McKenna, Neil

From: Caira, Celine (IC) <celine.caira@canada.ca>
Sent: Saturday, May 2, 2020 5:56 PM
To: Harris, Emily (SPAC/PSPC)
Cc: Kim, Sabrina; Gordon2, Travis (HC/SC); Murdock, Kelly (SPAC/PSPC); Chan, Marco (IC); MacKnight, Aisling (HC/SC); Bélair, Thierry (HC/SC); Stickney, Matt; Theis, Rick; Khalil, Samantha; Zimmerman, Shannon; Gagnon, Chantal; Simard2, Veronique (IC); Hage-Moussa, Vanessa (IC); Power, Michael (IC); Jagric, Alexander (IC)
Subject: Re: Spartan

Adding comms/issues from our end.

Sent from my iPhone

On May 2, 2020, at 5:48 PM, Harris, Emily (SPAC/PSPC) <emily.harris@canada.ca> wrote:

From our end, JDM knows this is a health lead.

Sent from my iPhone

On May 2, 2020, at 5:44 PM, Kim, Sabrina <Sabrina.Kim@pmo-cpm.gc.ca> wrote:

Thank you! Adding. What is being sent to JDM?

Is Spartan or someone else going to be able to say this to the journalist? **"The company indicated that they have distributed approximately 3,500 tests and that they have been used for research purposes at this time."**

Also, some Qs:

- The 3, 500 tests only went to ON, MB, AB, NS and QC?
- Have all of the provinces who received the kits been informed of this by the GoC?
- While Spartan says that the 3, 500 tests were used exclusively for research purposes – technically the April 11th authorization would have allowed for them to have been used for actual testing, which is why the authorization is going to be amended tmrw. Is that right?
- Will the prior availability of clinical validation data be applied by HC as a criterion when considering approval for all test kits going forward?
- Are there other test kits that had been authorized by HC prior to receiving clinical validation data, beyond Spartan? And if yes, is any of the simultaneous clinical validation data still underway?

From: Harris, Emily (SPAC/PSPC) <emily.harris@canada.ca>
Sent: Saturday, May 2, 2020 4:59 PM
To: Gordon2, Travis (HC/SC) <travis.gordon2@canada.ca>
Cc: Murdock, Kelly (SPAC/PSPC) <kelly.murdock@canada.ca>; Caira, Celine (IC) <celine.caira@canada.ca>; Chan, Marco (IC) <marco.chan@canada.ca>; Kim, Sabrina

<Sabrina.Kim@pmo-cpm.gc.ca>; MacKnight, Aisling (HC/SC) <aisling.macknight@canada.ca>; Bélair, Thierry (HC/SC) <thierry.belair@canada.ca>
Subject: Re: Spartan

Flagging that Journal de Montreal was asking about this earlier this week.

Sent from my iPhone

On May 2, 2020, at 4:55 PM, Gordon2, Travis (HC/SC) <travis.gordon2@canada.ca> wrote:

> Hi all,
>
> Looks like we've got issues on the Spartan test kit. Wanted to flag for you given pressers tomorrow. Our Department is working on lines. I believe ISED and PSPC departments would have flagged for you as well.
>
> Needless to say, Spartan should be scrubbed from any proactive remarks.
>
> Will keep you informed incl passing on any media lines once complete.
>
> Cheers,
> Travis
>
> **From:** Wen, Vanessa (HC/SC) <vanessa.wen@canada.ca>
> **Sent:** 2020-05-02 4:27 PM
> **To:** Gordon2, Travis (HC/SC) <travis.gordon2@canada.ca>
> **Cc:** Faustin, Isabelle (PHAC/ASPC) <isabelle.faustin@canada.ca>; Nowers, Kathryn (HC/SC) <kathryn.nowers@canada.ca>; Bélair, Thierry (HC/SC) <thierry.belair@canada.ca>
> **Subject:** RE: Spartan
>
> Hi Travis,
>
> Please see below and attached.
>
> Thanks,
> Vanessa
>
> **Submission and first conditional authorization for research purposes only (March 26th)**
>
> - On March 26, 2020, Health Canada issued a conditional authorization to a Spartan, under the Interim order, for "research use only".
>
> **Authorization with new conditions enabling the sale (April 11th)**

- On April 11, Health Canada completed its scientific review and amended the conditions on the authorization, enabling the sale of the Spartan Cube.
- The authorization followed a scientific assessment by Health Canada to ensure that the device is supported by evidence that it meets requirements for safety and effectiveness.
  The Spartan submission included lab test results that confirmed that the instrument could detect the COVID virus with a high level of sensitivity, however these tests were not conducted in a clinical setting.
- The Interim Order enables Health Canada to authorize devices under an expedited scientific review process, on the basis of minimum requirements.
- Health Canada's scientific review relied on analytical data only. Consistent with other trusted regulators, in the context of the pandemic, evidence of performance in a clinical setting is not requested. This regulatory flexibility for this type of test was applied knowing that further clinical validation is carried out by public health laboratories in order to determine test performance in clinical settings.
- There were conditions on the authorization for the provision of limited studies and sales reporting.

Routine clinical studies following authorization for sale

- As part of Good Laboratory Practices, following authorization of the device by Health Canada, the NML and other provincial health laboratories across Canada undertook clinical validation studies upon receipt of the device. These studies seek to confirm that the product will work as intended for the purpose of diagnosis, and are standard studies undertaken for any authorized diagnostic technology.
- While this scientific study in clinical setting by the NML and public health labs is separate from Health Canada's authorization process, the NML is working in collaboration with Health Canada's Medical Devices Directorate to share knowledge gained through these studies.

<u>Preliminary studies</u>

- On April 26, 2020, the NML shared the results of their preliminary studies. They reported that the Cube performance in their lab tests was consistent with the evidence submitted by Spartan Bioscience to Health Canada.
- The preliminary studies did not investigate the effectiveness of the Spartan Bioscience swabbing system.
- Since the results were overall positive, the next step was to conduct testing using swabs collected directly from patients.

Further studies

- Further studies under clinical conditions were conducted where the Spartan swabs were used for specimen collection.
- On May 1, the NML provided Health Canada with a final report (see attached). This report identified that the Spartan Cube successfully detected positive samples only 47% of the time among samples tested in three different provinces (Alberta, Ontario and Manitoba).
- This inferior performance is in contrast with the initial laboratory-based assessment of the Spartan test done by the NML, which indicated that the analytical sensitivity performed as advertised.
- It is believed that this performance difference between lab and clinical settings is not related to the device itself, but rather to the swabs, which may not successfully collect appropriate mucosal material for the test.

Issuance of new conditions allowing for research purposes only (May 2nd)

- In light of the clinical results, Health Canada will issue on May 2nd an amended Letter of Conditions that will restrict the use of the product to research use until adequate evidence of clinical performance can be provided. The new conditions are as follow :
    - No distribution of the Spartan COVID-19 System is authorized until such time as Health Canada assesses the documentation to be submitted by Spartan and removes this condition.
    - The Spartan COVID-19 System is authorized for Research Use Only until such time as Health Canada assesses the documentation to be submitted by Spartan and removes this condition.
    - Within one month, Spartan Bioscience shall submit an investigational testing (clinical trial) application to Health Canada to obtain clinical evidence to support the intended use of the Spartan COVID-19 System. The clinical trial shall assess all aspects of the Spartan COVID-19 System, including the sampling method and proprietary swab.

  The first two conditions will not be modified until sufficient clinical information is provided to support the intended use of the Spartan COVID-19 System, and is deemed by Health Canada to be acceptable.

Recent engagement activities and next steps

- Health Canada held a call with Spartan on May 1st, at 8:00 pm. The purpose of the call was to discuss the information the Department received from the National Microbiology Laboratory on the Spartan test's performance in clinical setting; and the regulatory actions taken in light of this information.
- The company indicated that they have distributed approximately 3,500 tests and that they have been used for research purposes at this time. They will confirm this in writing.
- In an informal call the company on May 2nd, Spartan indicated being receptive to a voluntary recall of their devices.
- Health Canada will issue a letter on May 2nd detailing the new conditions and the next steps in relation to the voluntary recall.
- ISED and PSPC are kept informed of the situation.
- PHAC is engaging provinces.
- A subsequent call with the company is planned on Monday with the NML to further discuss the details of the study.

Media

- Media lines are currently being completed.
- There is a response to a media inquiry from the Journal de Montréal that should go out today. We can expect media coverage as of today and tomorrow.

From: Gordon2, Travis (HC/SC) <travis.gordon2@canada.ca>
Sent: 2020-05-02 9:52 AM
To: Wen, Vanessa (HC/SC) <vanessa.wen@canada.ca>
Cc: Faustin, Isabelle (PHAC/ASPC) <isabelle.faustin@canada.ca>
Subject: Spartan

Hey VW:

Understand HPFB will be restricting Spartan to a research authorization. I'm sure MLs are on the way, but can we get:

1. A summary of the deficiencies with the product that make it unsuitable for clinical use;
2. Why it was approved in the first place for clinical use?
3. Timeline for when this will go public.
4. **Isabelle –** Can we get a copy of the NML report on the device? I understand this informed HPFB's move.

I will need to flag for procurement partners in Government.

Thanks,
Travis

--
Travis Gordon

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<CPHLN FINAL REPORT_Spartan SARSCoV2 Test_SWG Validation_2020May 1.docx>