

## President Signs Executive Order to Ensure Essential Medical Products Are Made in the USA

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President Donald Trump signed an Executive Order (EO) on Thursday, August 6, 2020 directing federal agencies to “Buy American” when purchasing “essential” drugs, medical supplies and equipment rather than purchase these products from foreign manufacturers. The EO does not identify which products are deemed essential, but it directs the Food and Drug Administration (FDA) to identify an initial list of essential medicines, medical countermeasures, and critical inputs.

Agencies are directed to “consider a variety of actions to increase their domestic procurement” of these essential products and to “identify vulnerabilities in our Nation’s supply chains” for these medical products.

- In furtherance of the first goal, agencies may use procedures to limit competition to only domestically-produced essential medicines, medical countermeasures, and critical inputs and may divide procurement requirements among two or more domestic manufacturers. Agencies are also directed to develop and implement procurement strategies to increase the manufacture of these products in the U.S. The EO also empowers the Secretary of Defense to restrict the procurement of essential medical products to domestic sources and reject otherwise acceptable offers for such products from outside sources when necessary for national defense reasons.
- The order directs the Office of Management and Budget (OMB) to work with agencies to review their authority to limit the online procurement of essential medicines and countermeasures to e-commerce platforms that adhere to best practices on combating trafficking in counterfeit and pirated goods.
- To advance the second goal, OMB is also required to work with FDA to identify vulnerabilities in the supply chain through various information collection efforts and to review FDA regulations to determine whether any pose a barrier to domestic production of essential medical products. OMB must also consult with the Department of Defense to identify supply chain vulnerabilities for essential medical products that are necessary for the U.S. Armed Forces.
- FDA is further directed to accelerate approval or clearance for domestic producers of essential medical products, issue guidance regarding the development of Advanced Manufacturing techniques, increase site inspections and unannounced inspections of foreign regulated facilities, and refuse admission to imports of essential products if the facilities refuse or unreasonably delay an inspection.

The EO also directs the Environmental Protection Agency (EPA) to streamline regulatory requirements to “provide for the development of Advanced Manufacturing facilities and the expeditious domestic production of critical inputs.” The order defines “Advanced Manufacturing” as “any new medical product manufacturing technology that can improve drug quality, address shortages of medicines, and speed time to market, including continuous manufacturing and 3D printing.”

Trump signed the “Combating Public Health Emergency and Strengthening National Security by Ensuring Essential Medicines, Medical Countermeasures and Critical Inputs Are Made in the United States” EO prior to delivering his remarks at a Whirlpool Corporation Manufacturing plant in Ohio. During his remarks, Trump explained that the order will end reliance on China and other countries, allowing the country to reassert its “economic independence.” According to the President, the executive order will “sweep away regulatory barriers” and “support advanced manufacturing processes” that will lower prices for medical products. According to the EO, it is critical that the country reduce its dependence on foreign manufacturers for these products.

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