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

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 has been in contact with the Government of the Northwest Territories (GNWT) and is following up with their supplier of recalled KN95 masks to verify that the company has taken appropriate action in accordance with regulatory requirements. Given that this is an active file, the Department is not able to provide additional details at this time.

As a matter of practice, Health Canada does not provide details regarding ongoing compliance verification cases. Health Canada is following its standard process to verify that the supplier has taken appropriate action in accordance with regulatory requirements. If it is confirmed that the company sold products that were subject to the recall, the Department will verify that the company complies with regulatory requirements related to the recall and then post the recall information on the Health Canada website. The company information would be publicly available at that time.

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 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.

A list of all recalled respirators to date is posted on the Health Canada website (https://healthycanadians.gc.ca/recall-alert-rappel-avis/hc-sc/2020/73137a-eng.php) and will be updated as required, on a weekly basis. Manufacturers whose products failed NIOSH testing 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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Health Canada uses all sources of information available, including the CDC website, and conducts inspections and assessments of shipments at the border to identify suspected fraudulent products such as N95 and KN95 respirators.

Health Canada has communicated about fraudulent products to all MDEL holders and will continue to inform licence holders of their regulatory obligations to verify product quality and authenticity of devices as well as monitor the CDC website, which has extensive tools and resources on detecting fraudulent product.

The Department also issued a public 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.

Health Canada will take action should any counterfeit product be identified in Canada and advise Canadians if needed. Examples of potential actions may include product seizures, recalls or licence suspensions.

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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The Department has sufficient evidence on file to support this authorization (i.e. quality manufacturing and validated test results from independent testing facilities) so the authorization is in effect.

Health Canada reached out to counterparts at the US FDA. 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 https://www.cdc.gov/niosh/npptl/respirators/testing/NonNIOSHresults.html?from=groupmessage&isappinstalled=0

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 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.

Additional Information for the Committee

For greater clarity on the Health Canada Deputy Minister's response to a question on re-labelling of personal protective equipment during the OGGO meeting on May 22, 2020, we would like to provide the following additional details:

In light of recent international criticism concerning medical supplies and PPE exported from China, Chinese authorities have introduced a series of measures to ensure the quality of the PPE it exports. As of April 1, 2020, PPE must comply with Chinese national and/or foreign standards, amongst other things. These new measures are enforced by Chinese Customs authorities, at the point of export. This has culminated in a joint declaration requirement that must be signed by both the exporter and the importer (e.g., PHAC) before the product can leave China, as well as new labeling requirements for select products.

The joint declaration stipulates that the product meets the standards and certification requirements of the destination country; however, for products that are not certified as medical devices in China, the joint declaration must also specify that the item is "not for medical use" even if it meets Canada's technical specifications for healthcare settings.

The resulting outcome of this attestation is that products not medically certified in China must be labeled in Simplified Chinese as "not for medical use". This labelling has been found both on the outer shipping boxes and inside each of the individual product packages as paper inserts and in some cases an ink stamp.

Once received in Canada, PHAC does not plan to remove labels inserted into each individual product stating “not for medical use” in Simplified Chinese. To do so would significantly delay distribution and in some cases, destroy the integrity of packaging. Instead, PHAC will label the outer shipping boxes with a confirmation of quality and any instructions for use prior to distribution to provinces and territories. This labeling approach is as advised by Health Canada.

If PHAC cannot account for the quality, it will not be allocated to the provinces and territories for frontline healthcare response. Supplies that do not meet specifications are subsequently assessed for potential for use in non-healthcare settings.