COVID-19 Media Lines
Shipments from China: Labelling of Personal Protective Equipment

Issue Statement:
The Government of China has introduced more stringent certification and export controls for masks and other personal protective equipment (PPE). This has culminated in a joint declaration requirement that must be signed by the exporter and importer (i.e., the Public Health Agency of Canada) before the product can leave China, as well as new labelling requirements for select products.

The joint declaration stipulates that a product must meet 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 health care settings. The product is subsequently labelled in Simplified Chinese as “not for medical use” both on the outer shipping boxes and inside each of the individual product boxes.

In Canada, PHAC conducts a quality verification on all PPE received by the Government of Canada, both from international and domestic suppliers, to ensure the PPE meets the technical specifications for health care settings for COVID-19 before distribution to provinces and territories.

Given the large volume of shipments of PPE ordered by the Government of Canada, the process of removing labels inserted inside each individual product box would cause significant delays in distribution and, in some cases, would destroy the integrity of the packaging. Instead, PHAC will place a label on the outside of all shipping boxes confirming that the product meets the Government of Canada technical specifications for health care settings. These key messages have been drafted in anticipation of media questions.

Key Messages:

- The Government of Canada’s top priority in the procurement of personal protective equipment (PPE) and other medical supplies is the health and safety of frontline health care workers.

- The Public Health Agency of Canada (PHAC) verifies the quality of all PPE and medical supplies received by the Government of Canada, whether procured internationally or domestically, to confirm that they meet our technical specifications for health care settings for the COVID-19 response. The same process also applies to donations.

- To date, a large majority of the products received by the Government of Canada have met the technical specifications for health care settings for the COVID-19 response.

- Following a stringent review, PHAC determined that approximately 10 million KN95 respirators did not meet our technical specifications, and did not allocate them to provinces and territories.
- As the demand for PPE and other medical supplies remains high for frontline health care, we will continue to assess all shipments imported to Canada against the Government of Canada’s technical specifications for health care settings.

- Because of China's certification and export controls for masks and other PPE, some products exported from China specify that the item is "not for medical use" in Simplified Chinese, even if it meets Canada's technical specifications for health care settings.
- PHAC will label products sourced from China that meet the Government of Canada's specifications on the outer shipping boxes once they are received, confirming quality and stating that they are suitable for use in health care settings.

- To maintain the integrity of the PPE packaging, PHAC will not be removing labels inserted inside each of the individual product boxes that communicate in Simplified Chinese that the product is "not for medical use." The process of removing these inserts would cause significant delays in the distribution.

- This is a labelling issue and is not reflective of PPE quality. As it will have ongoing implications for shipments received by the Government of Canada, PHAC will continue to work closely with the provinces and territories to clearly communicate that products distributed have been appropriately assessed, and are safe for use by frontline health care workers.

- If PHAC cannot account for the quality, the product will not be allocated to the provinces and territories, and will be subsequently assessed for potential use in non-health care settings.

Questions and Answers:

Q1. If the Public Health Agency of Canada isn't opening the boxes of personal protective equipment, how is it verifying the quality?

The process for quality verification varies depending on the medical device, but typically, PHAC pulls samples from a shipment for testing purposes. Those samples are not subsequently distributed. When PHAC distributes a partially full shipment box, it is labelled with an indication that product was removed by PHAC for the purposes of quality verification.
In some cases, for known suppliers with a history of performance, conformity to standards, and ability to provide documented evidence of testing and certification to standards, the quality verification process is a paper exercise that, upon review, confirms that testing is not required.

Q2. How does the Public Health Agency of Canada ensure that PPE shipped from foreign manufacturers meets Canadian standards?

For PPE received by PHAC, the process for verification varies depending on the medical device. For example, KN95 respirators, as an accepted alternative to N95 respirators, are visually inspected to check for defects in design and construction, and tested to confirm they meet specifications for filtering face pieces. Gowns and surgical masks are visually inspected and tested for fluid penetration.