**Health Canada's response to a request for information made by the Standing Committee on Government Operations and Estimates (OGGO) on May 22, 2020**

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**Question:**

**Mrs. Kelly block:** It's my understanding that the Government of the Northwest Territories is recalling defective KN95 masks. Did these come from supplies purchased by the federal government?

**Hon. Patty Hajdu:** No, they did not.

**Mrs. Kelly Block:** Well, then they must have come from a supplier which the Government of the Northwest Territories purchased based on a medical device establishment licence, granted to a supplier by your department. What is the name of the company that held the MDEL that sold the masks to the Government of the Northwest Territories?

**Hon. Patty Hajdu:** I don't have the precise name. I don't know if officials know the name of the distributor. We can follow up.

**Mrs. Kelly Block:** Thank you very much for that.

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Health Canada contacted the Government of the Northwest Territories (GNWT) and followed up with their supplier of recalled KN95 masks, 213 Advisory Inc., to verify that the company has taken appropriate action in accordance with regulatory requirements.. This file is now closed and the company name has been added to Health Canada's list of recalled respirators (https://healthycanadians.gc.ca/recall-alert-rappel-avis/hc-sc/2020/73137a-eng.php).

The Department continues to follow-up with any company that has imported or distributed respirators that do not meet their labelled filtration standards. These products must be re-labelled as face masks instead of respirators, for use in settings where a 95% filtration rate is not required. According to the *Medical Devices Regulations*, re-labelling of a medical device that has been sold and fails to conform to claims relating to its effectiveness is considered a recall. Health Canada assesses the recall documentation submitted by companies to ensure that it is complete and compliant with regulatory requirements.

Health Canada's list of recalled respirators to date (https://healthycanadians.gc.ca/recall-alert-rappel-avis/hc-sc/2020/73137a-eng.php) is updated as required, on a weekly basis. Manufacturers whose products failed NIOSH testing or testing undertaken for the Public Health Agency of Canada are included on the list, along with the name of the product and any distributors or importers that have confirmed to be importing the product and submitted recall documentation to Health Canada as required by the regulations.

Health Canada will continue to take action to ensure that any company that has imported or distributed respirators that do not meet filtration standards recalls/re-labels the products as face masks for use in settings where a 95% filtration is not required.

**Question:**

**Mr. Ziad Aboultaif (Edmonton Manning, CPC):** Many of the KN95 masks on Canada's recall list were tested by the CDC as early as April 13 and had filtration rates as low as 20%, which is significantly lower than Canada's 95% requirement. Why did we okay these suppliers?

**Dr. Stephen Lucas:** We became aware of the USFDA's revised guidance on May 7, enacted rapidly to assess that, and issued on May 10. We contacted the medical device's establishment holders to indicate that the labelling needed to be changed. We issued a public advisory on May 11 and on May 9 we cancelled the authorization to one company in regard to the N-95 mask. That's the chronology of our work.

**Mr. Ziad Aboultaif:** Three of the suppliers were found to be counterfeit by CDC. Can you name those three suppliers?

**Dr. Stephen Lucas:** I don't have the specific supplier names here. When information comes to us on false claims for counterfeit materials our compliance and enforcement officers work on it immediately and take appropriate action including referral to law enforcement officers.

**Mr. Ziad Aboultaif:** If I understand correctly from your answer basically you don't know the names of these three suppliers and there could be more out there.

How are you tracking those counterfeit PPEs?

**Dr. Stephen Lucas:** That's not what I said. What I said is as information comes to our knowledge, be it information in Canada or from another country we act on it immediately in terms of identifying the supplier issuing the appropriate compliance and enforcement action. If there's non-compliance then it's referred to law enforcement officers.

In terms of specific company names I will follow up with our compliance and enforcement organization to provide that information if it's in the public domain.

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During these uncertain times, it is important that Canadians have the latest information on how to remain safe and healthy. With this in mind, Health Canada regularly assesses, reviews, and monitors the use and performance of medical devices in Canada.

In response to information that imported KN95 masks were not meeting appropriate standards, the Department communicated to all MDEL holders to warn about fraudulent products and to determine if such products had been imported into Canada.

We will continue to inform licence holders of their regulatory obligations to verify product quality and authenticity of devices as well as provide information and resources to support this effort. As part of its ongoing compliance monitoring activities, Health Canada frequently

informs and reminds licence holders to regularly monitor the Department's online list of respirators that have been found to fail performance standard testing, as well as international guidance on detecting fraudulent products.
Health Canada uses all sources of information available, including information from the CDC and other international regulators. The CDC regularly updates its website to add new suppliers of potential counterfeit respirators and as such it is not possible to determine which three suppliers Mr. Ziad Aboultaif was referring to.

Further, Health Canada conducts inspections and assessments of shipments at the border to identify suspected fraudulent products such as N95 and KN95 respirators.

In regards to concerns that Canadians may have unknowingly purchased fraudulent health products, Health Canada issued an advisory on April 14 to warn the public about potential counterfeit respirators: https://healthycanadians.gc.ca/recall-alert-rappel-avis/hc-sc/2020/72707a-eng.php. On July 6, the Department issued a subsequent advisory to remind Canadians about the risks of counterfeit products and actions taken to prevent their sale in Canada. This advisory includes a list of counterfeit products that will be updated when new products are identified: https://healthycanadians.gc.ca/recall-alert-rappel-avis/hc-sc/2020/73493a-eng.php.

Should any counterfeit product be identified in Canada, Health Canada will take immediate action. Examples of such compliance and enforcement measures include product seizures, recalls or licence suspensions. Should there be concerns regarding the public's use of such products, we will continue to inform Canadians.

**Question:**

**Ms. Kelly Block:** Minister, personal protective equipment made by the Guangdong Golden Leaf Technology Development Co. has been delisted by the CDC. Why is this company allowed to sell PPE in Canada, or why have they been?

**Hon. Patty Hajdu:** Thanks to the member I'll have to follow-up on that question.

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PPE and medical supplies that are received by the government – whether donated or procured by PSPC – are verified to ensure they meet appropriate standards for use. However, some KN95 masks imported into Canada by medical device companies and individuals may not have been tested.

Health Canada was made aware of concerns regarding personal protective equipment made by the Guangdong Golden Leaf Technology Development Co. Upon learning of these issues, the Department reached out to counterparts at the US FDA to obtain more information and coordinate approaches.

In response to quality concerns, manufacturers of Chinese respirators that had not been tested by CDC NIOSH were given up to 45 days to do so. The Guangdong Golden Leaves Technology Development Co., Ltd. KN95 respirators successfully met the NIOSH requirements and are now back on the CDC's list, which can be accessed at: https://www.cdc.gov/niosh/npptl/respirators/testing/NonNIOSHresults.html?from=groupmessage&isappinstalled=0

Following concerns raised with certain KN95 masks, Health Canada reviewed all of the interim order approvals related to KN95s, including the one issued for the Guangdong Golden Leaves. In May, the Department sent a letter to the company to request additional information about their product. Since then, Health Canada has received sufficient evidence to support this company's authorization, including proof of quality manufacturing and validated test results from independent and accredited testing facilities. As such, the authorization is in effect.

Due to concerns with certain KN95 models, we are now requiring independent testing data for all new KN95 device approvals under the Interim Order.

**Question:**

**Mr. Kelly McCauley:** Let me ask you. Of the 11 million masks, the N95 that have come in so far, about 9 million give or take have been found faulty, substandard or poor filtration. We've heard they could be used otherwise for perhaps surgical masks or other issues.

Who is deciding what they can actually be used for? We've heard conflicting information from the Prime Minister.

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Health Canada is committed to ensuring that the medical devices available to Canadians meet the necessary safety and effectiveness standards. The Department has contacted companies that may be importing or distributing certain respirators, including KN95 respirators that may not meet expected performance standards in Canada to request that they stop sale and relabel the products as face masks instead of respirators.

Health Canada provided guidance on their website (https://healthycanadians.gc.ca/recall-alert-rappel-avis/hc-sc/2020/73063a-eng.php) indicating that the N95 respirators and equivalent respirators (such as the KN95) that may not meet the standards required for frontline healthcare workers could be used as face masks in settings where a 95% filtration rate is not needed.

Health Canada advised that provincial and territorial health authorities and healthcare institutions should review their inventories of KN95 respirators to confirm that they meet the Government of Canada technical specifications for healthcare settings for COVID-19 response.

Canadians using these masks outside healthcare settings can continue to do so. They should report any health product adverse events to Health Canada.