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China and the United States Adjust Export/Import Policies on PPE

April 6, 2020

Food, Drug, and Device

This alert provides an update on the regulatory measures regarding medical-use and industrial-use personal protective equipment (PPE) from China to combat COVID-19, including a brief summary of measures the U.S. Food and Drug Administration (U.S. FDA) is taking to facilitate import of PPE from China into the United States. The regulatory guidance from both countries is changing frequently. Therefore, this alert only reflects the available guidance and PPE policies as of April 6, 2020.

China and the United States have worked over the last two weeks to adjust their export/import policies for PPE, in particular medical-use and industrial-use respirators and other face masks. China has pursued a mix of domestic enforcement and export restrictions on PPE to ensure quality, whereas the U.S. FDA has gradually eased restrictions and permitted use of a broader range of PPE, including that made in China for industrial use (e.g., KN95 masks), to enter the United States subject to the conditions set forth below.

China Adopts Increased Enforcement for Counterfeit or Substandard PPE

China's chief drug and device regulator, the National Medical Products Administration (NMPA), has issued notices emphasizing existing medical device regulatory requirements that only licensed entities can manufacture and distribute medical-use masks and other PPE that hold the necessary medical device licenses. Industrial-use equipment should not be labeled medical-use.

- On March 27, 2020, NMPA issued a notice that requires local medical products administrations and police departments in China's provinces to enforce against unregistered COVID-19 in vitro diagnostic (IVD) test kits. The notice encourages the reporting of such illegal test kits to local medical products administrations.
- On April 3, 2020, NMPA issued a list of twenty different cases of companies making or selling counterfeit or substandard PPE. The companies and responsible persons involved face a mixture of administrative fines and seizures as well as criminal penalties. NMPA named the companies and the illegal activities in the list.

China Imposes Additional Requirements for Medical-Use PPE Exports

On March 31, 2020, China's Ministry of Commerce (MOFCOM), NMPA, and General Customs Administration (GACC) issued a notice (Customs Notice) jointly requiring exporters of medical-use PPE for COVID-19 to make a certification to GACC that the medical-use PPE for export is approved for marketing as a medical device in China and meets the standards of the destination country. The Customs Notice covers medical-use masks (i.e., respirators), medical protective clothing, ventilators, infrared thermometers, and COVID-19 test kits (presumably IVD test kits) (collectively, Covered Products").

Companies must fill out a form (attached to the Customs Notice) and include the medical device registration numbers of the Covered Products, a statement that the products meet the requirements of the destination country, and information on the manufacturing site in China. This will permit verification that the Covered Products were made in a facility licensed for medical device manufacturing that is compliant with China's medical device good manufacturing practice regulations.

The Customs Notice also attaches a list of the existing medical device registrations for Covered Products that are subject to the policy. The registration information in this list will continue to be updated in NMPA's database (not on the GACC page). NMPA has since launched a special page with lists of properly approved medical device PPE (available here) to permit further verification.

The Customs Notice does not cover products that are labeled and declared for industrial use, such as KN90, KN95, or KN100, or KP90, KP95, or KP100 masks. These masks comply with a mandatory national standard for Respiratory Protective Equipment: Non-powered Air-purifying Particle Respirators (GB 2626-2006), but are not approved as medical devices in China.

U.S. Eases Import Restrictions on Industrial Respirators from China

On the United States side, medical-use respirators that are cleared (under a valid 510k) and manufactured in a registered U.S. FDA facility may enter the United States as they normally would. Masks approved by the National Institute for Occupational Safety and Health (NIOSH) (e.g., N95) from China may be eligible to come into the United States under an existing emergency use authorization (EUA).

As of April 3, 2020, FDA will also permit the import of a disposable non-NIOSH-approved respirator manufactured in China if it meets one of the following criteria for authentication under a separate, China-specific EUA: (1) It is manufactured by an entity that holds one or more NIOSH approvals for other models of filtering facepiece respirators (FFRs) produced in accordance with the applicable standards of authorization in other countries that can be verified by U.S. FDA; (2) it has a regulatory authorization under a jurisdiction other than China that can be authenticated and verified by U.S. FDA; or (3) it demonstrates acceptable performance to applicable testing standards as documented by test reports from a recognized independent test laboratory that can be verified by U.S. FDA.

U.S. FDA will also permit the import, distribution, and use of respirators identified in the Centers for Disease Control and Prevention's "Strategies for Optimizing the Supply of N95 Respirators:

Crisis/Alternate Strategies," even without authorization under the EUAs identified above. However, U.S. FDA has expressly stated that the agency cannot confirm the authenticity of such respirators and encourages importers to take measures to do so.

U.S. FDA has summarized its current regulatory approach to all categories of face masks and respirators in its guidance document Enforcement Policy for Face Masks and Respirators During the Coronavirus Disease (COVID-19) Public Health Emergency. U.S. FDA has also identified specific intended use codes and other entry data requirements for use throughout the course of the public health emergency in the United States.

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If you have any questions concerning the material discussed in this client alert, please contact the following members of our U.S. and China Food, Drug and Device practices:

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