Kim, Sabrina

From: Kim, Sabrina
Sent: Saturday, May 23, 2020 10:29 AM
To: Halucha, Paul
Subject: Fwd: Heads-up: Communications for recall of K95 masks

20 MDEL holders based off U.S. list

Sabrina Kim
Issues Advisor
Office of the Prime Minister
613-795-7803

Begin forwarded message:

> **From:** "Kye, Suzanne" <Suzanne.Kye@pco-bcp.gc.ca>
> **Date:** May 10, 2020 at 10:34:34 PM EDT
> **To:** "Kim, Sabrina" <Sabrina.Kim@pmo-cpm.gc.ca>, "MacKillop, Ken" <Ken.MacKillop@pco-bcp.gc.ca>
> **Cc:** Belliveau, Sébastien <Sebastien.Belliveau@pmo-cpm.gc.ca>, "Stickney, Matt" <Matt.Stickney@pmo-cpm.gc.ca>, "Mondou, Isabelle" <Isabelle.Mondou@pco-bcp.gc.ca>, "Deagle, Jordan" <Jordan.Deagle@pmo-cpm.gc.ca>, "Trogen, Emily" <Emily.Trogen@pmo-cpm.gc.ca>, "MacKendrick, Andrew" <Andrew.MacKendrick@pmo-cpm.gc.ca>, "Theis, Rick" <Rick.Theis@pmo-cpm.gc.ca>, "Khalil, Samantha" <Samantha.Khalil@pmo-cpm.gc.ca>, "Gagnon, Chantal" <Chantal.Gagnon@pmo-cpm.gc.ca>, "Ahmad, Cameron" <Cameron.Ahmad@pmo-cpm.gc.ca>, "Travers, Patrick" <Patrick.Travers@pmo-cpm.gc.ca>, "Lamothe, Colleen" <Colleen.Lamothe@pmo-cpm.gc.ca>, "Tessier, Jean" <Jean.Tessier@pco-bcp.gc.ca>, "Samaan, Valerie" <Valerie.Samaan@pco-bcp.gc.ca>, "Massabki, Myriam" <Myriam.Massabki@pco-bcp.gc.ca>, "O'Nions, Christine" <Christine.O'Nions@pco-bcp.gc.ca>, "Patterson, Adine" <Adine.Patterson@pco-bcp.gc.ca>, "Gagnon, Patricia" <Patricia.Gagnon@pco-bcp.gc.ca>, "Jones, Murray" <Murray.Jones@pco-bcp.gc.ca>, "Paxton, Taylor" <Taylor.Paxton@pco-bcp.gc.ca>
> **Subject: RE: Heads-up: Communications for recall of K95 masks**
>
> Hi Sabrina,
>
> To loop back on your question, yes, you are correct, it is 65 manufacturers and out of that 20 of them are MDEL holders. Hope to have the advisory and accompanying comms products to you tomorrow.
>
> Thanks,
> Suzanne
>
> ---
>
> **From:** Kim, Sabrina <Sabrina.Kim@pmo-cpm.gc.ca>
> **Sent:** Sunday, May 10, 2020 1:52 PM
> **To:** MacKillop, Ken <Ken.MacKillop@pco-bcp.gc.ca>
> **Cc:** Belliveau, Sébastien <Sebastien.Belliveau@pmo-cpm.gc.ca>; Kye, Suzanne <Suzanne.Kye@pco-bcp.gc.ca>; Stickney, Matt <Matt.Stickney@pmo-cpm.gc.ca>; Mondou, Isabelle <Isabelle.Mondou@pco-bcp.gc.ca>; Deagle, Jordan <Jordan.Deagle@pmo-cpm.gc.ca>; Trogen, Emily <Emily.Trogen@pmo-cpm.gc.ca>; MacKendrick, Andrew <Andrew.MacKendrick@pmo-cpm.gc.ca>; Theis, Rick <Rick.Theis@pmo-cpm.gc.ca>; Khalil, Samantha <Samantha.Khalil@pmo-cpm.gc.ca>; Gagnon, Chantal <Chantal.Gagnon@pmo-cpm.gc.ca>; Ahmad, Cameron <Cameron.Ahmad@pmo-cpm.gc.ca>; Travers,

Patrick <Patrick.Travers@pmo-cpm.gc.ca>; Lamothe, Colleen <Colleen.Lamothe@pmo-cpm.gc.ca>; Tessier, Jean <Jean.Tessier@pco-bcp.gc.ca>; Samaan, Valerie <Valerie.Samaan@pco-bcp.gc.ca>; Massabki, Myriam <Myriam.Massabki@pco-bcp.gc.ca>; O'Nions, Christine <Christine.O'Nions@pco-bcp.gc.ca>; Patterson, Adine <Adine.Patterson@pco-bcp.gc.ca>; Gagnon, Patricia <Patricia.Gagnon@pco-bcp.gc.ca>; Jones, Murray <Murray.Jones@pco-bcp.gc.ca>; Paxton, Taylor <Taylor.Paxton@pco-bcp.gc.ca>
Subject: Re: Heads-up: Communications for recall of K95 masks

Hello,

One clarification question - is it 105 manufacturers in China that may have produced respirators that don't meet standards or is the number smaller? It says 105 below however we are told from HC MinO that it may be 65 manufacturers.

- MDEL holders will be required to issue a letter to customers (e.g. could be hospitals or other customers) by end of day on May 12, informing them **that the KN95 respirators from 105 manufacturers in China may not provide consistent and adequate respiratory protection to healthcare personnel** exposed to COVID-19 and that they can continue using the masks as medical masks or commercial masks instead of medical respirators, where a 95% filtration is not needed.

Thank you!
Sabrina

Sabrina Kim
Issues Advisor
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On May 9, 2020, at 2:11 PM, MacKillop, Ken <Ken.MacKillop@pco-bcp.gc.ca> wrote:

> Adding DM Mondou
>
> ---
>
> **From:** Belliveau, Sébastien <Sebastien.Belliveau@pmo-cpm.gc.ca>
> **Sent:** May 9, 2020 2:10 PM
> **To:** Kye, Suzanne <Suzanne.Kye@pco-bcp.gc.ca>; Stickney, Matt <Matt.Stickney@pmo-cpm.gc.ca>
> **Cc:** Deagle, Jordan <Jordan.Deagle@pmo-cpm.gc.ca>; Trogen, Emily <Emily.Trogen@pmo-cpm.gc.ca>; MacKendrick, Andrew <Andrew.MacKendrick@pmo-cpm.gc.ca>; Theis, Rick <Rick.Theis@pmo-cpm.gc.ca>; Khalil, Samantha <Samantha.Khalil@pmo-cpm.gc.ca>; Kim, Sabrina <Sabrina.Kim@pmo-cpm.gc.ca>; Gagnon, Chantal <Chantal.Gagnon@pmo-cpm.gc.ca>; Ahmad, Cameron <Cameron.Ahmad@pmo-cpm.gc.ca>; Travers, Patrick <Patrick.Travers@pmo-cpm.gc.ca>; Lamothe, Colleen <Colleen.Lamothe@pmo-cpm.gc.ca>; Tessier, Jean <Jean.Tessier@pco-bcp.gc.ca>; MacKillop, Ken <Ken.MacKillop@pco-bcp.gc.ca>; Samaan, Valerie <Valerie.Samaan@pco-bcp.gc.ca>; Massabki, Myriam <Myriam.Massabki@pco-bcp.gc.ca>; O'Nions, Christine <Christine.O'Nions@pco-bcp.gc.ca>; Patterson, Adine <Adine.Patterson@pco-bcp.gc.ca>; Gagnon, Patricia <Patricia.Gagnon@pco-bcp.gc.ca>; Jones, Murray <Murray.Jones@pco-bcp.gc.ca>; Paxton, Taylor <Taylor.Paxton@pco-bcp.gc.ca>
> **Subject:** Re: Heads-up: Communications for recall of K95 masks

Adding Matt.

Sent from my iPhone

On May 9, 2020, at 2:05 PM, Kye, Suzanne <Suzanne.Kye@pco-bcp.gc.ca> wrote:

Good afternoon PMO,

A heads-up that Health Canada is advising Canadians that it has requested importers and distributors issue voluntary recalls of certain KN95 respirators. This follows regulatory action by the U.S. Food and Drug Administration (FDA) to revoke authorization of some KN95 and KP95 masks manufactured in China in response to concerns about their safety and quality. Many products currently being sold in the United States do not meet filtration standards, as per their labelling.

As per usual practice, the recall will be posted on the Health Canada recall database (date TBC). MLs and a Public Advisory are being prepared. The Public Advisory would notify healthcare professionals not to use the recalled masks to protect themselves from COVID-19 in situations requiring 95% filtration. It would also note that the recalled masks could be used as surgical or procedural masks in low-risk situations or in non-medical settings where less high filtration standards are needed. Health Canada web content on the use of masks and respirators during the COVID-19 outbreak would be updated to reflect these changes.

Health Canada will provide a heads-up to provinces and territories before any public communication.

Sequencing of events:

- Letters to be sent to the 63 MDEL holders within the next 24 hours (timing: May 10, TBC).
- Heads-up to be provided to PTs (timing: May 10, TBC).
- Official recall notice to be posted on the Recalls and Safety Alerts database (timing: May 10, TBC).
- Public Advisory issued informing Canadians of this recall (timing: May 10, TBC).
- Web content to be updated to reflect these changes (timing: May 10 or 11, TBC).

Will keep you posted on the communications products as they move.

Thank you,
Suzanne

MORE CONTEXT:

Non-NIOSH Approved Disposable Filtering Facepiece Respirators Manufactured in China

- On May 7, 2020 the United States Food and Drug Administration (FDA) reduced the number of FDA-approved manufacturers of Non-NIOSH Approved Disposable Filtering Facepiece Respirators Manufactured in China.

- The list was originally posted on April 3, 2020 under an Emergency Use Authorization (EUA) in order to facilitate access to Filtering Facepiece Respirators (FFR), including for KN95 FFRs, in order to support the COVID-19 pandemic response in the U.S. The testing was done by one of the testing laboratories within the National Institute of Occupational Health and Safety (NIOSH), and included 105 manufacturers of FFR. The manufacturers identified did not pass filtration testing requirements.

- Health Canada has verified its licenses and authorizations against the same list of 105 manufacturers and has found the following:
  - 1 manufacturer has been authorized through the Interim Order for Exceptional Importation and Sale; and
  - 63 Medical Device Establishment Licence (MDEL) holders have indicated to Health Canada on their license application that they are importing or distributing products from one or more of the manufacturers tested by NIOSH and may be importing FFR. It is important to note that while MDEL holders have identified one or more of the manufacturers on their MDEL applications, it is possible they have not imported or distributed these masks.

- A letter was sent to the one implicated company with an IO authorization (Senke) on May 8 to cancel its authorization and note next steps related to the recall of their respirator. Letters may also be issued to the 5 other companies authorized under the IO, requesting testing data from an independent lab on the efficacy of their KN95 masks.

- MDEL holders will be sent a letter on May 10, asking them to immediately stop sale and relabel their KN95 respirators as:
  a. medical masks (not respirators) that can be distributed to healthcare settings, where a filtration of 95% is not needed; or
  b. commercial masks distributed to non-healthcare settings, where a filtration of 95% is not needed.

- MDEL holders will be required to issue a letter to customers (e.g. could be hospitals or other customers) by end of day on May 12, informing them that the KN95 respirators from 105 manufacturers in China may not provide consistent and adequate respiratory protection to healthcare personnel

exposed to COVID-19 and that they can continue using the masks as medical masks or commercial masks instead of medical respirators, where a 95% filtration is not needed.

- MDEL holders wishing to continue selling the identified products as medical respirators will be informed they can apply for an authorization under Health Canada's Interim Order for Importation and Sale. Independent laboratory performance testing results would be required to accompany the submission to demonstrate the respirators' effectiveness.

- The letter to MDEL holders will be sent to the 63 identified as possibly importing KN95s from the implicated manufacturers on May 10, 2020 and they will be required to send full recall plans to Health Canada by end of day May 14, 2020. Health Canada inspectors will follow-up to ensure effectiveness and completion of the recall as per normal procedures.

- An MDEL Bulletin will also be issued on May 10, 2020, to all MDEL holders to advise them of the recall and to proactively prevent further importation and sale of these products. Similarly, a bulletin will be issued to all medical device Submission Number holders to identify any possible importing from implicated manufacturers, which would be subject to recall requirements.

Suzanne Kye
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