

4 - PROCUREMENT OF PERSONAL PROTECTIVE EQUIPMENT

KEY MESSAGES:

- The Government of Canada is continuously working to secure critical personal protective equipment (PPE) supplies and medical equipment, and to expedite delivery of supplies to our frontline healthcare workers.
- Canada is receiving PPE shipments, and is working rapidly to allocate the supplies to the provinces and territories as per an approach agreed upon by federal-provincial-territorial Ministers of Health.
- The Public Health Agency of Canada is also deploying PPE and ventilators from its National Emergency Strategic Stockpile in response to urgent requests for assistance from provinces and territories.
- In addition, the Government of Canada is also receiving offers of donations from international and domestic organizations via the donations portal on the Government of Canada COVID-19 website.

IF PRESSED ON HOW THE GOVERNMENT OF CANADA IS ADDRESSING THE GLOBAL SHORTAGE OF PPE SUPPLIES

- The Government of Canada, through the leadership of Public Services and Procurement Canada (PSPC), and Innovation Science and Economic Development Canada, has galvanized Canadian industry to increase domestic manufacturing capacity, including re-tooling facilities to produce PPE and medical equipment and supplies, including ventilators and rapid testing kits.

KEY FACTS AND FIGURES

- To date, PHAC has allocated approximately 2 million N95 respirators and equivalents (e.g., KN95 respirators), 30 million surgical masks, 11 million pairs of nitrile gloves, and 2 million face shields to PTs, in addition to various other PPE and other medical supplies.
- PSPC has confirmed contracts for substantial amounts of PPE and other medical supplies including for over 130 million N95 respirators and equivalents, 315 million surgical masks, 1 billion pairs of nitrile gloves, and 55 million face shields.
- PPE and medical supplies received by the Public Health Agency of Canada, whether procured internationally or domestically, are assessed to confirm they meet the technical specifications for healthcare settings for COVID-19 prior to distribution to provinces and territories. The process is the same for donations.
- Supplies that do not meet specifications are subsequently assessed for potential for use in non-healthcare settings.

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- PSPC has confirmed contracts for a variety of PPE and other medical supplies including over 130 million N95 respirators and equivalents (e.g., KN95 respirators), 315 million surgical masks, 1 billion pairs of nitrile gloves, and 55 million face shields.
- The Public Health Agency of Canada is receiving staggered delivery of shipments, and as of May 11, has distributed various quantities of supplies including approximately 2 million N95 respirators and equivalents (e.g., KN95 respirators), 30 million surgical masks, 11 million pairs of nitrile gloves, and 2 million face shields to provinces and territories, and more is expected to arrive and be distributed in the coming days.
- Additionally, the Public Health Agency of Canada has also distributed to provinces and territories donations of over 400 thousand N95 and equivalent respirators, 450 thousand surgical masks, and 350 thousand pairs of gloves.

IF PRESSED ON WHEN THE GOVERNMENT OF CANADA BEGUN TO PROCURE PPE IN RESPONSE TO COVID-19

- In January and February 2020, the Public Health Agency of Canada had confirmed orders for a variety of PPE including approximately 400 thousand N95 respirators, 920 thousand surgical masks, 870 thousand pairs of nitrile gloves, and 14 thousand protective gowns.
- Over the course of March, the Public Health Agency's of Canada's focus shifted to the F/P/T collaborative bulk procurement process that resulted in additional orders including approximately 34 million N95 respirators, 4 million surgical masks, 50 thousand pairs of gloves, and 35 million protective gowns.

IF PRESSED ON THE SETTING OF GOVERNMENT OF CANADA TECHNICAL SPECIFICATIONS FOR HEALTHCARE SETTINGS FOR COVID-19 AS AVAILABLE ON THE BUY AND SELL WEBSITE

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- The technical specifications for healthcare settings for COVID-19 were established by a Technical Assessment Committee comprised of representatives from the Public Health Agency, Health Canada, and the National Research Council.
- The technical specifications were established in consideration of international guidelines from organizations such as the World Health Organization, the United States Centre for Disease Control and Prevention, and the United States Food and Drug Administration, and are published on the Public Services and Procurement Canada's Buy and Sell website.
- With intense global competition, vendors with an established history of supplying standard PPE in Canada were referred to procurement immediately.
- For new vendors and suppliers, both foreign and domestic, companies were confirmed to have the necessary regulatory authorizations, such as a Medical Device Establishment License; their product specifications were reviewed by the Technical Assessment Committee; and for foreign entities, Global Affairs Canada was consulted to further verify the vendor's history.

IF PRESSED ON HEALTH CANADA'S INTERIM ORDER FOR MEDICAL DEVICES

- On March 18, the Minister of Health signed the Interim Order for Medical Devices to expedite Health Canada's regulatory approvals of product reviews and licenses. As the regulatory authority, Health Canada continues to monitor the safety, quality, and efficacy of all medical devices for use in the diagnosis, treatment, mitigation and prevention of COVID-19.

IF PRESSED ON HOW THE GOVERNMENT OF CANADA IS ENSURING THE QUALITY OF PPE SUPPLIES

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- Due to intense global competition for PPE and other medical supplies, countries have needed to engage with a diverse number of new suppliers and manufacturers.
- As a result, PPE and medical supplies received by the Public Health Agency of Canada, whether procured internationally or domestically, are assessed to confirm they meet the technical specifications for healthcare settings for COVID-19 prior to distribution to provinces and territories. The process is the same for donations.
- For example, a KN95 respirator undergoes visual inspection to verify for defects in design and construction, and is tested using specialized capacity at the National Research Council to confirm performance expectations. Surgical masks undergo a fluid resistance and a breathing resistance test.
- Supplies that do not meet specifications are subsequently assessed for potential for use in non-healthcare settings.
- To date, a large majority of the products received by the Government of Canada have met the technical specifications for healthcare settings for COVID-19 response; however, as a result the Public Health Agency of Canada's stringent review process, approximately 8.5 million KN95 respirators were assessed as not meeting the technical specifications.

IF PRESSED ON CONSIDERATIONS TO TEST SUPPLIES AT SOURCE LOCATION BEFORE ACCEPTING DELIVERY

- At the beginning of April, given the high demand for PPE domestically and the highly competitive international environment, it was critical to have supplies rapidly delivered to the Public Health Agency of Canada for quality verification and testing prior to allocating to provinces and territories.
- As domestic manufacturing capacity is coming online and in anticipation of the delivery of large volumes of supplies both internationally and domestically, the Government of Canada is currently assessing its

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logistical options to facilitate both the delivery of quality product and maintain efficiency in distribution to provinces and territories.

IF PRESSED ON THE SUPPLIER OF KN95 RESPIRATORS SOURCED FROM CHINA

- Due to ongoing quality issues, the Government of Canada has suspended shipments from this specific supplier and is pursuing the appropriate recourse actions.

IF PRESSED ON THE USE OF KN95 RESPIRATORS

- Health Canada, as the regulator for medical devices in Canada, traditionally accepts the U.S. National Institute for Occupational Safety and Health (NIOSH) certification as an appropriate quality standard for N95 respirators used by health care providers.
- In support of COVID-19 response, to expand the availability of these types of respirators for sale or import in Canada, Health Canada is also accepting equivalent alternate standards used in other countries such as the KN95 and FFP2 respirators (including those with head straps or ear loops).
- This is in alignment with the United States Food and Drug Administration's guidance that was recently revised on May 7, 2020.
- On May 11, Health Canada issued a recall notice to approximately 60 companies importing or distributing KN95 respirators in Canada indicating that their product may not meet safety and effectiveness standards for healthcare setting for COVID-19 response.
- The notice confirmed that this action did not implicate KN95 respirators purchased by the Government of Canada and tested by the Public Health Agency of Canada.

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IF PRESSED ON THE DISTRIBUTION OF PPE TO PROVINCES AND TERRITORIES

- On April 2, to support rapid distribution of products across Canada, the federal-provincial-territorial Ministers of Health approved an *Allocation of Scarce Resources Interim Response Strategy*.
- This Strategy was established on the principles of transparency, equity, and solidarity, implementing an approach to support frontline healthcare response to COVID-19 while retaining surge capacity in the National Emergency Strategic Stockpile to address critical shortages as identified by provinces and territories.
- This approach continues to guide our allocation process, but can be adjusted as Canada's COVID-10 response evolves.

IF PRESSED ON HOW THE GOVERNMENT OF CANADA IS ADDRESSING THE EXPEDITED DELIVERIES OF PPE SUPPLIES TO PROVINCES AND TERRITORIES

- On April 1, the Government of Canada awarded a contract to Amazon to facilitate the logistics of distributing PPE and supplies to support the COVID-19 response.
- Amazon is working directly with the Canadian Armed Forces and Canada Post to manage warehousing, and Purolator, to deliver the products to provincial and territorial health authorities, across the country, for the frontline healthcare response.
- As of April 12, each province and territory has received over a dozen shipments of PPE via Amazon system interface.
- Due to the sheer volume of product anticipated to arrive over the coming months, on May 4, the Government of Canada posted a Request for Proposal on the Public Services and Procurement Canada's Buy and

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Sell website to explore additional logistic solutions to boost existing capacity.

- For a period of one year, this logistics provider will be expected to handle customs documentation, secure warehousing, inventory management, reporting and transportation of the personal protective equipment to various locations in each of the provinces and territories.
- They will also require the capacity to handle shipments from all modes of transportation, including receiving and moving products from sea ports, airports, railheads, and commercial transition points.
- This tendering process closed on May 8, and the Government of Canada is currently in the process of reviewing proposals.

IF PRESSED ON REUSE AND STERILIZATION OF N95 RESPIRATORS

- Health Canada has already authorized certain machines to decontaminate N95 respirators under the Interim Order for Medical Devices.
- The Public Health Agency of Canada has procured 82 sterilization devices with Stryker Canada. Of these, 81 units have been allocated to provinces and territories based on their needs, and one unit allocated to the National Research Council.
- These units are in the process of being deployed and installed, and will provide a total additional national capacity to reprocess approximately 275 thousand N95 respirators a week.

IF PRESSED ON FUTURE SUPPLY NEEDS IN THE CONTEXT OF A COVID-19 VACCINE

- The Public Health Agency of Canada and Health Canada are currently working with key partners and stakeholders to identify anticipated supply chain risks or capacity gaps that could experience impacts in

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anticipation of mass vaccination campaign scenarios across Canada for COVID-19.

- The Public Health Agency of Canada will continue to work with provincial and territorial partners to identify potential gaps in the supply chain and will be prepared to support the timely procurement of additional assets, such as needles, syringes as well as PPE and medication.

BACKGROUND

To address the procurement and distribution needs in support of frontline health care response to COVID-19, the Government of Canada deployed a multi-pronged approach of interdepartmental coordination that includes the Public Health Agency of Canada (PHAC), Health Canada, National Research Council (NRC), Global Affairs Canada, the Department of National Defense, Public Services and Procurement Canada (PSPC), and Innovation, Science and Economic Development Canada (ISED).

Federal/Provincial/Territorial (F/P/T) Bulk Procurement

ISED and PSPC continue to galvanize Canadian industries to increase domestic manufacturing capacity, including re-tooling facilities to produce equipment and supplies including portable ventilators, surgical masks, and rapid testing kits.

Throughout this process, PHAC, Health Canada and the NRC are playing a critical role, conducting technical reviews to verify that the products meet the Government of Canada technical specifications for COVID-19 as available on the PSPC's buy and sell website.

Urgent need is further facilitated by Health Canada, expediting regulatory approvals of product reviews and licenses through the Interim Order for Medical Devices signed by the Minister of Health on March 18, 2020. As the regulatory authority, Health Canada also continues to monitor the safety, quality, and efficacy of all medical devices for use in the diagnosis, treatment, mitigation and prevention of COVID-19.

Health Canada also continues to actively engage the medical device industry as well as provinces and territories to monitor for any signals of supply disruptions in Canada. Manufacturers and importers are also now required to notify the Minister of Health of medical device shortages of devices considered critical. Health Canada is closely monitoring the supply of any potential treatments for COVID-19 and working with companies to help ensure continued supply in Canada.

PPE Testing and Quality Assessments

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Sourcing PPE from new suppliers (both domestically and abroad) is challenging. Once products are delivered to PHAC they must undergo quality verification before distribution to provinces and territories (P/Ts). This process is supported by testing capacity within the NRC.

Test results are also used to inform future procurements. PSPC and PHAC work with suppliers to address issues at the source or avoid purchasing from unreliable suppliers in the future once issues are identified.

KN95 Respirators

On May 8, CBC reported that of the approximately 11 million KN95 respirators received by the Government of Canada and sourced by a Montreal-based supplier out of China, 8 million did not meet the Government of Canada's technical specifications for healthcare settings for COVID-19 response, 1 million met specifications, and 1.6 million were pending testing results. This number not meeting specifications has since increased to approximately 8.5 million as results are received for the remaining 1.6 million. PSPC has suspended shipments from this supplier and is pursuing the appropriate recourse on behalf of the Public Health Agency of Canada.

On May 7, the United States Food and Drug Administration (FDA) issued revised guidance, indicating that certain filtering facepiece respirators from China may not provide adequate respiratory protection. The FDA still considers KN95 respirators medical devices equivalent to N95s, but authorization for KN95 respirators will require additional validation and review by FDA.

Health Canada Medical Devices has subsequently updated its regulatory guidance, Optimizing the use of masks and respirators during the COVID-19 outbreak, and issued a recall for over 60 companies as identified on the U.S. National Institute for Occupational Safety and Health (NIOSH) website. Similar to the FDA, Health Canada will continue to authorize KN95 medical respirators in Canada through the Interim Order for Medical Devices pathway but as of May 7, Health Canada will request test results from independent testing facilities to validate the effectiveness of these respirators.

On May 11, Health Canada issued a recall notice advising that companies importing or distributing certain respirators, including KN95 respirators, in Canada that they may not meet safety and effectiveness standards for healthcare settings for COVID-19 response. Health Canada is following up with companies that may have imported and distributed respirators that did not pass testing conducted by the United States Centers for Disease Control and Prevention's National Personal Protective Technology Laboratory to request that they immediately stop sale and relabel current stock as face masks (not respirators).

F/P/T Allocation and Distribution

As agreed to by F/P/T Ministers of Health, PHAC is allocating procured PPE using an 80/20 formula—80% is distributed to P/Ts on a per capita basis and the remaining 20%

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replenishes the inventory of the National Emergency Strategic Stockpile (NESS), including a 2% allocation to Indigenous Services Canada. The purpose of the NESS is to provide surge capacity to P/Ts when their own resources are not sufficient.

To support distribution, PSPC awarded a contract with Amazon valued at up to \$5 million. This contract is primarily for use of the Amazon interface to push out the allocation of supplies to P/Ts. Amazon is working with the Canadian Armed Forces, Canada Post and Purolator.

On May 4, to facilitate the intake and distribution of large volumes of PPE and medical supplies, PSPC posted a Request for Proposal (RFP) notice on the PSPC Buy and Sell website to solicit interest from major logistics service providers. This new expression of interest relates to an overall logistics solution, going beyond distribution and includes warehousing, customs documentation and brokerage, and inventory management. The RFP closed on May 11, and the review of the expressions of interest is now underway.

Reuse and sterilization

Due to increased demand of N95 respirators, PHAC has also been working closely with Health Canada, the NRC, and ISED on identifying companies with experience manufacturing the equipment used in reprocessing in order to authorize these technologies to safely and effectively reprocess N95 respirators.

Health Canada issued its first authorization under the Interim Order for Medical Devices to Stryker for its Sterizone VP4 on April 5, 2020, and has since authorized additional devices including Sterrad and Steris sterilizers that are widely available and distributed across Canadian hospitals.

PARLIAMENTARY ANALYSIS:

Liberal Party of Canada (LPC)

- LPC members have made statements of interest on this issue.

Conservative Party of Canada (CPC)

- CPC members have been critical about orders of PPE from China arriving in Canada empty, or with faulty equipment. They have questioned why these orders are not quality-checked in China prior to shipment to Canada, and have expressed concern over counterfeit PPE.
- CPC members have questioned extensively why Canada donated millions of units of PPE to China early on in the outbreak.

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- CPC members have criticized the length of time it is taking companies producing PPE to receive the appropriate approvals from Health Canada, asking for these to be fast-tracked.
- CPC members have stated that in light of the inadequate supply of PPE in Canada and with an over reliance of PPE from overseas, a “Made in Canada Solution” for PPE should be established going forward.

Bloc Quebecois (BQ), New Democratic Party (NDP), Green Party (GPC)

- The NDP believe that PPE stockpiles should be better stocked and that Canada should not depend on other countries for essential medical equipment and supplies.
- GPC members have noted that maintaining proper PPE stockpiles should be a government priority going forward.