Media Lines

Amendments to the Authorization of the Spartan Test Kit

Issue. On April 11, Health Canada authorized Spartan Bioscience's test kit for COVID-19 under the Interim Order pathway. On May 1, the National Microbiology Laboratory provided Health Canada the results of its clinical validation of the Spartan kit. The report explains that while the Spartan Cube performed in a laboratory setting as per manufacturer specifications, there were performance issues identified during the clinical trial. These issues appear to be related to the proprietary swab, which may not collect sufficient mucosal material for testing. Health Canada has modified the conditions of its authorization to allow the product to be sold "for research use only." This means that effective May 2, 2020, authorized use of this device no longer includes testing patients for COVID-19.

Health Canada has asked the company to voluntarily recall its products to ensure they are not used in a diagnostic context for the time being. The company has agreed to do so. Health Canada has not cancelled the authorization, in recognition of the analytical performance of the device. The recall will be issued for a partial removal of the Spartan product from the market; it can continue to be sold for research purposes only.

Key messages

- On March 26, 2020, Health Canada issued a conditional authorization to Spartan Bioscience Inc. for its Spartan Cube for research use only.

- 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 the basis of minimum requirements.

- On April 11, 2020, Health Canada completed its scientific review to ensure the device met safety and effectiveness requirements. The authorization conditions were amended and the restriction on sales of the product for purposes other than research was lifted.

- Health Canada's regulatory decision was based on laboratory product testing rather than clinical data about its effectiveness. The review took into account the fact that subsequent clinical validation would be carried out in public health laboratories to determine the device's performance in the clinical setting. This is consistent with the approach taken by other trusted regulators.

- On May 1, 2020, the National Microbiology Laboratory (NML) provided Health Canada with a final report on clinical testing performed in three provinces (Alberta, Ontario and Manitoba) using Spartan swabs to collect specimens directly from patients under clinical conditions.

- The report stated that while the Spartan Cube performed in a laboratory setting as per manufacturer specifications, there were performance issues identified in the clinical trial. These issues appear to be related to the proprietary swab, which may not collect sufficient mucosal material for testing.

- In light of the clinical results, on May 2, 2020, Health Canada placed conditions on the company's authorization that restrict the use of the product to research use only, until adequate evidence of clinical performance can be provided.

- Health Canada has not cancelled the authorization, given evidence that the device performs well in laboratory settings. The Spartan device can continue to be sold for research purposes only until the company can provide data showing the device performs appropriately in a clinical setting.

- Health Canada will continue to work with Spartan while the company strives to meet the regulatory requirements that will allow the screening test to be used at the point of service.

If pressed on how many tests have been distributed following authorization of the test kits

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

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

- Health Canada has asked the company to voluntarily recall its products to ensure they are not used in a diagnostic context for the time being. The company has agreed to do so.

- On May 2, the Department sent the company a regulatory letter indicating the new authorization conditions, in accordance with section 6 of the Interim Order. The letter also sets out the steps to follow for the voluntary kit recall.

- Health Canada has restricted the sale of testing kits to research use only, until adequate evidence of clinical performance can be provided and assessed.

If pressed on the details of the recall

- The recall would include:
    - issuing an advisory to inform all customers of the risks associated with the use of the device for diagnostic purposes and steps to take to mitigate the risk;
    - requesting the recovery of all instruments and unused single use elements (e.g., reagents and swabs) from the non-laboratory-based environments and laboratory-based environments using this device for diagnostic purposes;
    - requesting the recovery of the swabs only from laboratories that will continue to use the device for research purposes.

If pressed on Health Canada's review of the Spartan product

- On March 26, 2020, Health Canada issued an authorization to Spartan Bioscience Inc. for its Spartan Cube with the condition that sales of the product be limited to research purposes only. The authorization was made under the Iterim Order for medical devices in the context of COVID-19, which enables Health Canada to authorize devices under an expedited scientific review process, on the basis of minimum requirements.

- On April 11, Health Canada completed its scientific review to ensure that the device was supported by evidence that it meets the requirements for safety and effectiveness. The conditions of the authorization were amended and the restriction on sales of the product for purposes other than research was lifted.

- Health Canada's regulatory decision was based on in-laboratory testing of the device and not on clinical trial data of its effectiveness. The review took into consideration that further clinical validation would be carried out by public health laboratories to determine performance in clinical settings. This is consistent with the approach taken by other trusted regulators.

- On May 1, 2020, the NML provided Health Canada with a final report on clinical testing performed in three provinces (Alberta, Ontario and Manitoba) using Spartan swabs to collect specimens directly from patients under clinical conditions. These clinical trials are essential, as they uncover performance issues that would not emerge in the laboratory. The report explains that while the Spartan Cube performed in a laboratory setting as per manufacturer specifications, there were performance issues identified during the clinical trial. These issues appear to be related to the proprietary swab, which may not collect sufficient mucosal material for testing. In light of the clinical results, Health Canada amended the conditions of its authorization in order to limit sales of the Spartan Cube to research purposes only, until the company can solve the kit's performance issues and provide data on device sales.

If pressed on the Public Health Agency of Canada's National Microbiology Laboratory (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 performs test validation and assesses the performance of diagnostic supplies such as COVID-19 testing kits.

- This test validation is part of scientific research and is independent of Health Canada's regulatory approval process. While this validation process is separate from Health Canada's authorization process, the NML is working in collaboration with Health Canada to share knowledge gained through the review process.

- The NML tests COVID-19 laboratory supplies for clinical diagnostic purposes to ensure they meet the gold standard used in public health laboratories. This validation process is to determine if the product can be used to obtain reliable and accurate results when diagnosing COVID-19.

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 Health Canada authorized for sale in Canada.

Questions and answers

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.

Could there be similar issues with other medical devices approved under the Interim Order?
Each product is reviewed individually based on its technology, and different requirements related to standards of evidence may be needed. Although we do not anticipate any problems at this time, Health Canada will not hesitate to take any required action should problems arise.

Were any test kits used to diagnose patients?
Spartan Bioscience has informed Health Canada that none of the tests was used for diagnostic purposes. As part of the voluntary recall requested by Health Canada, the company will again have to confirm that none of the kits was used for diagnostic purposes.

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 device was completed under expedited timelines as part of the Iterim Order announced on March 18, 2020.

Health Canada's regulatory decision was based on in-laboratory testing of the device and not on clinical trial data of its effectiveness. 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 these rapid test kits in the field to help ensure that they perform appropriately and deliver accurate results. In light of the clinical results, Health Canada has placed conditions on the company's authorization to restrict the use of the product to research use only, until adequate evidence of clinical performance can be provided.

For information on the performance of the Spartan device, please contact the manufacturer directly.