

PROCUREMENT OF PERSONAL PROTECTIVE EQUIPMENT

SYNOPSIS

The global COVID-19 pandemic has resulted in an unprecedented shortage in personal protective equipment (PPE) and other medical supplies. To support the needs of Canada’s frontline healthcare response, the Government of Canada, in coordination with the provinces and territories, launched a significant bulk procurement, engaging a diverse number of new suppliers and manufacturers both internationally and through the Government of Canada’s domestic “Call to Action” to increase domestic production.

SOMMAIRE

La pandémie mondiale de COVID-19 a entraîné une pénurie sans précédent d’équipement de protection individuelle (EPI) et d’autres fournitures médicales. Pour répondre aux besoins liés à l’intervention des travailleurs de la santé de première ligne du pays, le gouvernement du Canada, en collaboration avec les provinces et les territoires, a lancé un important processus d’acquisition en grande quantité en mobilisant un certain nombre de nouveaux fournisseurs et fabricants, tant à l’étranger qu’au pays dans le cadre de son « appel à l’action » visant à accroître la production nationale.

POTENTIAL QUESTIONS

- What is the Government of Canada doing to address shortages of PPE and other medical supplies?
- How is the Public Health Agency of Canada equipping frontline healthcare workers with the PPE required to protect their health and mitigate the spread of COVID-19?

QUESTIONS POSSIBLE

- Quelles sont les mesures prises par le gouvernement du Canada pour pallier la pénurie d’EPI et d’autres fournitures médicales?
- De quelle manière l’Agence de santé publique du Canada fournit-elle aux travailleurs de la santé de première ligne l’EPI dont ils ont besoin pour protéger leur santé et empêcher la propagation de la COVID-19?

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.

MESSAGES CLÉS

- Le gouvernement du Canada travaille sans relâche en vue d'obtenir l'EPI et le matériel médical essentiels et d'accélérer la livraison des fournitures aux travailleurs de la santé de première ligne.
- Le Canada reçoit des cargaisons d'EPI et travaille rapidement pour acheminer les fournitures aux provinces et aux territoires selon une approche convenue par les ministres de la Santé du fédéral, des provinces et des territoires.
- L'Agence de santé publique du Canada achemine également de l'EPI et des ventilateurs provenant de la Réserve nationale stratégique d'urgence afin de répondre aux demandes urgentes d'assistance des provinces et des territoires.
- De plus, le gouvernement du Canada reçoit aussi des offres de dons d'organisations nationales et internationales par l'intermédiaire du portail de dons du site Web du gouvernement du Canada consacré à la COVID-19.

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.
- 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, 130 million protective gowns, and 30 thousand ventilators.
- The Public Health Agency of Canada is receiving staggered delivery of shipments, and to date, has allocated approximately 2 million N95 respirators and equivalents (e.g., KN95 respirators), 30 million surgical masks, 11 million pairs of nitrile gloves, **and 4 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 **450** thousand N95 and equivalent respirators, 450 thousand surgical masks, and **400** thousand pairs of gloves.

SI ON INSISTE POUR SAVOIR COMMENT LE GOUVERNEMENT DU CANADA ENTEND PALLIER LA PÉNURIE MONDIALE D'EPI...

- Grâce au leadership de Services publics et Approvisionnement Canada (SPAC) et d'Innovation, Sciences et Développement économique Canada (ISDE), le gouvernement du Canada a mobilisé l'industrie canadienne afin qu'elle augmente la capacité de fabrication au pays, notamment grâce au réoutillage des installations afin d'y produire de l'EPI et des fournitures et équipements médicaux, comme des ventilateurs et des trousse de test rapide.
- SPAC a confirmé la signature de contrats en vue d'acquérir une panoplie d'EPI et d'autres fournitures médicales, notamment plus de 130 millions de respirateurs N95 et de respirateurs équivalents (p. ex. des respirateurs KN95), 315 millions de masques chirurgicaux, 130 millions de blouses de protection et 30 000 ventilateurs.
- L'ASPC reçoit des expéditions de façon échelonnée, et, à ce jour, elle a acheminé environ 2 millions de respirateurs N95 et de respirateurs équivalents (p. ex. des respirateurs KN95), 30 millions de masques chirurgicaux, 11 millions paires de gants doublés de nitrile, et 4 millions écrans faciaux aux provinces et aux territoires. D'autres expéditions de fournitures devraient arriver au pays et être distribuées au cours des prochains jours.
- De plus, l'ASPC a également remis aux provinces et aux territoires plus de 450 000 respirateurs N95 et masques équivalents, 450 000 masques chirurgicaux et 400 000 paires de gants qui lui ont été donnés.

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

- 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 verified to 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 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 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 of the Public Health Agency of Canada's stringent review process, approximately 9.9 million KN95 respirators were assessed as not meeting the technical specifications.

SI ON INSISTE POUR SAVOIR COMMENT LE GOUVERNEMENT DU CANADA ASSURE LA QUALITÉ DE L'EPI...

- En raison de l'intense concurrence mondiale pour l'achat d'EPI et d'autres fournitures médicales, les pays ont dû mobiliser un certain nombre de nouveaux fournisseurs et fabricants.
- Par conséquent, l'EPI et les fournitures médicales reçus par l'ASPC, qu'ils aient été achetés à l'étranger ou au pays, font l'objet d'une vérification afin de confirmer qu'ils satisfont aux spécifications techniques prévues pour les établissements de soins de santé relatives à la COVID-19 avant d'être distribués aux provinces et aux territoires. Le processus est le même pour les dons.
- Par exemple, un masque KN95 fait l'objet d'une inspection visuelle pour détecter tout défaut de conception et de fabrication et il est testé pour confirmer qu'il répond aux attentes en matière de rendement. Les masques chirurgicaux sont soumis à un test de résistance aux fluides et à la respiration.
- Les fournitures qui ne répondent pas aux spécifications sont ensuite évaluées pour déterminer si elles peuvent être utilisées dans des établissements où des soins de santé ne sont pas offerts.
- À ce jour, la grande majorité des produits qu'a reçus le gouvernement du Canada respectent les spécifications techniques prévues pour les établissements de soins de santé en vue de l'intervention à la COVID-19 ; cependant, en raison du processus d'examen rigoureux de l'Agence de la santé publique du Canada, environ 9.9 millions de respirateurs KN95 ont été jugés non conformes aux spécifications techniques.

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.

SI ON INSISTE SUR LE FAIT QUE LES RESPIRATEURS KN95 PROVIENNENT DE CHINE...

- En raison de problèmes de qualité soutenus, le gouvernement du Canada a mis en suspens les expéditions qui proviennent de ce fournisseur en particulier et prend les recours qui s'imposent.

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.

SI ON INSISTE SUR L'EMPLOI DE RESPIRATEURS KN95...

- À titre d'organisme de réglementation des instruments médicaux au Canada, Santé Canada accepte habituellement la certification du National Institute for Occupational Safety and Health (NIOSH) en tant que norme de qualité appropriée pour les respirateurs N95 employés par les fournisseurs de soins de santé.
- À l'appui de l'intervention relative à la COVID-19 et pour augmenter l'offre de ces types de respirateurs pouvant être vendus ou importés au Canada, Santé Canada accepte également d'autres normes équivalentes, employées dans d'autres pays, comme les respirateurs KN95 et FFP2 (dont ceux munis de serre-tête ou boucles latérales).
- Cette approbation cadre avec les recommandations de la Food and Drug Administration des États-Unis récemment revues le 7 mai 2020.

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 will provide a total additional national capacity to reprocess approximately 275 thousand N95 respirators a week.

SI ON INSISTE SUR LA RÉUTILISATION ET LA STÉRILISATION DES RESPIRATEURS N95...

- Santé Canada a déjà autorisé certaines machines servant à décontaminer des masques N95 en application de l'arrêté d'urgence se rapportant aux appareils médicaux.
- L'Agence de la sante public du Canada a acheté 82 appareils de stérilisation auprès de Stryker Canada. De ceux, 81 appareils ont été acheminé aux provinces et aux territoires en fonction des besoins provinciaux et territoriaux, et un appareil sera remis au Conseil national de recherche du Canada.
- Ces appareils permettront de retraiter environ 275 000 respirateurs N95 supplémentaires par semaine à l'échelle du pays.

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

- 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.
- In addition to the Amazon contract, the Government of Canada has solicited interest from companies to provide logistic services to help receive and distribute the extraordinary volume of orders of PPE across Canada in a timely manner. We are in the process of reviewing proposals.

SI INSISTE POUR SAVOIR COMMENT LE GOUVERNEMENT DU CANADA ENTEND ACCÉLÉRER LES LIVRAISONS D'EPI AUX PROVINCES ET AUX TERRITOIRES...

- Le gouvernement du Canada a attribué un contrat à Amazon pour faciliter la logistique de la distribution de l'EPI et des fournitures à l'appui de la lutte contre la COVID-19.
- Amazon collabore directement avec les Forces armées canadiennes et Postes Canada pour gérer l'entreposage ainsi qu'avec Purolator pour livrer aux autorités sanitaires des provinces et des territoires partout au pays les produits destinés aux travailleurs de la santé de première ligne.
- En plus du contrat avec Amazon, le Canada a sollicité l'intérêt d'entreprises capables de fournir des services logistiques, pour qu'elles voient à la réception et à la distribution de la quantité exceptionnelle de commandes d'EPI dans l'ensemble du Canada dans des délais raisonnables. Nous examinons actuellement les propositions.

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

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 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 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 9.9 million as results are received for the remaining 80 thousand. PSPC has suspended shipments from this supplier and is pursuing the appropriate recourse on behalf of the Public Health Agency of Canada.

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.

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% 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 a **multimodal** 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.

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