FedEx Regulatory Alerts & Updates

Regulatory Alert: Canada - Additional Measures in Response to the COVID-19 Pandemic

April 9, 2020

To assist in the overwhelming demand and urgent need for medical supplies that limit the spread and assist in the treatment of COVID-19, Health Canada (HC) and the Canada Border Services Agency (CBSA) have introduced procedures to streamline the importation of these products.

Health Canada (HC)

On March 18, 2020, the Minister of Health for Canada approved the ***Interim Order Respecting the Importation and Sale of Medical Devices for Use in Relation to COVID-19***. This introduced provisional measures to assist in the expedited importation and facilitated access of medical equipment to the Canadian market – including hand sanitizers, disinfectants, swabs and personal protective equipment (PPE).

Interim Order Authorization (IOA):
Key to these new measures is the introduction of a simplified application process for importers and manufacturers to authorize their medical devices for import and sale in Canada due to COVID-19, only while the order is in effect. HC will issue ***interim order authorization (IOA) letters*** for all the medical devices they approve. IOA letters will enable the import of approved medical devices into Canada without a Medical Device Establishment Licence (MDEL). A copy of the IOA letter must accompany shipments containing approved medical devices to help prevent any clearance delays.

Applicants must provide adequate product detail for HC to approve their products including, but not limited to, the following:

a. The name of the device
b. The class of the device
c. The identifier of the device, including the identifier of any medical device that is part of a system, test kit, medical device group, medical device family or medical device group family
d. The name and address of the manufacturer as it appears on the device label
e. The address where the device is manufactured, if different from the one referred to in paragraph (d) of the Interim Order
f. The diagnosis, treatment, mitigation or prevention for which the device is required
g. The known information in relation to the quality, safety and effectiveness of the device
h. The directions for use, unless directions are not required, for the device to be used safely and effectively
i. An attestation by the applicant that documented procedures are in place in respect of distribution records, complaint handling, incident reporting and recalls
j. A copy of the label of the device

Applicants must also comply with current labelling requirements and HC mandatory recall provisions for health products, as listed and stated in Appendix A – Mandatory Actions. All application fees for this purpose are currently being waived by HC.

For more information on the application process, please see the HC Guidance document.

Expedited MDEL Approvals:
HC will also expedite the review and issuance of Medical Device Establishment Licences (MDELs). An MDEL is required for companies who wish to manufacture, import or distribute medical devices, including Class I PPEs (e.g., gowns, masks, face plates, etc.), irrespective of the Interim Order. Health Canada's standard service for issuing an MDEL is 120 days; however, MDELs for COVID-19-related Class 1 products will be expedited to within a **24-hour** service standard for this purpose only.

Companies that have these products and who need an MDEL application expedited should do the following:

1. Complete the MDEL Application Form (FRM-0292) available on HC's website
2. Email the completed MDEL application form to hc.mdel.application.leim.sc@canada.ca
3. Indicate "URGENT – COVID-19 – MDEL application for Insert Company Name" in the subject line of the email

Relaxed Regulations:
As part of the interim measures, HC is also permitting MDEL holders to manufacture, import and distribute medical products that do not fully comply with current regulatory requirements. Current MDEL holders seeking to import non-compliant products (e.g., non-bilingual labels) must take the following steps:

1. Complete the attached notification form ("**HC Personal Protective Equipment (PPE) – Notification form**")
2. Send the completed form and a copy of the label for each medical device to hc.mdel.application.leim.sc@canada.ca
3. Indicate "COVID – notification NC label" in the subject line of your email

Please click here for the current list of approved non-compliant products for COVID-19.

Canada Border Services Agency (CBSA)

Streamlined Tariff Classification:
To assist in the streamlined release of authorized medical supplies for COVID-19 (as identified by the World Customs Organization), the CBSA has provided a current list of these products and their corresponding tariff classifications on Customs Notice 20-12.

To help distinguish medical supplies that are imported for COVID-19, the CBSA has requested importers to add "URGENT – COVID-19" to the commodity description of their authorized goods.

Emergency Goods:
COVID-19 medical supplies imported on behalf of federal, provincial and municipal organizations (i.e., health centers, medical response teams, local police, etc.) could also qualify for relief of any import duties and taxes under the Goods for Emergency Use Remission Order.

For more information, please see CBSA Customs Notice 20-08.

Timeline for Implementation: Immediate

References:

Interim order respecting the importation and sale of medical devices for use in relation to COVID-19:

https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/announcements/interim-order-importation-sale-medical-devices-covid-19.html

Appendix A - Mandatory Actions:
https://www.canada.ca/en/health-canada/services/drugs-health-products/compliance-enforcement/information-health-product/drugs/recall-policy-0016/policy.html#aa

Applications for medical devices under the Interim Order for use in relation to COVID-19 - Guidance document:
https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/announcements/interim-order-importation-sale-medical-devices-covid-19/guidance-medical-device-applications.html

Medical Device Establishment Licence (MDEL) application: Instructions (FRM-0292):
https://www.canada.ca/en/health-canada/services/drugs-health-products/compliance-enforcement/establishment-licences/forms/medical-device-establishment-licence-application-form-instructions-0292.html

Hard-surface disinfectants and hand sanitizers (COVID-19): Disinfectants and hand sanitizers accepted under COVID-19 interim measure:
https://www.canada.ca/en/health-canada/services/drugs-health-products/disinfectants/covid-19/products-accepted-under-interim-measure.html

Customs Notice 20-12 - COVID-19: Tariff Classification and Other Information to Import Medical Supplies:
https://www.cbsa-asfc.gc.ca/publications/cn-ad/cn20-12-eng.html#list

Goods for Emergency Use Remission Order:
https://laws-lois.justice.gc.ca/eng/regulations/C.R.C.,_c._768/page-1.html

Customs Notice 20-08:
https://www.cbsa-asfc.gc.ca/publications/cn-ad/cn20-08-eng.html