

Government Response to the 11th Report of the Standing Committee on Public Accounts Entitled: Securing Personal Protective Equipment and Medical Devices

Introduction

The Government of Canada has considered the 11th Report of the Standing Committee on Public Accounts (PACP), entitled, “Securing Personal Protective Equipment and Medical Devices” on the 2021 Report 10 of the Auditor General of Canada. The Government would like to thank the members of the Committee for their study, and its recommendations, and wishes to inform them that it partially accepts one, and fully accepts three of the recommendations. The Government would also like to confirm that it will provide progress reports and/or final progress reports to PACP on three of the recommendations by the requested dates, and one on an alternative schedule.

In February 2022, the Public Health Agency of Canada (PHAC), Health Canada (HC) and Public Services and Procurement Canada (PSPC) tabled a Management Response and Action Plan (MRAP), in response to the Auditor General’s report “Securing Personal Protective Equipment and Medical Devices” with the Committee. The progress reports requested by PACP will provide status updates on ongoing MRAP initiatives.

The experience of COVID-19 has provided a lived experience of a pandemic, which has and continues to disparately impact diverse populations, the nature of which Canada and the world has not seen in over 100 years. Prior to the pandemic, the Government’s existing emergency response plans provided a framework to guide the Canadian response to COVID-19. That said, improvements are always possible and the Government remains committed to incorporating lessons learned from the COVID-19 pandemic where appropriate. The Government is especially attuned to the need for incorporating health equity in pandemic preparedness and response, as expressed in the 2021 report of the Chief Public Health Officer “A Vision to Transform Canada’s Public Health System”.¹ PHAC, HC and PSPC acknowledge that the use of lessons learned will help evolve their response and will be critical to support improvements suggested by the Auditor General and PACP.

Moreover, PHAC, HC and PSPC remain committed to continuing their work with partners, including provincial, territorial, federal, Indigenous and international partners, as these engagements will be a significant factor in determining the way forward.

Timelines for many of the actions detailed in the Government Response are dependent on the federal government and its partners’ capacity to dedicate time to this work, given the ongoing COVID-19 pandemic response. For this reason, the schedule to complete many aspects of the MRAP provided to the Auditor General includes target dates following the end of the

¹ Chief Public Health Officer of Canada. (2021) “A Vision to Transform Canada’s Public Health System.” <https://www.canada.ca/en/public-health/corporate/publications/chief-public-health-officer-reports-state-public-health-canada/state-public-health-canada-2021/report.html#a3.3>

pandemic. Nonetheless, the Government Response highlights that work is ongoing and progress has already been made on several initiatives. In the evolving context of the pandemic, as partners may have greater capacity to engage on initiatives, the government will continue to work with partners to advance any outstanding commitments in as timely a manner as possible.

A response and status update for all of the PACP recommendations (as of May 2022) follows.

| Recommendation 1 – National Emergency Strategic Stockpile Management Plan | |
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| Standing Committee on Public Accounts | Auditor General |
| <p>That, by 31 December 2022 the Public Health Agency of Canada should provide the House of Commons Standing Committee on Public Accounts with its comprehensive National Emergency Strategic Stockpile management plan, in collaboration with provincial, territorial, First Nations, Inuit, and Metis governments. This plan should incorporate relevant recommendations made in previous internal audits—including those regarding an electronic inventory management system—as well as lessons learned from the COVID-19 pandemic. A final report should also be provided 12 months after the end of the pandemic.</p> | <p>The Public Health Agency of Canada should develop and implement a comprehensive National Emergency Strategic Stockpile management plan with clear timelines that responds to relevant federal stockpile recommendations made in previous internal audits and lessons learned from the COVID-19 pandemic.</p> |
| Response and Status Update | |
| <p>The Public Health Agency of Canada partially agrees with this recommendation. The top priority for the agency continues to be supporting Canada’s response to the COVID-19 pandemic. The Agency will continue to identify and implement incremental improvements during its ongoing efforts to respond to COVID-19. However, work is underway to develop a comprehensive management plan with clear timelines for implementation within 1 year of the end of the pandemic. PHAC will provide a status update on progress related to the comprehensive management plan within six months following the end of the pandemic, as appropriate, rather than having a completed comprehensive plan by December 2022. Due to the nature of the pandemic and the resources and collaboration required for the comprehensive management plan timelines are linked to the end of the pandemic. The World Health Organization declares the start and end of a public health emergencies of international concern based on the global epidemiology.</p> <p>The experience of COVID-19 has provided a lived experience of a pandemic, the nature of which Canada has not seen in over 100 years. Recognizing that existing policies, practices, and resources were leveraged to guide the current response, lessons learned from the COVID-19 pandemic will inform how the National Emergency Strategic Stockpile (NESS) is managed going forward.</p> | |

The role of the NESS is to provide medical supplies, equipment, and countermeasures to provinces and territories at their request when their own resources are insufficient, such as during infectious disease outbreaks, natural disasters and other public health events. The COVID-19 pandemic challenged global supply chains for medical equipment and in response, the Government of Canada undertook ongoing bulk procurement on behalf of provinces, territories, and federal departments with a healthcare mandate to secure medical equipment and supplies for the healthcare sector.

The Agency continues to proactively distribute incoming medical supplies and equipment, such as personal protective equipment and vaccine supplies, to provinces, territories, and federal departments with a healthcare mandate to support Canada’s COVID-19 response.

The Agency is concurrently working on a comprehensive management plan with associated performance measures and targets for the NESS to support responses to future public health emergencies. This plan will focus on key areas such as optimizing life-cycle materiel management, strengthening governance models, enhancing infrastructure and systems, and working closely with provinces and territories and other key partners to better define needs and roles and responsibilities. As responsibility for public health is shared between various levels of government in Canada, a successful transformation of the NESS will require the feedback and perspectives of those who directly benefit from its services to help optimize the NESS for the future.

Performance measures and surge support targets for future public health emergencies will be incorporated as part of the comprehensive management plan. The program impact is measured on a broader scale that includes all Canadians. However, NESS will continue to consider the needs of diverse populations, as appropriate, in decisions about the type and mix of medical supplies that may be required to support public health emergency management. For example, when there is a precaution or contraindication for the use of certain medical countermeasures (e.g., vaccines, antibiotics) in a specific population (e.g., pregnant women, immune compromised individuals), the NESS considers the availability and feasibility of acquiring an alternative product to protect a broader range of Canadians.

Recommendation 2 – Terms and Conditions Progress Report

| Standing Committee on Public Accounts | Auditor General |
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| That, by September 30, 2022, the Public Health Agency of Canada should provide the Committee with a progress report in regard to enforcing the terms and conditions in its contracts with third-party warehousing and logistics service providers, with particular attention given to the provision of timely, accurate, and complete data in order to control the inventory of personal protective equipment and medical devices. | The Public Health Agency of Canada should enforce, as appropriate, the terms and conditions in its contracts with third-part warehousing and logistics service providers – including the long-term contract signed in September 2020 – for the provision of timely, accurate, and complete data to help control inventory of personal protective equipment and medical devices. |
| Response and Status Update | |

The Public Health Agency of Canada supports this recommendation. Lessons learned from early contracts with third-party warehousing and logistics service providers have informed contracting practices. Contracts now include clear service-level expectations about the timeliness of activities around inventory intake and data reporting.

PHAC also documented a governance protocol for the long-term warehousing and logistics contracts which outlines how incidents, issues and disputes are resolved between the third-party logistics provider and the Agency.

Since the long-term contracts were established, the Agency continues to work closely with its third-party warehousing and logistics service providers for the provision of timely, accurate, and complete data to help control the inventory of personal protective equipment and medical devices and, if required, will take appropriate actions to enforce the terms and conditions in these contracts.

| Recommendation 3 – Respirator Classification Report | |
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| Standing Committee on Public Accounts | Auditor General |
| That, by 31 December 2022, Health Canada should provide the Committee with a report regarding the classification of respirators including the justification of whether or not they should remain a Class 1 device. | Health Canada should determine whether respirators are appropriately classified given that Class I medical devices are not subject to a Health Canada review for safety and effectiveness. |
| Response and Status Update | |
| <p>Health Canada supports this recommendation. Health Canada regulates medical devices in accordance with an established set of risk-based classification rules set out in the <i>Medical Devices Regulations</i> (MDR). Factors that currently lead to higher risk classifications, and a higher degree of premarket oversight, include whether the device is invasive (e.g., implanted), and whether the device treats or diagnoses a condition (e.g., COVID-19). Based on the established classification rules, respirators are currently classified in the lowest risk category (Class I). Under the MDR, there is no pre-market review for Class I medical devices; however, manufacturers of all classes of medical devices are responsible for ensuring that the devices they sell meet the safety and effectiveness requirements of the MDR.</p> <p>Health Canada also actively monitors safety, effectiveness and quality evidence to help prevent low quality respirators from entering, and remaining on, the Canadian market. This is done through post-market surveillance activities, including inspections, and scientific evaluations, enabled through a COVID-19 Interim Order issued by the Minister of Health. An interim order is one of the fastest mechanisms available to the federal government for putting in place temporary regulations to help make health products available and protect patient safety during large-scale public health emergencies. When concerns about the quality, safety or effectiveness of any device, including respirators, are identified, Health Canada takes appropriate action to mitigate risks to Canadians, such as issuing public alerts on necessary recalls to raise awareness: https://healthycanadians.gc.ca/recall-alert-rappel-avis/index-eng.php?cat=3</p> | |

Recognizing the significance of respirators to the COVID-19 response and the importance of the safety, effectiveness and quality requirements for respirators during the COVID-19 pandemic, under the Interim Order, Health Canada has exercised the flexibility to conduct pre-market review of certain lower risk devices, including respirators. In addition Health Canada is reviewing the classification of lower risk devices, including respirators, in the context of a broader regulatory modernization agenda, and specifically, the Agile Regulations for Medical Devices initiative. This initiative will help us determine if respirators are appropriately classified. In December 2021, subject matter experts from Health Canada's Medical Devices Program have started analyzing the existing classification regime to inform options for potential adjustments under the Agile Regulations initiative.

The first phase of implementing Agile Regulations for Medical Devices is expected to be published in *Canada Gazette*, Part I in the Fall of 2022. Any adjustments with respect to medical device classification would follow, although a target date has not yet been finalized.

Recommendation 4 – Internal Process for Conducting Checks

| Standing Committee on Public Accounts | Auditor General |
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| That, by September 30, 2022, Public Services and Procurement Canada should provide the Committee with a report explaining how its internal processes for conducting checks verify the financial strength of suppliers before awarding contracts that involve advance payment, while allowing for flexibility to address urgent needs and accepting procurement risks during crises. | Public Services and Procurement Canada, while addressing urgent needs and accepting procurement risks, should conduct checks of the financial strength of suppliers before awarding contracts that involve advance payment. |

Response and Status Update

Public Services and Procurement Canada (PSPC) agrees and accepts recommendation 4, and will provide the Committee with a report within the prescribed timeline.

PSPC is continuously evolving and strengthening its procurement approaches. As part of the Department's response to the COVID-19 pandemic, particularly in the first 100 days, procuring the goods and services required to combat the pandemic was an around-the-clock effort. Procurement initiatives were undertaken in an unprecedented environment of extremely competitive global markets and at times depleting global supply chains. This presented challenges ranging from being able to action contracts outside of regular business hours, addressing logistics, and undertaking new critical activities such as the Essential Services Contingency Reserve. While PSPC established processes at the outset of the pandemic aimed at ensuring oversight and due diligence, the Department recognizes that procurement processes can always be improved, and in the context of advance payments, this includes undertaking financial checks, such as validating suppliers' financial capability in an emergency situation.

Over the course of the pandemic, PSPC continues to improve and strengthen its processes, particularly

with respect to due diligence. At the outset, there was an exponential increase in worldwide demand for personal protective equipment and medical devices, coupled with export restrictions by certain countries, which drastically reduced global supply and stressed supply chains at multiple points. The limited supply made the market for this equipment very competitive and resulted in increased prices. In such an environment, advance payments were sometimes required by suppliers. The Department had to accept some risks in order to procure large quantities of equipment, for example, advance payments to suppliers; without this, fewer pieces of equipment would have been available to front line workers and vulnerable Canadians.

As a result, PSPC implemented certain measures to mitigate the risks associated with advance payments to accelerate the establishment of a supply chain and manufacturing capacity. When risks were identified, the Department responded by fragmenting orders, reducing advance payment amounts and using escrow accounts to ensure a balance between financial risks and ensuring supply of PPE. As a result of this due diligence process, instances of elevated financial risk were escalated to senior management for decision-making, resulting in a number of decisions not to proceed to contract award.

PSPC implemented a dedicated team for the contract management of all awarded contracts. The role of this team was to conduct weekly outreach to suppliers to track pending deliveries of PPE and critical medical equipment. Any deviation from the contract terms and conditions were reported to the assigned contracting officer to implement remediation measures. PSPC also sent a formal communique to all contracting officers in November 2021 regarding financial capability assessments and advance payments, which outlined the policy framework, including providing specific references to the appropriate areas of PSPC's Supply Manual (section 4.70.30.20 *Advance Payments* and section 5.60.1 *Financial Capability*) and the Treasury Board of Canada Secretariat's *Guide to Advance Payments*, and provided information on the steps that contracting officers must follow to fulfil their obligations with respect to mitigating financial risks.