

## NATIONAL EMERGENCY STRATEGIC STOCKPILE MANAGEMENT AND PERSONAL PROTECTIVE EQUIPMENT AND MEDICAL DEVICE PROCUREMENT

### SYNOPSIS

The global COVID-19 pandemic has resulted in an unprecedented shortage of personal protective equipment (PPE), medical equipment, and 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 and additional pandemic stockpile, 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 du COVID-19 a entraîné une pénurie sans précédent d'équipements de protection individuelle (EPI) et d'autres équipements et fournitures médicaux. Pour répondre aux besoins de la réponse de première ligne du Canada en matière de soins de santé, le gouvernement du Canada, en coordination avec les provinces et les territoires, a lancé un important approvisionnement en vrac et un stock supplémentaire en cas de pandémie, engageant un nombre diversifié de nouveaux fournisseurs et fabricants tant à l'échelle internationale que par l'intermédiaire du gouvernement du Canada. «Appel à l'action» national pour augmenter 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?
- What is the Government of Canada doing to prepare for resurgence and/or mass vaccination campaign scenarios?

### QUESTIONS POTENTIELLES

- 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?
- Que fait le gouvernement du Canada pour se préparer aux scénarios de résurgence et / ou de campagne de vaccination de masse?

### KEY MESSAGES

- The Government of Canada is continuously working to secure critical personal protective equipment, or PPE, as well

as medical equipment and supplies.

- We are also working to expedite the delivery of this equipment to our frontline healthcare workers.
- Canada is receiving a steady supply of PPE with shipments arriving daily, and we rapidly allocate the inventory to the provinces and territories.
- We allocate PPE and medical equipment and supplies based on an 80/20 formula, with 80% being allocated to provinces and territories to distribute within their jurisdiction. This formula has developed in consultation with provinces and territories.
- In response to urgent requests for assistance from provinces and territories, we are also deploying PPE, medical equipment and supplies from the National Emergency Strategic Stockpile, or NESS.
- The NESS was designed to provide health emergency assets when provincial, territorial and local resources are exhausted.
- With the unprecedented nature of the current pandemic, the role of the NESS has evolved to include more proactive procurement of PPE, medical equipment and supplies.
- Lessons learned will inform the future of our approach to the NESS.

#### MESSAGES CLÉS

- Le gouvernement du Canada travaille sans relâche en vue d'obtenir de l'équipement de protection individuelle, ou EPI, ainsi que des fournitures et de l'équipement médical.
- Nous nous efforçons également d'accélérer la livraison de ce matériel à nos travailleurs de santé de première ligne.

- Au fur et à mesure que le Canada reçoit des livraisons, nous répartissons rapidement les stocks entre les provinces et les territoires.
- Nous attribuons les EPI et les fournitures médicales selon une formule 80/20, 80% étant alloués aux provinces et aux territoires pour distribution dans leur juridiction. Cette formule a été élaborée en consultation avec les provinces et les territoires.
- En réponse aux demandes d'aide urgentes des provinces et territoires, nous déployons également des EPI, des fournitures médicales et du matériel provenant de la Réserve stratégique nationale d'urgence, ou **RNSU**.
- La **RNSU** a été conçu pour fournir des moyens sanitaires d'urgence lorsque les ressources provinciales, territoriales et locales sont épuisées.
- Compte tenu de la nature sans précédent de la pandémie actuelle, le rôle de la **RSNU** a évolué pour inclure l'achat plus proactif d'EPI, de fournitures et d'équipements médicaux.
- Les leçons tirées de l'expérience viendront éclairer l'avenir de notre approche de la **RSNU**.

***IF PRESSED ON STOCKPILING OF PPE AND THE CANADIAN PANDEMIC INFLUENZA PLAN***

- The Canadian Pandemic Influenza Plan is a federal, provincial, and territorial guidance document for the healthcare sector.
- Its purpose is to assist jurisdictions with their emergency planning, including their requirements to stockpile PPE, medical equipment and supplies.
- Provincial and territorial governments are responsible for providing medications, supplies and equipment required for healthcare services.

**SI L'ON INSISTE SUR LA CONSTITUTION DE STOCKS DE PPE ET SUR LE PLAN CANADIEN DE LUTTE CONTRE LA PANDÉMIE DE GRIPPE**

- Le Plan canadien de lutte contre la pandémie d'influenza est un document d'orientation fédéral, provincial et territorial pour le secteur de la santé.
- Son but est d'aider les juridictions dans leur planification d'urgence, y compris leurs besoins en matière de stockage d'EPI, de fournitures et d'équipements médicaux.
- Les gouvernements provinciaux et territoriaux sont chargés de fournir les médicaments, les fournitures et les équipements nécessaires aux services de soins de santé.

**IF PRESSED ON HOW THE GOVERNMENT OF CANADA IS WORKING TO SECURE A SUFFICIENT QUANTITY OF PPE IN CANADA**

- The Government of Canada has **supported** Canadian industry to increase domestic manufacturing capacity, including re-tooling facilities to produce PPE, medical equipment and supplies.
- As of August 28, Public Services and Procurement Canada has confirmed contracts for a variety of PPE, **medical equipment and supplies** including:
  - over 153 million N95 respirators and equivalents (e.g., KN95 respirators; FFP2);
  - 396 million surgical masks;
  - 60.3 million face shields;
  - 1.1 billion pairs of gloves;
  - 132 million protective gowns; and,
  - 40 thousand ventilators.
- The Public Health Agency of Canada has established additional pandemic supply of PPE to increase resurgence capacity.
- The Public Health Agency of Canada is receiving staggered

delivery of shipments, and allocating them to provinces and territories.

- The Public Health Agency of Canada is working with Health Canada, provinces and territories to review the supply and demand of PPE, medical equipment and supplies, based on worst-case epidemiological scenarios, to determine maximum needs.
- The Public Health Agency of Canada also continuing to work with provincial and territorial partners in identifying **supply** gaps and ongoing **bulk** procurement needs.

***SI ON INSISTE SUR LA MANIÈRE DONT LE GOUVERNEMENT DU CANADA TRAVAILLE POUR OBTENIR UNE QUANTITÉ SUFFISANTE D'EPI AU CANADA***

- 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.
- Depuis le 28 août, Services publics et Approvisionnement Canada a confirmé la signature de contrats en vue d'acquérir une panoplie d'EPI et d'autres fournitures médicales, notamment :
  - plus de 153 millions de respirateurs N95 et de respirateurs équivalents (p. ex. des respirateurs KN95);
  - 396 millions de masques chirurgicaux ;
  - 60.3 millions d'écrans faciaux;
  - 1,1 billions paires de gants;
  - 132 millions de blouses de protection ; et,
  - 40 mille ventilateurs.
- L'Agence de la santé publique du Canada a établi un approvisionnement supplémentaire en cas de pandémie d'EPI pour accroître la capacité de résurgence.
- L'Agence de la santé publique du Canada reçoit les livraisons

échelonnées et les répartit entre les provinces et les territoires.

- L'Agence de la santé publique du Canada continue également de travailler avec les partenaires provinciaux et territoriaux dans leur planification afin d'assurer un approvisionnement suffisant pour divers scénarios.
- Cela comprend l'identification des lacunes dans l'approvisionnement et des besoins d'approvisionnement **en vrac** continus.

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

- Due to intense global competition for PPE, **medical equipment and supplies**, countries have needed to engage with new suppliers and manufacturers.
- As a result, PPE, **medical equipment and supplies** received by the Public Health Agency of Canada – whether procured internationally or domestically – are verified to meet the technical specifications for healthcare settings **before they are** distributed to provinces and territories. To date, a large majority of the products received by the Government of Canada have met the technical specifications for healthcare settings for **the** COVID-19 response.
- As a result **of** the Public Health Agency of Canada's stringent review process, approximately 10 million KN95 respirators were assessed as not meeting the specifications for health care workers.
- Supplies that do not meet specifications are **then** assessed for potential use in non-healthcare settings.

***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'Agence de la santé publique du Canada, 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. 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 10 millions de respirateurs KN95 ont été jugés non conformes aux spécifications techniques.
- 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.

***IF PRESSED ON THE MADE-IN-CANADA VENTILATORS***

- Earlier this year, as part of the Plan to Mobilize Industry to fight COVID-19, contracts were awarded to four Canadian suppliers for the procurement of ventilators.
- **These ventilators receive authorization by Health Canada in order to be considered for use in a healthcare setting.**
- **The Public Health Agency of Canada continues to receive ventilators from both international and domestic suppliers.**
- **The Public Health Agency of Canada is working with provincial and territorial governments to develop an allocation**

strategy for these ventilators.

- The Public Health Agency of Canada will also be retaining an inventory of ventilators in the National Emergency Strategic Stockpile to meet the future needs of the healthcare sector.

**SI ON INSISTE SUR LES VENTILATEURS FABRIQUÉS AU CANADA**

- Plus tôt cette année, dans le cadre du Plan de mobilisation de l'industrie pour lutter contre le COVID-19, des contrats ont été attribués à quatre fournisseurs canadiens pour l'acquisition de ventilateurs.

- Ces ventilateurs reçoivent l'autorisation de Santé Canada afin d'être utilisés dans un établissement de santé.

- L'Agence de la santé publique du Canada continue de recevoir des ventilateurs de fournisseurs internationaux et nationaux

- L'Agence de la santé publique du Canada collabore avec les gouvernements provinciaux et territoriaux pour élaborer une stratégie d'allocation pour ces ventilateurs.

- L'Agence de la santé publique du Canada conservera également un inventaire des ventilateurs dans le stock stratégique national d'urgence pour répondre aux besoins futurs du secteur de la santé.

**IF PRESSED ON UNDERSTANDING THE DEMAND FOR PPE TO SUPPORT THE REOPENING OF THE ECONOMY**

- The Canadian Centre for Occupational Health and Safety is developing guidelines for various sectors based on public health guidance.
- The federal government is working with experts to better assess the PPE, medical equipment and supply needs of Canada's society and economy, based on the most up-to-date public health advice.



## ***S'IL EST PRIS POUR COMPRENDRE LA DEMANDE D'ÉPI POUR SOUTENIR LA RÉOUVERTURE DE L'ÉCONOMIE***

- Le Centre canadien d'hygiène et de sécurité au travail élabore des lignes directrices pour divers secteurs sur la base des directives de santé publique.
- Le gouvernement fédéral collabore avec des experts pour mieux évaluer les besoins en ÉPI de la société et de l'économie du Canada, en se fondant sur les conseils de santé publique les plus à jour.

### **BACKGROUND**

Canada's National Emergency Strategic Stockpile (NESS) contains supplies that provinces and territories (PTs) can request in emergencies, such as infectious disease outbreaks, natural disasters and other public health events, when their own resources are exhausted. These supplies include a variety of items such as: medical equipment and supplies; pharmaceuticals; and social service supplies, such as beds and blankets.

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).

#### NESS Mandate

The fundamental basis underpinning federal emergency management and the NESS is that provincial, territorial and local governments are prepared to be able to respond in a reasonable manner to the most common emergencies in their jurisdictions. This includes being responsible for the procurement and management of personal protective equipment and other medical supplies.

As such, the federal government's role in stockpiling emergency health assets is twofold:

- It provides surge capacity support to provinces and territories at their request when their own resources are not sufficient; and
- It is the sole provider of certain assets required for rare public health emergencies, for example, costly and rarely used vaccines or antidotes.

In an August 5, 2020 article by the Canadian Medical Association, it was suggested that a \$300-million emergency stockpile of pandemic supplies be privatized or run on a commercial basis by a Crown corporation. The article noted that certain doctors blame PHAC for what they argue was mismanagement of the stockpile, which resulted in waste and shortages of emergency medical equipment and supplies.

PHAC acknowledges that the pandemic created unprecedented demand for certain types of supplies. Canada, like most countries, is applying the lessons learned from the COVID-19 outbreak to our stockpiling strategies and considering all options going forward to ensure that the most effective stockpile practices are implemented and maintained.

### NESS Footprint

NESS facilities consist of a central depot in the National Capital Region and warehouses strategically located across Canada. In recent years, the NESS moved from nine warehouse locations across Canada to six. An independent assessment indicated that the six strategic locations would maintain the NESS' role as timely surge capacity support.

As of 2019, all NESS holdings were consolidated in eight warehouses in six cities. In Spring 2020, two additional NESS warehouses were leased in addition to 10 warehouses secured through third-party contracts, given the volume of supplies being donated to and purchased by the NESS as part of the federal government's COVID-19 response. The warehouse footprint grew from approximately two hundred thousand square feet in January 2020 to over one million, three hundred thousand square feet.

When a warehouse is closed, usable supplies are moved to a new location, while obsolete and expired supplies are disposed of as per Treasury Board policy.

### NESS Funding

In 2010-11, the ongoing annual base funding for the NESS, including salary and operating costs was \$5.6 million. By 2012-13, the annual base funding for the NESS was reduced to \$3 million. Additional funding has historically been provided to the NESS through internal reallocation decisions and incremental funding decisions through which PHAC has received funding linked to specific purchases, such as a four-year investment in medical countermeasures against smallpox and anthrax that began in 2015-16.

More than \$5 billion has been invested in the NESS since the onset of the COVID-19 outbreak in Canada.

### Canadian Pandemic Influenza Plan PPE Guidance

The **2006 CPIP** recommended *"a 16-week supply (i.e. two pandemic waves) of both influenza and non-influenza related materials to address sporadic interruptions of supply chains (e.g. resulting from mail and courier disruptions, border closures, supply limitations)"*.

The **2011 CPIP** indicates that methods to estimate PPE requirements are beyond the scope of the CPIP, and notes that PTs are responsible for ensuring the provision of medications, supplies, and equipment required for provision of pandemic health care services.

### 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.

Access is further facilitated by Health Canada, by expediting regulatory approvals of products 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 required to notify the Minister of Health of medical device shortages 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.

Health Canada is also modeling PPE, **medical equipment and supplies** supply and demand at provincial and territorial, as well as pan-Canadian levels, to understand and plan for possible pressure points across different sectors of the economy and to inform future procurement plans of PPE, **medical equipment and supplies**.

In addition, the government is also exploring opportunities for more environmentally conscious federal PPE, **medical equipment and supply** procurement.

#### PPE Testing and Quality Assessments

Sourcing PPE from new suppliers and manufacturers (both domestically and abroad) is challenging. Once products are delivered to PHAC they must undergo quality verification before distribution to provinces and territories (PTs). 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.

#### Government of China **Customs Regulations**

In response to international criticism concerning the quality of PPE, the Government of China has imposed more stringent certification and **customs regulations** for masks and other PPE.

As a result, PHAC, as an importer, is now required to sign a joint declaration with the exporter attesting that the products meet the standards and certification requirements of the destination country.

For products that are not certified as medical devices in China, the joint declaration will also stipulate that the item is "not for medical use" even if it meets Canada's technical specifications for healthcare settings. These products are subsequently labelled in Simplified Chinese as "not for medical use" both on the outer shipping boxes and inside each of the individual product package.

As noted above, all supplies procured internationally continue to undergo quality

verification by PHAC prior to distribution to PTs. To maintain the integrity of the PPE packaging, PHAC will be labelling the outer shipping boxes, confirming quality and stating that it is suitable for use in healthcare settings. PHAC will not be removing labels inserted inside each of the individual product boxes, as the process of removing these inserts in Simplified Chinese would cause significant delays in the distribution.

#### KN95 Respirators

On May 8, the 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. The number not meeting specifications has since increased to approximately 10 million. PSPC has suspended shipments from this supplier and is pursuing the appropriate recourse on behalf of PHAC. Where possible, supplies that do not meet specifications are subsequently assessed for potential use in non-healthcare settings.

#### Federal/Provincial/Territorial (FPT) Allocation and Distribution

As agreed to by FPT Ministers of Health, PHAC is allocating procured PPE using an 80/20 formula: 80% is distributed to PTs 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 to support the requirements of First Nations on reserve. The purpose of the NESS is to provide surge capacity to PTs when their own resources are not sufficient.

#### Made-in-Canada Ventilators

As a result of ISED's Call to Action, the Government of Canada identified four Canadian companies capable of manufacturing made-in-Canada ventilators in support of the fight against

COVID-19. Each has been contracted to provide made-in-Canada ventilators (for a total of up to 37,500): FTI Professional Grade (FTI), CAE, Canadian Emergency Ventilators/Starfish and Vexos.

Prior to delivery of ventilator units to PHAC, each of these companies must obtain authorization under Health Canada's Interim Order. Additionally, once authorized, all ventilator units undergo quality verification by PHAC as part of the NESS in-take process before they are designated ready for deployment to provinces and territories.

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