

Chinese regulators announce new requirements for exports of medical supplies and nonmedical masks

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On 31 March 2020 the China Ministry of Commerce, the National Medical Products Administration (NMPA), and the General Administration of Customs (GAC) issued the [Notice on the Orderly Exportation of Medical Supplies](#) (Notification 5), which established new export requirements for Chinese manufacturers and exporters of medical supplies from 1 April 2020. In order to support the global fight against COVID-19 and ensure the quality of goods exported in that effort, on 25 April 2020 the China Ministry of Commerce, GAC, and State Administration for Market Regulation (SAMR) issued [Notice on Further Strengthening the Quality Administration of Exported Epidemic Prevention Supplies](#) (Notification 12), which established new export requirements for nonmedical masks effective 26 April 2020.

These two notifications are being implemented concurrently in practice to regulate the exportation of medical supplies and nonmedical-use masks from China to overseas countries.

Exportation of nonmedical use (i.e., civil use) masks

Notification 12 provides that the nonmedical-use masks must meet the quality standards of either China (e.g., GB 2626-2006 or other applicable standards for civil-use masks) or foreign country.

- For nonmedical-use masks that meet the foreign country's quality standard (but not GB 2626-2006 or other applicable standards for civil-use masks), the manufacturer must be included into the list of nonmedical-use mask manufacturing enterprises that have obtained foreign standard certification or registration (approved list for nonmedical-use masks) issued by the China Chamber of Commerce for Import and Export of Medicines and Health Products (CCCMHPIE) in order to export such nonmedical-use masks. Foreign standard certification or registration may include emergency use authorization issued by the U.S. Food and Drug Administration (FDA), National Institute for Occupational Safety and Health (NIOSH)-approved N95, and CE marking of the European Economic Area (EEA).
- Manufacturers of nonmedical-use masks claiming that their products satisfy China's quality standard need not be included in the aforementioned CCCMHPIE approved list for nonmedical-use masks in order to export their nonmedical-use masks. However, their nonmedical-use masks will not be able to be exported if the manufacturer is on a SAMR-

issued list of manufacturing enterprises that had produced nonqualified, nonmedical-use masks (denial list for nonmedical-use masks).

- Going forward, when making customs declaration, the local customs will review and inspect exported products against the aforesaid two lists prior to releasing goods for export.
- In addition, a joint declaration of the exporter and importer under Notification 12 must be submitted for exports of nonmedical-use masks. In the joint declaration the exporter and the importer confirm that the exported products meet the quality standards of China or of the foreign country and the importer shall guarantee that the product quality standards are compliant with quality requirements of the importing country and not use the masks for medical purposes.
- Although Notification 12 is silent as to whether the foreign quality standard must be that of the receiving country, there has been some acknowledgement in practice that the foreign country standard need not necessarily be that of the country receiving the exported items.

Exportation of five categories of medical supplies

Notification 5 addresses the export of COVID-19 medical products, specifically five categories of medical supplies: testing reagents for COVID-19, medical masks (including medical protective masks, surgical masks, and disposable medical masks), medical protective clothing, ventilators, and infrared thermometers.

- Manufacturers with a medical device registration certificate issued by China's NMPA may export their medical supplies subject to the submission of the medical device registration certificate and an assurance letter under the Notification 5, without having to be added to the list of manufacturing enterprises for medical supplies that have obtained foreign standard certifications or registrations issued by CCMHPIE (approved list for medical supplies).
- Manufacturers without a medical device registration certificate may export their medical supplies only after being added to the approved list of medical supplies. Foreign standard certifications or registrations in this approved list may include authorization from the FDA and NIOSH of the United States, CE of the EEA, the Therapeutic Goods Administration of Australia, and the Pharmaceuticals and Medical Devices Agency of Japan. Further, the manufacturer would have to submit an export declaration of medical supplies under Notification 12, confirming that the products meet the quality standards of the importing country.

Next steps

In view of Notification 5 and Notification 12, exporters of nonmedical-use masks and the enumerated medical supplies should check against the list published by CCCMHPIC and SAMR and be prepared to submit the relevant declaration forms. Manufacturers who have obtained foreign standard certifications or registration and wish to be included into approved lists may file an application with local commerce bureau, along with evidentiary documents. In addition, manufacturers should ensure that their supplies meet the corresponding testing standards¹ and the declared purpose is consistent with actual purpose when making customs clearance. Given the potential frequent and dynamic updates on export requirements, we recommend that relevant stakeholders closely monitor the implementation rules and respond quickly to any developments.

¹ On 7 May 2020 FDA withdrew approval for more than 60 manufacturers in China to export N95-style masks to the United States due to low-quality products from those companies. FDA [issued a notice](#) about Chinese manufacturers of masks that previously received an EUA, and FDA updated their [list](#) of approved Chinese manufacturers for N-95-style masks.

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