**The Public Health Agency of Canada’s (PHAC) Mitigation Strategy:**

**PPE Shipments from China**

***Government of China’s Export Controls***

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. 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 labelling 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.

To that end, with this attestation, 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.

***Quality Verification of Internationally and Domestically Procured PPE***

PHAC’s top priority in the procurement of PPE and other medical supplies is the health and safety of our frontline healthcare workers.

All medical devices procured either internationally or domestically, and distributed in Canada, must meet all applicable Canadian regulatory requirements. All medical device products are subject to Health Canada’s safety and effectiveness requirements, and manufacturers of medical devices are responsible for ensuring that the devices they sell meet those requirements.

To illustrate an example, if a shipment of PPE is imported to Canada by the Public Agency of Canada and is labelled as “not for medical use”, the shipment undergoes quality verification and is tested by PHAC officials to confirm that it meets the Government of Canada technical specifications for healthcare settings.

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 verify 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.

If the determination is made that the product meets the required technical specifications for healthcare settings, they are distributed to provinces and territories for frontline healthcare response with labeling from PHAC confirming the quality.

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.

***Mitigation Strategy: Labelling of PPE Shipments from China***

Products sourced from China that meet the Government of Canada’s specifications will be labelled by PHAC, on the outer shipping boxes, confirming quality and stating that it is suitable for use in healthcare 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 and in some cases, destroy the integrity of packaging.

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 by PHAC have been appropriately assessed and are safe for use by our frontline healthcare workers.