Media Lines

Amendments to the authorization of the Spartan screening kit

Question. An article in the *Ottawa Citizen* on July 13, 2020, indicated that Health Canada took some time to render a revised decision on the Spartan COVID-19 screening kit, putting the company at a disadvantage.

Context

On April 11, 2020, Health Canada authorized the use of Spartan Bioscience's COVID-19 screening kit.

On May 1, 2020, the National Microbiology Laboratory sent Health Canada the results of its clinical validation of the Spartan kit. The report indicated that while the Spartan Cube worked well in the laboratory, there were performance issues in the clinical trial related to the proprietary swabs that did not collect enough mucosal material for screening.

On May 2, 2020, Health Canada amended the product's authorization conditions to limit the sale to "research purposes only." This means that the product can no longer be used to screen patients for COVID-19.

At Health Canada's request, the company issued a voluntary partial recall of the product to prevent it being used as a diagnostic tool.

Health Canada has imposed authorization conditions on the Spartan screening kit to limit its sale to research purposes only until we receive sufficient evidence of its clinical performance. Spartan must conduct a second clinical trial to demonstrate the clinical effectiveness of the new type of swab.

Key messages

- Canadians need accurate screening test results to stop the spread of COVID-19 in the country.
- Once Health Canada authorizes screening kits, it continues to ensure that they are safe and effective. When in doubt, Health Canada takes the necessary action to protect the health and safety of Canadians.
- Health Canada imposed authorization conditions on the Spartan screening kit to limit its sale to research purposes only until we receive sufficient evidence of its clinical performance.
- On June 23, 2020, Health Canada authorized Spartan's clinical trial to evaluate the effectiveness of the Spartan system's various collection methods for COVID-19.
- Spartan will present a final study report when the clinical trial is complete.
- Spartan must conduct a second clinical trial to demonstrate the clinical effectiveness of the new type of swab identified in the first clinical trial.

- Health Canada continues to work with Spartan as the company strives to meet the regulatory requirements to allow the use of its screening kits at points-of-care.

If pressed

- Spartan has not yet provided the clinical information necessary to remove the product's authorization conditions.

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

- Health Canada has not cancelled the authorization because the product works well in the laboratory. The Spartan product can continue to be sold for research purposes.

Additional key messages on authorization

- On March 26, 2020, Health Canada issued an authorization with conditions to Spartan Bioscience Inc. for the use of the Spartan Cube.

- This authorization was granted under the Interim Order respecting medical devices for use in relation to COVID-19, which enables Health Canada to authorize the use of instruments after an accelerated scientific review process.

- On May 1, 2020, the National Microbiology Laboratory (NML) submitted to Health Canada its final report on the clinical trials conducted with the Spartan swabs for collecting samples directly from patients under clinical conditions.

- The report outlined that although the Cube worked well in the laboratory, there were performance issues in the clinical trial. These issues may be related to the proprietary swabs not collecting enough mucosal material for the screening.

- Health Canada imposed authorization conditions on the Spartan screening kit to limit the sale to research purposes only until the company could provide data demonstrating the product's adequate clinical performance.

If pressed on the number of kits distributed after the authorization of the screening kit

- Spartan Bioscience submitted its distribution package to Health Canada on May 2, 2020, and confirmed that it had distributed 5,500 screening kits to four public health agencies for clinical research:
    - Alberta Health Services
    - CHU de Québec – Université Laval
    - Ontario Agency for Health Protection and Promotion
    - Public Health Agency of Canada

- These agencies are aware of the new authorization conditions imposed by Health Canada.

- At Health Canada's request, the company issued a voluntary partial recall of the product to prevent it being used as a diagnostic tool.

- Health Canada has limited the sale of the screening kits to research purposes only until the company provides adequate evidence of the product's clinical performance.

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

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

- Given the urgency of the situation, companies are asking the NML to conduct scientific reviews and evaluate the performance of diagnostic equipment such as COVID-19 screening kits.

- The NML reviews the laboratory supplies associated with COVID-19 clinical screening to ensure that they comply with the gold standard used in public health laboratories and that they can be used to obtain reliable and accurate results for COVID-19 screening.

- This review function is part of scientific research and is independent of Health Canada's regulatory approval process. Although the review process is separate from Health Canada's approval process, the NML works directly with Health Canada to share knowledge gained during the review process.

If pressed on the government's purchase of the Spartan kit

- The Government of Canada has entered into a procurement contract with Spartan to secure supply of these kits. The contract is conditional on Health Canada's approval to sell the kits domestically.

Questions and answers

Q1. What is the Spartan kit and how does it work?
The Spartan screening kit consists of a portable analyzer called the Spartan Cube. The Cube tests Spartan's COVID-19 detection cartridges and proprietary swabs. The kit can diagnose COVID-19 in under an hour without having to send the sample to a laboratory.

Q2. Why didn't Health Canada wait for the results of the clinical trial before authorizing the sale of the Spartan kit?
The scientific review of the Spartan test kit was accelerated under the Interim Order announced on March 18, 2020.

Health Canada's regulatory decision was based on the kit's laboratory trials. The review considered that an additional verification would be conducted by public health laboratories to determine the kit's clinical performance. This complies with the approach adopted 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 ensure that it works well and gives accurate results. Based on the clinical results, Health Canada amended the product's authorization to limit the sale to research purposes only until the company could provide adequate evidence of the kit's clinical performance.

For more information on the Spartan kit's performance, contact the manufacturer.

Q3. Has the NML validation report been made public, or is it available on request?

On May 1, 2020, the NML presented Health Canada with its final report on the clinical trials conducted in three provinces (Alberta, Ontario and Manitoba) with the Spartan swabs for collecting samples directly from patients suspected of having COVID-19. The report is an internal working document created by the federal-provincial-territorial public health laboratory network across Canada. It cannot be made public because it contains confidential information.

Q4. Since May 2, 2020, has the company provided the department with evidence of clinical performance?

Health Canada has been working with Spartan while the company strives to meet the regulatory requirements to allow the use of the screening kit at points-of-care. On June 23, 2020, Health Canada authorized Spartan's clinical trial to evaluate the effectiveness of the Spartan system's various collection methods for COVID-19. The trial is focused on the screening kit and the system, which are currently being used for research purposes only.

Health Canada requested that Spartan send it a copy of the final study report once the clinical trial was complete. As of July 13, 2020, Health Canada had not received the study report.

Health Canada informed Spartan that it must conduct a second clinical trial to demonstrate the clinical effectiveness of the new type of swab identified in the first clinical trial. As of July 13, 2020, Health Canada had not received the second clinical trial application.