submit an Authorization Form please contact: hc.meddev-matmed.sc@canada.ca

COVID-19 – Update MDEL Issuance

In light of the unprecedented demand for Personal Protective Equipment (PPE) and other medical devices to help combat COVID-19 and the extraordinary number of companies making efforts to supply these products in Canada, Health Canada has encountered an unanticipated increase in applications for MDELs. In order to facilitate rapid access to needed supplies, Health Canada is implementing a temporary discretionary measure by assigning MDEL applicants an interim submission number while MDEL applications continue to be processed. A submission number is not an MDEL. It is a temporary number that is being assigned to applicants that have submitted the critical information required to ensure effective oversight of the activity being licensed and will facilitate quicker access to needed products to help combat COVID-19, including at the border. Once applications are fully processed, Health Canada will contact applicants to issue or to refuse to issue an MDEL, at which time, the temporary submission number will no longer be valid.

By making use of this submission number to conduct licensable activities, applicants are attesting that they have accurately provided all the necessary information in their MDEL application, per section 45 of the Medical Devices Regulations. This includes an attestation described under sections 45 (g) and (h) related to documented procedures in place in respect of distribution records, complaint handling, recalls and mandatory problem reporting. In addition, under section 45 (i), if they import or distribute Class II, III or IV devices, applicants are attesting that their establishments have documented procedures in place, where applicable, for handling, storage, delivery, installation, corrective action and servicing in respect of those devices. Lastly, applicants are attesting that they will conduct activities in accordance with all of the requirements set out under the Medical Devices Regulations. Standard MDEL application fees will apply if an MDEL is issued. More information on the requirements can be found in the following MDEL Guidance: Guidance on Medical Device Establishment Licensing (GUI-0016)

Health Canada is aware of and tracking increasing volumes of counterfeit products, products of substandard specifications, and those of inferior quality. Applicants are responsible for ensuring imported and sold products that meet the definition of a medical device are compliant with the Medical Devices Regulations. Health Canada will conduct site inspections to verify the necessary procedures are in place. Health Canada will also conduct spot checks to verify compliance and reserves the right to refuse shipments at the border or take any necessary action to address any risk to health, including any misleading claims or false information submitted in the application form. When a non compliance is confirmed, Health Canada will take immediate action to address the non-compliance and stop the importation and sale of any products that are found to pose a risk to health to Canadians. Specifications for the various types of PPE products can be found at Buyandsell.gc.ca.