Media Lines

Amendments to the Authorization of the Spartan Test Kit

Issue Statement: An article in the Ottawa Citizen on July 13, 2020, suggests that Health Canada has been slow to render a revised decision on the Spartan COVID-19 test kit, putting the company at a disadvantage.

Background:

On April 11, 2020, Health Canada authorized Spartan Bioscience's test kit for COVID-19.

On May 1, 2020, the National Microbiology Laboratory shared the findings of its clinical validation of the Spartan device with Health Canada. The report identified that while the Spartan Cube performed well in a laboratory setting, there were performance issues identified in the clinical trial related to the proprietary swab, which did not collect enough mucosal material for testing.

In response to this finding, on May 2, 2020, Health Canada amended the terms and conditions attached to the authorization of the device to restrict its sale "for research use only." This means that the device is no longer authorized to detect COVID-19 in patients. At Health Canada's request, the company issued a partial voluntary recall of the device to prevent its use in diagnostic settings.

Health Canada placed conditions on the authorization of the Spartan test kit to restrict its sale for only research, until we receive adequate evidence of clinical performance. Spartan will need to complete a second clinical trial to demonstrate clinical efficacy of the new swab design.

Key Messages

- Canadians rely on accurate diagnostic test results to help limit the spread of COVID-19 in Canada.
- After Health Canada authorizes test kits for use in Canada, it continues to monitor them for safety and effectiveness. If concerns arise, Health Canada takes appropriate action to protect the health and safety of Canadians.
- Health Canada has placed conditions on the authorization of the Spartan test kit to restrict its sale for only research, until we receive adequate evidence of clinical performance.
- On June 23, 2020, Health Canada authorized Spartan's clinical trial to "evaluate the efficacy of various sample collection methods for use with the Spartan COVID-19 System."
- Spartan is to submit a final study report when the clinical trial is complete.
- Spartan will need to complete a second clinical trial to demonstrate clinical efficacy of the new swab design identified during the first clinical trial.

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- Health Canada continues to work with Spartan to address the regulatory requirements to enable use of the device as a point-of-care test kit.

If pressed:

- Spartan has not yet provided the clinical information required to remove the conditions on the device's authorization.

- As of July 13, 2020, Health Canada has not received an application for a second clinical trial.

- Health Canada has not cancelled the authorization, given evidence that the device performs well in laboratory settings. The Spartan product can continue to be sold for research purposes.

Supplementary Key Messages on Authorization:

- On March 26, 2020, Health Canada issued an authorization with terms and conditions to Spartan Bioscience Inc. for its Spartan Cube.

- This authorization was made under the Interim Order for medical devices in the context of COVID-19, which enables Health Canada to authorize devices under an expedited scientific review process.

- On May 1, 2020, the National Microbiology Lab provided Health Canada with a final report of clinical testing performed using Spartan swabs to collect specimens directly from patients under clinical conditions.

- The report showed that, while the Spartan Cube performed well in a laboratory setting, there were performance issues in the clinical trial. These issues may be related to the proprietary swab, which may not collect enough mucosal material for testing.

- Health Canada placed conditions on the authorization of the Spartan test kit to restrict its sale for only research, until adequate evidence of clinical performance is provided.

If pressed on how many tests were distributed following authorization of the test kits:

- Spartan Bioscience Inc. shared its distribution record with Health Canada on May 2, 2020,and confirmed it had distributed 5,500 test kits to four public health organizations for research in a clinical setting:
  - Alberta Health Services;
  - CHU de Québec-Université Laval;
  - Ontario Agency for Health Protection and Promotion; and
  - Public Health Agency of Canada.

- These organizations are aware of the new Health Canada conditions on Spartan's authorization.

- At Health Canada's request, the company issued a partial voluntary recall to prevent its use in diagnostic settings.

- Health Canada has restricted the sale of the test kits to research use until the company provides adequate evidence of the device's clinical performance.

If pressed on the Public Health Agency of Canada's National Microbiology Laboratory's (NML) review of the test kit:

- As part of its research efforts, the Public Health Agency of Canada's NML performs scientific reviews of new medical devices.

- In response to the urgent nature of COVID-19, the NML is being asked by companies to perform scientific reviews and to assess the performance of diagnostic supplies such as COVID-19 testing kits.
- The NML reviews these COVID-19 laboratory supplies for clinical diagnostic to ensure they meet the gold standard used in public health laboratories and can be used to obtain reliable and accurate results when diagnosing COVID-19.
- This test verification function is part of scientific research and is independent of Health Canada's regulatory approval process. While this assessment is separate from Health Canada's authorization process, the NML works closely in collaboration with Health Canada to share knowledge gained through the review process.

If pressed on the Government's procurement of the Spartan test:

- The Government of Canada has a procurement contract with Spartan to secure supply of these devices. The contract is conditional on the Spartan test kit being authorized for sale by Health Canada.

Questions and Answers:

Q1. What is the Spartan device and how does it work?

Spartan's test kit consists of a portable analyzer called the Spartan Cube. The Cube performs the test with Spartan's COVID-19 test cartridges and proprietary swabs. The test kit can diagnose COVID-19 in less than an hour without having to send a sample to a lab.

Q2. Why didn't Health Canada wait for the results of the clinical studies before authorizing the Spartan device for sale?

The scientific review of the Spartan diagnostic test kit was completed under expedited timelines as part of the Interim Order announced on March 18, 2020.

Health Canada's regulatory decision was based on in-laboratory testing of the device. The review took into consideration that further validation would be carried out by public health laboratories in order to determine performance in clinical settings. This is consistent with the approach taken by other trusted regulators.

As planned, Health Canada continued to monitor and assess the safety and effectiveness of the Spartan rapid test kit in the field to help ensure that it performs appropriately and delivers accurate results. In light of the clinical results, Health Canada amended the terms and conditions on the company's authorization to restrict the sale of the product for research use only, until adequate evidence of clinical performance can be provided.

For more information about the Spartan test kit's performance, please contact the manufacturer directly.

Q3. Is the NML's validation report available to the public or on request?

On May 1, 2020, the NML provided Health Canada with a final report of clinical testing performed in three provinces (Alberta, Ontario and Manitoba) using Spartan swabs to collect specimens directly from patients under investigation for COVID-19. The report is an internal working document written by the network of federal/provincial/territorial public health laboratories across Canada. It is not available for public distribution as it contains confidential information.

Q4. Since May 2, 2020, has the company worked with the Department to provide evidence of clinical performance?

Health Canada continues to work with Spartan to address the regulatory requirements to enable utilization of the point of care test kit.

Health Canada authorized Spartan's clinical trial on June 23, 2020. The objective of the clinical trial is to "evaluate the efficacy of various sample collection methods for use with the Spartan COVID-19 System." The trial uses the test kit and system that are currently authorized for "research use only."

Health Canada has requested that Spartan submit a copy of the final study report upon completion of the clinical trial. As of July 13, 2020, Health Canada has not received the study report.

Health Canada has advised Spartan that it will need to complete a second clinical trial to demonstrate clinical efficacy of the new swab design identified during the first clinical trial. As of July 13, 2020, Health Canada has not received the application for the second clinical trial..