Media Lines

Authorizations for 3D-printed swabs under the *Interim Order respecting the importation and sale of medical devices for use in relation to COVID-19*

Issue Statement: On June 23, 2020, Health Canada authorized the CANSWAB 3D-printed nasopharyngeal swab. No purchase contracts are in place yet; however, the company expects to deliver hundreds of thousands of these devices by fall 2020 to support the response to COVID-19.

The authorization will be published on Health Canada's list of approved medical devices on July 2, 2020 (tbd). ISED is planning to announce the authorization on July 2 (TBC) and will share its announcement materials with Health Canada for review. Media calls are expected.

Key Messages:

- In response to the COVID-19 pandemic, Health Canada continues to authorize medical devices under an expedited regulatory review process.
- On June 23, 2020, Health Canada authorized the CANSWAB 3D-printed nasopharyngeal swab. This is the first 3D-printed swab authorized by Health Canada.
- The CANSWAB will be used by healthcare professionals to collect samples from patients for COVID-19 diagnosis. The swab is a clear, flexible and slender rod with a texturized bristled tip for specimen collection.
- The swab was authorized under the Interim Order for COVID-19 medical devices, which enables Health Canada to authorize devices under an expedited scientific review process. The swab has not been authorized in any other country to date.
- 3D-printed devices must meet the same criteria for safety, quality and effectiveness as devices manufactured through other means. Health Canada determined that the CANSWAB met these requirements under the Interim Order process.
- A list of devices authorized through this Interim Order is available at: https://www.canada.ca/en/health-canada/services/drugs-health-products/covid19-industry/medical-devices/authorized/other.html
- Health Canada continues to monitor the safety, quality, and effectiveness of all medical devices for use in the diagnosis, treatment, mitigation and prevention of COVID-19 once they are on the market. As with all medical devices, manufacturers must follow strict post-market safety requirements, such as mandatory problem reporting, recall procedures and complaint handling.

If pressed on ISED's role

- Innovation, Science and Economic Development Canada and Public Services and Procurement Canada continue to actively support Canadian industries to increase domestic manufacturing capacity, including re-tooling facilities to produce equipment and supplies including ventilators, surgical masks and testing kits.

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- Through these efforts, the Government of Canada continues to sign new procurement agreements with Canadian companies that can provide urgently needed equipment.

- Throughout this process, the Public Health Agency of Canada, Health Canada and the National Research Council of Canada are playing critical roles, conducting technical reviews to verify that the products meet the Government of Canada technical specifications for COVID-19 as available on the Public Services and Procurement Canada's buy and sell website.

If pressed on the company

- The swabs are manufactured by Precision ADM, an engineering and manufacturing company headquartered in Winnipeg, Manitoba.

- This is Precision ADM's first Interim Order Authorization in Canada.

If pressed on the role of the National Research Council

- In May 2020, the National Microbiology Laboratory (NML) transferred verification testing of swabs to the National Research Council.

- Assessment criteria are based on existing guidelines from Health Canada and the United States Centers for Disease Control and Prevention.

- The testing process includes:
  - assessing the swab for comfort and mechanics (i.e., is it suitable to insert in someone's nose without harming them);
  - determining whether the swab can collect and release sufficient quantity of virus compared to the gold standard NML Laboratory swab; and
  - providing feedback to companies in real time.

Questions and Answers

Q1. Is 3D printing a safe way to manufacturer medical devices?
Yes. Health Canada has previously approved other 3D-printed medical devices, including face shields.

In April 2019, Health Canada issued guidance for industry on manufacturing 3D-printed implantable medical devices, which offer greater customization than standard manufacturing. The guidance specifies that the same evidence requirements apply to 3D-printed devices as those for non-3D printed devices in terms of their characterization and evidence of safety and effectiveness, including physical and mechanical bench testing, biocompatibility testing, software validation and clinical evidence.