Lockington, Elliott (SPAC/PSPC)

From: Media <media@tpsgc-pwgsc.gc.ca>
Sent: October 7, 2020 5:52 PM
To: fitz-morris, James (SPAC/PSPC); Roy, Cecely (SPAC/PSPC)
Cc: Me'Shel Gulliver Bélanger; Elizabeth Lindsay; Bryan Blom; Jean-François Létourneau; Media
Subject: For PSPC FYI – CBC News (Exan Auyoung) - Rapid testing and approval process

Good evening James and Cecely,

Sharing the response below for info only. Health was planning to deliver the response at around 5:30 today. We've confirmed with them that we had no concerns.

Thanks,
JF
+++++

PSPC,

We plan to provide the responses below to CBC later today, following approvals.

Please contact us with any concerns **by 5:30pm**, if possible.

Thanks,
André

***

Reporter/Outlet: CBC News (Exan Auyoung)

Date Received: October 6

Deadline to Reporter: October 7

Impact: MEDIUM (2)

Complexity: MEDIUM (2)

Questions and Responses:

Q1. Why has approval for rapid tests been so slow, some of which have long been approved by other countries, including the FDA?

The health and safety of Canadians is the Government's utmost priority. Before any test is authorized for use in Canada, it is subject to a thorough assessment through Health Canada's regulatory process to ensure it is supported by sufficient evidence of safety, effectiveness and quality.

Canada and the U.S. have different rules and approval processes. Each regulator reviews applications against different criteria or requirements. Health Canada's consistent approach throughout the pandemic has ensured that the testing devices available for sale in Canada have been accurate and reliable, and we have avoided some of the challenges other countries have experienced with lower-quality tests. The department has proactively contacted numerous manufacturers of tests authorized in the U.S. to seek their interest in entering the Canadian market.

Health Canada reviews all COVID-19-related submissions under the Interim Order as quickly as possible, without compromising patient safety. On October 5, Health Canada authorized the Abbott Panbio antigen test kit for COVID-19 diagnosis. It is the first antigen test kit authorized by Health Canada.

Q2. What is Health Canada's stance on tests that don't involve medical practitioners?

A2- Health Canada welcomes new technology and will prioritize applications for all types of test kits. Point-of-care diagnostic devices allow testing to occur in alternative healthcare settings and do not require shipping a specimen to a lab for analysis. This allows for quicker test results for patients. Quicker test results enable healthcare providers and patients to take appropriate actions, such as treating, contact tracing and isolating positive patients more rapidly to help reduce the spread of the disease.

Health Canada authorizes testing devices based on the information that is provided to us. For example, if a company provides evidence that trained operators who are not medical practitioners can use the device appropriately and obtain accurate results, then Health Canada can authorize that device for use by trained operators. If Health Canada only receives evidence that healthcare professionals can use the device appropriately, then the indications for use will be limited to health care professionals.

Q3. What standards is Health Canada basing their approvals on with antigen/rapid tests?

Health Canada is the exclusive regulator of testing devices in Canada. In order to support manufacturers of antigen tests, Health Canada has consistently invited them to consult the US FDA guidance on antigen tests. This guidance provides manufacturers with information on the types and quantity of data that Health Canada would need to receive in order to be able to evaluate an application for authorization of an antigen test. Additionally, on September 29, Health Canada published its own guidance on antigen tests, clarifying the minimum requirement for sensitivity of antigen tests. This minimum requirement is the same as the one used by the US Food and Drug Administration (FDA).

This additional clarification improves the transparency of Health Canada's considerations, and gives additional direction to manufacturers who are developing new testing technologies. The alignment with the minimum set by the US FDA also continues to allow Health Canada to facilitate the submission of devices authorized by the US FDA, so as to encourage those companies to bring their products to the Canadian market.

Q4. How does Health Canada define accuracy?

On September 29, Health Canada published information for industry on the minimum sensitivity requirements that must be met when seeking authorization for COVID-19 antigen tests. Sensitivity is a measure of the diagnostic accuracy of a test.

Q5. What is Health Canada's stance when it comes to the importance of test sensitivity versus speed and its capacity to recognize a viral load indicating when a person is contagious?

A5- Health Canada welcomes new technology and will prioritize applications for all types of test kits.

Although the process is expedited, a medical device is authorized only after a scientific assessment by Health Canada reviewers to ensure that it is supported by evidence showing it meets standards for safety and effectiveness. Health Canada's consistent approach throughout the pandemic has ensured that the testing devices available for sale in Canada have been accurate and reliable. Health Canada is committed to ensuring that tests are safe and effective while working as quickly as possible to authorize testing technologies.

Recently, Health Canada published guidance to industry indicating that we have determined a minimum required sensitivity for antigen testing devices of 80%. This minimum is aligned with the US FDA requirement.

This required minimum sensitivity is reflective of Health Canada's recognition that Canadian testing strategies may support the use of tests with different sensitivities and limits of detection in different

contexts. Health Canada is supporting these strategies—in addition to helping to avoid supply shortages—by authorizing a range of tests.

Q6. In light of many public health units' inability to contact trace overwhelming numbers (ie; TPH's recent announcement they are suspending contact tracing outside of outbreaks) and the need for Ontario to send swabs to California due to lab backlog, can we expect to see more antigen tests approved sooner than later?

A6 - The Government of Canada understands the importance of increasing testing capacity as early diagnosis is critical to slowing and reducing the spread of COVID-19 in Canada. This is why Health Canada reviews all types of COVID-19 tests, including new, innovative testing options and technologies.

Health Canada is taking all steps available to us as a regulator to give Canadians and our health system access to as many testing options as possible, as quickly as we can, without compromising safety.

André Gagnon
Media Relations Advisor | Conseillère des relations avec les médias
Serving Health Canada and the Public Health Agency of Canada | Au service de Santé Canada et de l'Agence de la santé publique du Canada
Government of Canada | Gouvernement du Canada
(m) 613-462-2571
(e/ce) andre.gagnon@canada.ca