

McKenna, Neil

From: Kim, Sabrina
Sent: Thursday, September 10, 2020 9:08 AM
To: Stickney, Matt
Subject: CAE - Ventilator Update

FYI CAE is still having problems with their vents. Health says it would take a minimum of 4-6 weeks to address the problems and finalize the licensing process.

They're asking for additional payments, which ISED recommends but PSPC and PHAC are mulling over it. And there's still potential for short-term layoffs out of CAE, as they've hired a workforce to do the manufacturing and those ppl won't be needed for at least a few weeks. Could be as many as 250 workers. Full update below from Celine!

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Begin forwarded message:

From: "Caira, Celine (IC)" <celine.caira@canada.ca>
Date: September 10, 2020 at 8:54:46 AM EDT
To: "Kim, Sabrina" <Sabrina.Kim@pmo-cpm.gc.ca>
Subject: FW: CAE - Ventilator Update

Sharing a disappointing update on the CAE vent front. Looks like it will take 4-6 weeks to resolve this. I will raise today with PSPC and HC.

Unfortunately this is not a great update.

As you will recall, CAE's first delivery proved deficient with a series of manufacturing and software issues. At the time, both PHAC/HC and CAE were optimistic that the problems would be readily addressed. That said, the problems were serious enough that HC removed their interim authorization so that no further sales/deliveries could take place until the problems were resolved.

CAE subsequently re-submitted their vent to HC (bit of a chronology below if you are interested). CAE has been making calls to try and get HC to speed up their review. They have also been asking PSPC to advance additional funds since their burn rate is not aligned with their deliveries due to the delay.

In speaking to HC/PHAC, the organizations have now finished their review and the results continue to show significant shortcomings with patient safety implications. The vents are not delivering the prescribed amount of air in all settings and are not keeping the lungs open at the correct and prescribed diameters.

CAE will receive this report this week (maybe as early as today). HC/PHAC are still committed to working with them, but HC estimates it would take a minimum of 4 to 6 weeks to address the problems and finalize the licensing approval process.

While CAE will need to accept and address the deficiencies, two short-term issues are expected. First is the request for additional advanced payments. PSPC and PHAC are considering this request, but it is not clear that it will be accepted. From an ISED perspective, we should continue to find ways to support the development (it is not an easy task we have asked them to undertake) but ultimately it will be PSPC and PHAC who will need to make this decision.

The second issue is the potential for short-term lay-offs from CAE. They have a workforce hired to do the manufacturing, and these people will not be needed for a few weeks. This could be as many as 250 people, of which a third are essentially temporary workers, and the rest are CAE employees who were brought back from COVID-related furlough.

Chronology (as per HC ADM)

- Health Canada previously issued an authorization for the CAEAir1 v.1 ventilator. After a failed PHAC assessment of the ventilator, CAE was asked to confirm in writing that they would not further distribute any units of their ventilator.
- Health Canada instructed the company that 3 conditions would need to be met before this limitation would be lifted:
 - CAE would have to file an amendment to their application to account for changes made to address PHAC's findings
 - CAE would have to file evidence of their quality management systems and documentation for review by Health Canada (because the issues that surfaced during the PHAC assessment suggested a lack of QMS oversight)
 - CAE would have to provide samples of their ventilator to PHAC for assessment
 - HPFB ADM and a/DG MDD spoke to CAE August 27 during which CAE tried to encourage HC to complete its review more quickly, indicating that they would have to undertake layoffs due to regulatory delays. HC communicated the importance of our role as a regulator and that we will be as responsive as possible, but that we will not compromise on patient safety.
 - CAE has filed an amendment, which remains under review at this time. The most recent information related to this amendment was received August 24.
 - CAE has filed evidence of their QMS. It resulted in the following findings to date:
 - A number of software features failed the software verification and validation. A number of features appear to be linked to essential device features.
 - Clinical validation of the design did not cover the entire range of operational parameters; only specific set points were tested.
 - Some design transfer activities have not been completed, indicating that the company is not ready to begin high-volume production.
 - HC asked CAE to ship the samples on Aug 31 and they were received by PHAC on Sept 1. PHAC's assessment is not yet complete but has revealed failures relating to patient safety.
 - Health Canada believes it will be necessary to request further adjustments to the ventilator, further validation testing and possible adjustments to the QMS system.
 - Given the experience to date, HC will insist that corrected samples be assessed by PHAC again before lifting the conditions from the authorization.
 - Health Canada has recently received an application for v2 of the CAEAir1 (Aug 26). This application remains on hold at this time pending completion of review of the documentation submitted in respect of v1.
 - There was a call last week with ISED and PSPC on which the ADM HPFB participated. HPFB ADM recommends that, given CAE is a reputable Canadian company, economic departments consider providing them with additional financial investment to assist them in completing their work to develop a quality device that can ensure patient safety.