Updated as of May 1, 2020

China's Process for Allowing the Export of COVID-19 Products without NMPA Approval

(Summary of Notice No. 12 issued by MOFCOM/GACC/SAMR on April 25)

On April 25, the Chinese government announced a process through which it will permit the export of five categories of devices without NMPA approval. The five categories of devices are:

1. COVID-19 test kits
2. medical masks
3. medical-use protective clothing (i.e., gowns)
4. ventilators, and:
5. infrared thermometers

AdvMed member companies who manufacture these types of products in China AND whose products have the required overseas approval (i.e., an FDA Emergency Use Authorization) **should complete the *Export Declaration of Medical Supplies ("Export Declaration")* and provide it to their local MOFCOM office as soon as possible.** (Note: AdvaMed's China Office can assist with any questions members have about this form). AdvaMed has received reports that the Chinese bureaucracy is having some difficulty in checking the Chinese-language name of the manufacturer listed on the submitted materials with the English name on the FDA registration. We therefore recommend that members in China list their company name both in Chinese and English on the Export Declaration.

The application then works its way through the Chinese bureaucracy. Those products granted export approval will be placed on a list maintained by the China Chamber of Commerce for Import and Export of Medicines and Health Products (Note: CCCMPHIE is quasi-government trade association that reports to MOFCOM). The CCCMPHIE white list is being updated at this link:
http://en.cccmhpie.org.cn/Web/Content.aspx?queryStr=w7x08q7x15x15o3w8w1vS9z8w7x1X10x16x0X10x16o3w8w1u9v1u9v3v2v3

In days subsequent to the initial April 25 joint announcement by MOFCOM, GACC, and SAMR (i.e., "Notice No. 12"), the Chinese government has unveiled additional details on how the approval process will work bureaucratically within the Chinese system. See bullet points below that explain this process; the attached flow chart explains this process in even greater detail and clarity.

- The manufacturer submits the *Export Declaration of Medical Supplies* (the "Declaration") to the local MOFCOM, which will review it to ensure that the company is legitimate and that the products meet the criteria for inclusion on the CCCMHPIE white list.

- After their initial review, the local MOFCOM office submits the application information to the national-level MOFCOM for approval (on a once-a-week schedule; no later than 5 pm each Wednesday). Simultaneously, the local MOFCOM submits a copy of the

application to CCCMPHIE, which will confirm the products' FDA registration information and/or EUAs that FDA is posting online.

- Once the submitted information is confirmed, the manufacturer will be included on the white list that CCCMHPIE is maintaining (See link above).

- Chinese customs will be instructed by MOFCOM not to block the export of these approved medical devices.

AdvaMed's team in China has been communicating with Chinese government agencies—including CCCMPHIE—to clarify whether exports of components and testing samples are eligible. The head of CCCMPHIE confirmed to Lynn Jiao in our China office that AdvaMed will be called upon to assist MOFCOM/CCCMPHIE in its screening work of products' registration status in foreign countries. We hope our involvement in this work will accelerate the process of products being added to the white list.

Just to be very clear, FDA-registered establishments who manufacture products in China under the five categories will not be automatically added to the white list. The manufacturer must apply for inclusion on the white list.

If you have any questions, please contact the head of our China Office, Lynn Jiao, at LJiao@AdvaMed.org or Kyle Churchman, Director of Global Strategy and Analysis, at KChurchman@AdvMmed.org.