Lockington, Elliott (SPAC/PSPC)

From:	Media <media@tpsgc-pwgsc.gc.ca>
Sent	May 2, 2020 8:52 PM
To:	Harris, Emily (SPAC/PSPC); Roy, Cecely (SPAC/PSPC); fitz-morris, James (SPAC/PSPC)
Cc:	Media; Jean-François Létourneau; Elizabeth Lindsay; Me'Shel Gulliver Bélanger; Lucie Brosseau; James Stott; Bryan Blom; Sara Lacasse; Vivianne Soubhie; Martine Skelton; Rachel Lagacé
Subject:	FYI to MO: For PSPC/ISED FYI- Journal de Montréal, Philippe Orfali - Spartan Biosciences

Good evening,

For your information. The response below was shared with ISED and us by PHAC.
PHAC has advised PCO and ISED has informed their MO.

Thank you,

Stéfanie Hamel

Conseillère principale, Relations médias I Senior Advisor, Media relations
Services publics et Approvisionnement Canada I Public Services and Procurement Canada
Cellulaire : 819-576-4705

Expéditeur: "Gagnon, Andre (HC/SC)" <andre.gagnon@canada.ca>
Date: 2 mai 2020 à 19:37:15 HAE
Destinataire: Media <media@tpsgc-pwgsc.gc.ca>, "Media Relations / Medias relations (IC)" <ic.mediarelations-mediasrelations.ic@canada.ca>
Cc: "Payette, Louise (HC/SC)" <louise.payette@canada.ca>
Objet: For PSPC/ISED FYI- Journal de Montréal, Philippe Orfali - Spartan Biosciences

Media/Journalist: Le Journal de Montréal, Philippe Orfali

Date received: May 1, 11:21 a.m

Journalist's deadline: **May 2, ASAP**

Impact: **HIGH (1)**

Complexity: **HIGH (1)**

Background: **"**I'm writing an article on the Spartan Bioscience "Cube"."

Question(s) and answer(s):

Media/Journalist: Le Journal de Montréal, Philippe Orfali

Date received: May 1, 11:21 a.m

Journalist's deadline: **May 2, ASAP**

Impact: **HIGH (1)**

Complexity: HIGH (1)

Background: "I'm writing an article on the Spartan Bioscience "Cube"."

Question(s) and answer(s):

Q1. Spartan Bioscience Inc. received some of the federal funding announced in mid-March to help combat the coronavirus pandemic. How much did it receive? Approval under the Interim order respecting the importation and sale of medical devices for use in relation to COVID-19 was received on Monday, April 11. What happened between April 11 and May 1 to make the PHAC/Health Canada consider revoking this license/certification? When did the ongoing clinical validation process to confirm the effectiveness of the Spartan Cube technology begin, and why is it still ongoing? Why was the license issued before this process was completed? How effective (%) do you rate the tests to be?

On March 26, 2020 Health Canada issued conditional approval to Spartan Bioscience Inc. for the use of its COVID-19 test kit, Spartan Cube, for research purposes only. The authorization was issued under an Interim Order for medical devices used with regard to COVID-19. The order allows Health Canada to approve the use of medical devices after an expedited scientific review that examines only whether the device meets the basic minimum requirements.

On April 11, 2020 Health Canada completed its scientific assessment to ensure that the device is supported by evidence and meets standards for safety and effectiveness. The Department conducted the scientific review based on technical data provided by the company and taking into account that further clinical validation would be conducted by public health laboratories. Health Canada has amended the conditions of its authorization so as to allow the sale of the Spartan Cube test kit. However, Health Canada required the company to submit data from further technical studies, as well as information about the sale of the product.

On April 30, 2020 the Public Health Agency of Canada's National Microbiology Laboratory (NML) completed preliminary clinical validation studies to confirm that the Spartan test is working as intended. The studies confirmed the laboratory results obtained by Spartan.

On May 1, 2020 NML provided Health Canada with the results of the clinical validation studies of the Spartan device conducted in three provinces (Alberta, Ontario and Manitoba), using Spartan swabs to collect samples from patients under clinical conditions.
They revealed that the device did not perform as expected because the swabs did not collect enough mucous tissue for the test.

Based on the results of the clinical validation studies, Health Canada has restricted the use of the product to investigational use until sufficient evidence of clinical performance can be provided and assessed. Health Canada did not revoke the authorization in its entirety, due to the device's excellent analytical performance. Spartan's product may continue to be used for investigational purposes only.

André Gagnon
Communications Advisor I Conseillère en communications
Serving Health Canada and the Public Health Agency of Canada I Au service de Santé Canada et de l'Agence de la santé publique du Canada
Government of Canada I Gouvernement du Canada
(bb) 613-462-2571
(e/ce) andre.gagnon@canada.ca