Leftick, Hilary

From: Hage-Moussa, Vanessa
Sent: Monday, September 28, 2020 6:54 PM
To: PMO.F Senior Staff / personnel supérieur F.CPM
Cc: Gagnon, Chantal; Lamothe, Colleen; Theis, Rick; Lemkay, Kevin
Subject: FYI - Tech briefing on COVID testing approval process tomorrow, followed by noon announcement

Tomorrow at 10am, PHAC/HC will hold a tech briefing (teleconference, for attribution) to provide an overview on the authorization of coronavirus testing applications and devices (COVID-19). The briefing will be led by:

- Dr. Supriya Sharma, Chief Medical Advisor (Spokesperson)
- Dr. Marc Berthiaume, Director, Bureau of Medical Sciences (Spokesperson)
- Dr. Guillaume Poliquin, A/Scientific Director General, National Microbiology Laboratory (technical expert on lab process)

Following this, at the noon PHAC update, Minister Anand will be announcing that we have finalized a contract with Abbott for their ID Now Covid-19 V1.0 rapid test. Details from the one-paper provided by PSPC below. Note that the Abbott has not yet received full HC approval yet, but the recommendation is to proceed with announcing the procurement piece, which is consistent with our approach re vaccines and therapeutics (which have not yet received HC approval). The message: when they are approved, we will be ready.

The tech briefing will serve to provide journalists with context on the regulatory process and to communicate that approvals are happening as quickly as possible but the fact remains that obtaining more fulsome data sets from companies and regulatory processes take a bit of time, and that the fallout of approving a test without all that info can be disastrous – a bunch of false positives/negatives walking around, major public health ramifications and recall headaches down the line.

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Abbott ID Now Covid-19 V1.0

This contract is based on a **requisition by National Microbiology Laboratory** and is intended to support the ramp-up of testing capacity by provinces and territories.

Health Canada has already **approved the instrument** (which can be used for different respiratory diseases, such as COVID-19, Influenza A, Influenza B, etc.) and is in the process of **reviewing the COVID-19 test kits used with this instrument**.
The sole-source contract with a maximum value of $334.9M has 3 key parts:

- **Firm order of 1,700 analyzers** (Health Canada Approved) for $10.0M (taxes included). This part is not conditional on the approval of the COVID-19 test kits. In the unlikely case that they are not authorized, the devices could be used for testing other respiratory diseases.

- **First option to buy 2.5M test kits and 800 additional analyzers** when Abbott receives Health Canada approvals for the test for $103.5M (taxes included). These supplies are to be delivered between October and December 2020.

- **Second option to buy an additional 5.4M test kits and an additional 1,300 analyzers** for $221.3M (taxes included), which would be exercised once Health Canada obtains additional funding. These supplies are to be delivered in Q1 2021.

A few key considerations:

- The **requirement for these devices and supplies has been identified by the National Microbiology Laboratory** who will be responsible for establishing a protocol for their use and deploying them in PTs. PSPC is executing the contract on their behalf.

- So far, we have struggled securing meaningful supplies of point-of-care tests. Spartan is unlikely to be approved before November-December 2020, while Cepheid has only managed to fulfill a small portion of our order. Abbott has allocated significant volumes for Canada and has **committed to an aggressive delivery schedule that would give us 2.5 million test kits by the end of the year** (note that since March, Canada as a whole has conducted just over 6M tests).

- While the Abbott ID Now test has slightly lower accuracy than the lab-based PCR tests or the Cepheid test, the emerging view is that the Abbott test is likely to be used as a **screening device that would allow provinces to divert asymptomatic patients away from the increasingly crowded testing centres** (PHAC and NML are expected clarify the precise deployment approach shortly).

- The **financial risk** associated with the test kits not receiving regulatory approval is **low**, all but $10M of the contract value is contingent on that approval and the NML can redeploy the analyzer devices even in the highly unlikely case that the accompanying COVID-19 test kits are not approved.

- This procurement is in line with the very **firm public commitment** that our government has made **to secure access to promising POC testing technologies** as they receive regulatory approval.