



COVID-19 Media Lines

PPE, Medical Supplies and Quality Assurance

Issue Statement: These media lines have been developed to explain the Public Health Agency of Canada and Health Canada's process to ensure quality assurance of donated medical supplies before they can be used in Canada.

Key Messages:

- Federal, provincial and territorial governments are working together to ensure access to high-quality testing for COVID-19 for all Canadians who need it.
- Canada appreciates the donations of medical supplies, such as test kits, it has received from Canadian companies and those provided by other countries.
- Donated medical devices are subject to Health Canada's Medical Devices Regulations. They may also be evaluated by the Public Health Agency of Canada's National Microbiology Laboratory (NML) to ensure these items meet our quality standards before they can be distributed for use in Canada.
- Health Canada will review all COVID-19-related submissions and applications as quickly as possible while maintaining standards for patient safety.

On the process for quality assurance of donated test kits

- A Medical Device Licence or an Authorization under the Interim Order is needed for the sale and import of higher risk medical devices to Canada, including diagnostic tests. A donation of a medical device is considered a sale. Therefore, donated devices would be subject to the Medical Devices Regulations and a scientific review prior to its importation or sale.
- Test kits donated to Canada from an international source may also be reviewed by the NML to validate their performance. The NML would then work with Health Canada and share any results that could contribute to the scientific review.
- If a donated test kit becomes licensed or authorized by Health Canada, the NML would work with provincial and territorial partners to distribute the kits for use in Canada.
- If the kit is not deemed ready for licensing, Health Canada will have further discussions with the company regarding next steps.



On licensing test kits and other medical devices

- Canada is facilitating the importation and sale of medical devices used to diagnose, treat, mitigate or prevent COVID-19.
- On March 18, 2020, the Minister of Health approved an Interim Order to allow quicker access to COVID-19-related medical supplies.
- Under the Interim Order, a medical device licence or authorization is needed to sell and import higher risk medical devices to Canada, including diagnostic tests. A donation of a medical device is considered a sale and the devices would, therefore, be subject to the Medical Devices Regulations.
- A list of COVID-19 medical devices authorized for sale in Canada, as well as the applications received under the Interim Order signed by the Minister on March 18, 2020, is available on Health Canada's website and is updated daily.

On PPE supply orders (from HPEG)

- Medicom is shipping 8.5M surgical masks this week. Additional supply is anticipated next week.
- PHAC is working with Public Services and Procurement Canada to finalize a long-term agreement with Medicom for the domestic production of masks.
- Ventilators: 1,570 ordered to begin delivery April 1; 1,300 to be ordered.
- Discussions are continuing within the Government of Canada (ISED, PSPC, HC and PHAC) to explore alternative PPE supply routes and scale up domestic production.
 - For example: Canada Goose received its medical devices establishment licence from Health Canada to proceed with the re-tooling of its manufacturing facility.

On the National Emergency Strategic Stockpile (from media response in approvals)

- The National Emergency Strategic Stockpile (NESS) contains limited quantities of personal protective equipment (PPE) and ventilators.
- Based on needs identified by provinces and territories, collaborative federal, provincial and territorial (FPT) procurement efforts are focused on procurement of large quantities of N95 respirators, surgical masks, face shields, nitrile gloves, gowns and other protective clothing, sanitizer, ventilators, and testing supplies.
- Small quantities of PPE supply are starting to arrive through the collaborative FPT procurements and will be distributed to provinces and territories.



- To address immediate short term needs, PHAC deploys PPE and ventilators to provinces and territories based on requests for assistance.

If pressed on supplies in the NESS:

- It is not the practice of the National Emergency Strategic Stockpile (NESS) to divulge details about the specific type and quantity of stock in its holdings. The NESS contains supplies of Personal Protective Equipment (PPE) and ventilators. Allocation and distribution is always determined based on need.

Questions and Answers

Q1. There have been multiple reports from other countries that donated medical supplies they received are of poor quality. How is the Government of Canada validating donations of medical supplies, such as the donation from the Bank of China, meet our quality standards?

The Government of Canada is receiving donations of medical supplies from companies both internationally and domestically, and is working to make them available for use by frontline healthcare workers. We can assure Canadians, that upon receipt of donated items, such as test kits, the Public Health Agency of Canada's National Microbiology Laboratory and Health Canada evaluate and validate the quality before they can be distributed for use in Canada.

For donations received by associations such as Bethune Medical Development Association of Canada, there is a requirement that these associations work with the respective province and/or territory to ensure that the donated supplies meet the technical specifications that safeguard the health and safety of Canada's healthcare workers.

For more information on this specific donation, please contact the Bank of China and the Bethune Medical Development Association of Canada.