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CLIENT ALERT

Trump Executive Order Seeks to Beef Up Domestic Supply Chain for Medical Products

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On August 6, 2020, President Trump issued an executive order designed to strengthen the domestic supply chain for essential medicines, medical countermeasures, and critical inputs deemed necessary for the United States. The order is aimed at reducing U.S. dependence on foreign manufacturers to ensure sufficient and reliable long-term domestic production of these products, to minimize potential shortages, and to mobilize the U.S. Public Health Industrial Base. Federal agencies are directed to consider a variety of actions to increase domestic procurement of essential medicines, medical countermeasures, and critical inputs, as well as to identify vulnerabilities in the country's supply chains.

The executive order directs agencies to use their respective authorities, in consultation with the Food and Drug Administration (FDA), to use procedures to limit competition to only those essential medicines,[1] medical countermeasures,[2] and critical inputs[3] produced in the United States, and to divide procurement requirements among two or more domestic manufacturers. The U.S. Trade Representative is directed to take all appropriate action to modify U.S. federal procurement product coverage under all relevant Free Trade Agreements and the World Trade Organization Agreement on Government Procurement to exclude coverage of essential medicines, medical countermeasures, and critical inputs. The order also authorizes the Secretary of Defense to restrict the procurement of these essential products to domestic sources, and reject normally acceptable offers for such products from sources in Qualifying Countries[4] in instances where considered necessary for national defense reasons. In addition, the order directs the Office of Management and Budget (OMB) to review the authority of each agency to limit the online procurement of essential medicines and medical countermeasures to e-commerce platforms that adhere to the Department of Homeland Security's best practices on combating trafficking in counterfeit and pirated goods.[5]

The exceptions to these directives are limited to (1) where the head of the agency determines in writing, with respect to a specific contract or order, that (a) their application would be inconsistent with the public interest; (b) the relevant essential medicines, medical countermeasures, and critical inputs are not produced in the United States in sufficient and reasonably available commercial quantities and of a satisfactory quality; or (c) their application would cause the cost of the procurement to increase by more than 25%, unless applicable law requires a higher percentage, in which case such higher percentage shall apply; and (2) with respect to the procurement of items that are necessary to respond to any public health emergency declared under section 319 of the Public Health Service Act (42 U.S.C. 247d), any major disaster or emergency declared under the Stafford Disaster Relief and Emergency

Assistance Act (42 U.S.C. 5121 *et seq.*), or any national emergency declared under the National Emergencies Act (50 U.S.C. 1601 *et seq.*).

The executive order requires FDA, in consultation with OMB, to identify vulnerabilities in the supply chain for essential medicines, medical countermeasures, and critical inputs by collecting certain information[6] from manufacturers of these products as part of the application and regulatory process. FDA and OMB must also work with the Department of Defense and other agencies to assess the security and mitigate vulnerabilities of the supply chains for essential medical products necessary for the U.S. Armed Forces. The executive order further directs FDA to review its regulations to determine whether any pose a barrier to the domestic production contemplated under the order and advise on whether any such regulations should be repealed or amended. Where appropriate under law, FDA is directed to accelerate approval or clearance for domestic producers of essential medicines, medical countermeasures, and critical inputs; issue guidance regarding the development of Advanced Manufacturing[7] techniques; negotiate with countries to increase site inspections and increase the number of unannounced inspections of regulated facilities manufacturing essential medicines, medical countermeasures, and critical inputs; and refuse admission, as appropriate, to imports of these products if the facilities in which they are produced refuse or unreasonably delay an inspection. Moreover, the FDA is instructed to identify the list of essential medicines, medical countermeasures, and critical inputs that are medically necessary to have available at all times in an amount adequate to serve patient needs.

Finally, the executive order authorizes the Secretary of Health and Human Services to prioritize the performance of federal government contracts on orders for essential medicines, medical countermeasures, or critical inputs over the performance of any other contracts or orders, and to allocate such materials, services, and facilities as the Secretary deems necessary.

Stay tuned for coverage of agency action in connection with this executive order.

We note that government orders on the local, state, and federal level are changing every day, and the information contained herein is accurate only as of the date set forth above.

All entities should consult legal counsel for compliance issues and questions related to rapidly evolving COVID-19 legislation and policy.

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For further information or questions on the Trump Administration's executive orders and plans for implementation, please contact Amandeep S. Sidhu, T. Reed Stephens, Christopher M. Parker, or your Winston relationship attorney.

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[1] "Essential Medicines" are those that the FDA Commissioner, in consultation with the Director of OMB, the Assistant Secretary for Preparedness and Response in the Department of Health and Human Services, the Assistant to the President for Economic Policy, and the Director of the Office of Trade and Manufacturing Policy shall identify the as medically necessary to have available at all times in an amount adequate to serve patient needs and in the appropriate dosage forms.

[2] "Medical Countermeasures" are items that meet the definition of "qualified countermeasure" in section 247d 6a(a)(2)(A) of title 42, U.S. Code; "qualified pandemic or epidemic product" in section 247d–6d(i)(7) of title 42, U.S. Code; "security countermeasure" in section 247d–6b(c)(1)(B) of title 42, U.S. Code; or personal protective equipment described in part 1910 of title 29, Code of Federal Regulations.

[3] "Critical Inputs" means active pharmaceutical ingredient (API), API Starting Material, and other ingredients of drugs and components of medical devices that the FDA Commissioner determines to be critical in assessing the safety and effectiveness of essential medicines and medical countermeasures.

[4] "Qualifying Countries" has the meaning set forth in section 225.003, Defense Federal Acquisition Regulation Supplement.

[5] *See* U.S. Dep't of Homeland Security, Combating Trafficking in Counterfeit and Pirated Goods (January 24, 2020).

[6] This information includes the sources of Finished Drug Products, Finished Devices, and Critical Inputs; the use of any scarce Critical Inputs; and the date of the last FDA inspection of the manufacturer's regulated facilities and the results of such inspection.

[7] "Advanced Manufacturing" means 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.

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