Media Lines

Concerns with the CAE Air1 Ventilator for COVID-19

Issue Statement: On June 16, 2020, Health Canada authorized the CAE Air1 ventilators to treat patients with COVID-19. The company had responded to Innovation, Science and Economic Development Canada's call to action as part of the Plan to Mobilize Industry to fight COVID-19. Contracts are in place to produce 10,000 of these devices by fall 2020 to help with the response to COVID-19.

In July 2020, Health Canada identified concerns with the CAE Air1 ventilator authorized under the *Interim Order respecting the importation and sale of medical devices for use in relation to COVID-19*. Health Canada issued conditions on its authorization to ensure that the device is not distributed until all identified concerns are addressed.

On September 1, 2020 at Health Canada's request, the Public Health Agency of Canada (PHAC) undertook an independent technical assessment of the device. PHAC produced a report of its findings in support of Health Canada's re-assessment, which concludes that the ventilators failed the technical assessment due to critical deficiencies that pose patient safety risks. The report was shared with CAE and Health Canada on September 11, 2020. Health Canada is taking action based on PHAC's findings, and CAE is not authorized to distribute its ventilator until such time as all the issues have been addressed to Health Canada's satisfaction.

As PHAC determines the payments for the CAE Air1 contract, the company is requesting an advancement in funds to continue to resolve issues. Otherwise, it will need to lay off staff.

The Government of Canada has a number of contracts for ventilators with several different suppliers in addition to CAE and continues to work with the provinces and territories to monitor current capacity and prepare for resurgence scenarios.

Key Messages:

- Canadians and their families rely on safe and effective health products, including ventilators and other medical devices.

- After Health Canada authorizes a medical device for use in Canada, the Department continues to monitor for safety and effectiveness once the product is on the market. If concerns arise, Health Canada takes appropriate action to protect the health and safety of Canadians.

- The CAE Air1 ventilator was authorized by Health Canada on June 16, 2020, under the *Interim Order respecting the importation and sale of medical devices for use in relation to COVID-19.*

- In late June, several ventilators were delivered to the Public Health Agency of Canada (PHAC) for quality assurance testing. During testing, a number of concerns were raised regarding oxygen delivery, stability and monitoring that could affect patient safety. There were also minor problems with the packaging and labelling text.

- As a result, on July 10, 2020, Health Canada issued conditions on the authorization of the CAE Air1 ventilator to ensure that the ventilator is not distributed until all identified issues are addressed. No ventilators were distributed in Canada other than to PHAC.

[APG]

- PHAC has subsequently conducted quality assurance testing on modified CAE ventilator units and shared its findings with both CAE and Health Canada on September 11.

- CAE is not authorized to distribute its ventilator until such time as all issues have been addressed to Health Canada's satisfaction.

- Health Canada and PHAC continue to work with the company to help resolve the problems with the ventilators so that they can be used safely by Canadians.

Supplementary Messages on Authorization:

- In response to the COVID-19 outbreak, Health Canada continues to authorize medical devices under an expedited regulatory review process.

- Health Canada completes a thorough scientific review to ensure that devices meet Health Canada's requirements for safety, quality and effectiveness.

- Health Canada continues to monitor the safety, quality and effectiveness of all medical devices once they are on the market. Manufacturers must follow strict post-market safety requirements, such as mandatory problem reporting, recall procedures and complaint handling.

- A list of devices authorized through the Interim Order is available at: https://www.canada.ca/en/health-canada/services/drugs-health-products/covid19-industry/medical-devices/authorized/other.html

If pressed on ISED's role (Questions related to these items may be referred to ISED)

- CAE responded to ISED's call to action as part of the Plan to Mobilize Industry to fight COVID-19.

- Through the 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 up to 10,000 made-in-Canada ventilators (for a total of up to 40,000): Ventilators for Canadians (FTI Professional Grade Inc.), CAE, Canadian Emergency Ventilators/Starfish and Vexos.

- As a condition of the contracts, each company's ventilator must be authorized by Health Canada.

- ISED and Public Services and Procurement Canada (PSPC) continue to actively support Canadian industries to increase domestic manufacturing capacity, including re-tooling facilities to produce equipment and supplies including ventilators, surgical masks and testing kits.

- Through these efforts, the Government of Canada continues to sign new procurement agreements with Canadian companies that can provide urgently needed equipment.

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

Questions and Answers

Q1. Could there be similar issues with other medical devices approved under the Interim Order?

In response to the COVID-19 outbreak, Health Canada continues to authorize medical devices under an expedited regulatory review process that involves a thorough scientific review to ensure that devices meet Health Canada's requirements for safety, quality and effectiveness.

After Health Canada authorizes a medical device for use in Canada, the Department continues to monitor for safety and effectiveness once they are on the market. If concerns arise, Health Canada takes appropriate action to protect the health and safety of Canadians.

Q2. Why didn't Health Canada wait for the results of the validation before authorizing the CAE Air1 device for sale?

The scientific review of the CAE Air1 ventilator was completed under expedited timelines as part of the Interim Order announced on March 18, 2020.

Health Canada's regulatory decision was based on a comprehensive review of the evidence provided by CAE, which demonstrated that the CAE Air1 was safe and effective.

When Health Canada authorizes medical devices, including ventilators, for use in Canada, it continues to monitor them for safety and effectiveness once they are on the market. If concerns arise, Health Canada takes appropriate action to protect the health and safety of Canadians.

Based on concerns raised by PHAC on September 11, CAE continues to have technical issues with its ventilators that present critical safety concerns.

Health Canada and PHAC continue to work with the company to help resolve the problems with the ventilators so that they can be used safely by Canadians.

Q3. Why hasn't Health Canada authorized the amended CAE Air1 ventilator for sale yet?

Health Canada is working with CAE to acquire the information needed to make a regulatory decision on the amended CAE Air1 ventilator. CAE has been forthcoming in providing Health Canada with requested information to date.

Four made-in-Canada ventilator companies are currently under contract with the Government of Canada, and their products all require authorization by Health Canada. The review of the made-in-Canada ventilator applications is a priority and is part of a separate review queue relative to other ventilator applications. Applications within the made-in-Canada queue are reviewed and processed in the order that they are received.

Health Canada continues to make exceptional efforts to process and review ventilator applications as quickly as possible, but will not compromise on patient safety.

Q4. How much funding has CAE received to date? Will the Government of Canada continue to fund CAE so that it can address the issues and avoid layoffs?

The total value of the CAE contract to produce 10,000 ventilators is $282.5 million. We cannot disclose any additional terms of the contract due to confidentiality reasons.

Health Canada and PHAC continue to work with the company to help resolve the problems with the ventilators so that they can be used safely by Canadians.

Q5. Given the delays in receiving ventilators from this contract, is Canada prepared for a possible resurgence this fall?

The Government of Canada has a number of contracts for ventilators in addition to CAE Air1 and is receiving units at the National Emergency Strategic Stockpile. PHAC also continues to work with the provinces and territories to monitor current capacity in their respective health systems and collectively prepare for resurgence scenarios.