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Sent:	May 1, 2020 2:15 PM
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Subject:	Media Heads-Up - Tier 1 / COVID-19 - Importation of personal protective equipment / CBC News (Regina)

The following media request has been identified as **Tier 1**.

Communications sector will work with your group to develop the first draft response. New information not previously approved should be identified in purple.

Highest level of approval: MO
Program ADM approved response: May-04-20 at 17:00

Media heads-up
CBC News (Regina)
Leo, Geoff (CBC News (Regina))
Date call received: May-01-20 at 14:00
Deadline: May-05-20 at 17:00
Tier 1 - COVID-19 - Importation of personal protective equipment

CONTEXT (for your information):

The reporter is working on a story about Ottawa's decision to allow the importation of medical devices like masks, gowns and gloves that don't meet Health Canada's standards. The story is based on the "Interim order respecting drugs, medical devices and foods for a special dietary purpose in relation to COVID-19." The reporter understands that because of the "unprecedented and urgent need for access to medical devices during the COVID-19 pandemic," the government has decided to allow "certain medical devices that may not fully meet regulatory requirements to be imported and sold in Canada." An explanatory note indicates that the devices, while not meeting Canada's standards must have been "manufactured according to comparable standards." The order flows from the minister's authority to take immediate action "to deal with a significant risk, direct or indirect, to health safety or the environment."

Health Canada says the global shortage of some key supplies is being exacerbated by individuals stockpiling and an increased global demand putting pressure on manufacturers and distributors. It says the interim order will "allow the exceptional sale of an unapproved medical device ... when the product is needed to respond to a shortage." It also says that list will be maintaining "up-to-date lists of the drugs, medical devices, and foods eligible for this exceptional importation pathway on Health Canada's website."

The reporter also notes that the government has imposed "a new requirement for manufacturers of medical devices considered to be critical during the COVID-19 pandemic to notify the Minister about shortages of those medical devices" which will help the minister determine which products should receive exceptional approval.

Health Canada says it consulted governments and industry about this but it doesn't specify precisely who was consulted and that "broad stakeholder consultation was not possible" because of the urgent nature of this decision. Since April 10, the government has begun approving specific products of specific manufacturers for importation and sale in Canada; the vast majority are from China. There are a wide range of approved products from gloves to face masks to N95 respirators to ventilators to gowns, etc.

The Public Health Agency of Canada will answer questions one through three on its end. Public Services and Procurement Canada will only answer questions four through six.

References:
Exceptional importation and sale of medical devices in relation to COVID-19: Overview
https://www.canada.ca/en/health-canada/services/drugs-health-products/compliance-enforcement/covid19-interim-order-drugs-medical-devices-special-foods/medical-device-exceptional-import.html

List of Medical Devices - Notification of Shortages
https://www.canada.ca/en/health-canada/services/drugs-health-products/medical-devices/shortages/covid19-mandatory-reporting.html

List of Medical Devices for Exceptional Importation and Sale
https://www.canada.ca/en/health-canada/services/drugs-health-products/compliance-enforcement/covid19-interim-order-drugs-medical-devices-special-foods/medical-device-exceptional-import/list.html#wb-auto-5

VALUE STATEMENT:

QUESTIONS AND ANSWERS:

Q1. When Health Canada says it is approving devices "that may not fully meet regulatory requirements" what requirements specifically is it willing to set aside or have lowered? Stakeholders I've spoken with about this note "the devil is in the details" and they say Ottawa owes an explanation as to what standards it is prepared to let slide.

The Public Health Agency of Canada will respond directly to the reporter.

Q2. I note that this interim order was in place on March 30 and by April 10 some products and manufacturers were already approved. That seems fast. Please explain the way in which the approval/auditing process has been expedited, streamlined or fast tracked to approve medical

devices so swiftly. Please describe how this "exceptional" process differs from the standard process.

The Public Health Agency of Canada will respond directly to the reporter.

Q3. Has Health Canada ever introduced an expedited process (exceptional importation) like this in its history? If so tell me about that.

The Public Health Agency of Canada will respond directly to the reporter.

Q4. Have these manufacturers been vetted by Deloitte or any other agent of the government of Canada before being added to this list? If not, will these companies be vetted before they receive purchase orders?

Q5. Of the 27 companies on the "List of Medical Devices for Exceptional Importation and Sale," how many have received orders from the government of Canada for personal protective equipment? Does the fact these companies are on this list indicate merely that they have been approved to bring in these products or does it mean they have received an order for these products?

Q6. As I understand it, Deloitte is not currently attempting to procure personal protective equipment right now; there has been a hold on procurement of personal protective equipment items for a week or more. Please explain why that is. Why would the company leading our procurement efforts to acquire vital and scare personal protective equipment be told to stop acquiring personal protective equipment?