Executive Order on Essential Medicines: A Timeline and Overview of Key Provisions

August 12, 2020

On August 6, President Trump issued an Executive Order (EO) titled "Ensuring Essential Medicines, Medical Countermeasures and Critical Inputs Are Made in the United States." The far-reaching EO seeks to ensure the domestic medical supply chain is capable of protecting the country's citizens, infrastructure and economy against outbreaks of emerging infectious diseases and chemical, biological, radiological and nuclear (CBRN) threats. The EO's multipronged approach contains four primary goals: (1) accelerating the development of cost-effective and efficient domestic production capacity and supply chain redundancy of Essential Medicines, Medical Countermeasures and Critical Inputs (EMMCCI); (2) ensuring long-term demand for EMMCCI that are produced in the United States; (3) creating, maintaining and maximizing domestic production capabilities for critical inputs, finished drug products and finished devices that are essential to public health and safety; and (4) combating the trafficking of counterfeit EMMCCI.

The EO sets forth a process to advance these goals by directing a range of actions by various federal agencies over the course of 180 days. At its core, the EO directs a range of federal agencies, using a variety of tools and authorities, to identify the types and amounts of EMMCCI medically necessary to have at all times and to assess and support the ability of the government to procure designated EMMCCI that is produced in the United States. To put it another way, the EO seeks to apply Buy America policies to the U.S. government's acquisition of EMMCCI through procurement contracts and in the process create a specific market for domestically sourced EMMCCI. An undertaking of this nature—with such far-reaching implications and on this timeline—is perhaps without precedent. Also, it is unclear whether the federal government's payment rate will be enough for manufacturers to forgo current production lines and pursue these types of contracts. Set forth below is an overview of key milestones contained in the EO as well as a synopsis of other key provisions.

Key Milestones

Within 90 Days

- **Designation of EMMCCI**. The Commissioner of the Food and Drug Administration (FDA), in consultation with the Director of the Office of Management and Budget

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(OMB), the Department of Health and Human Services (HHS) Assistant Secretary for Preparedness and Response (ASPR), the Assistant to the President for Economic Policy, and the Director of the Office of Trade and Manufacturing, shall identify the list of EMMCCI "that are medically necessary to have available at all times in an amount adequate to serve patient needs and in the appropriate dosage forms." (Sec. 3(c)).

- **Development and Implementation of EMMCCI Procurement Strategies to Strengthen the Public Health Industrial Base**. The head of each agency, in consultation with the FDA Commissioner, shall develop and implement procurement strategies, including long-term contracts, to strengthen and mobilize the Public Health Industrial Base in order to increase the manufacture of EMMCCI in the United States. (Sec. 2(c)). The EO defines Public Health Industrial Base as "the facilities and associated workforces within the United States, including research and development facilities, that help produce [EMMCCI] for the Healthcare and Public Health Sector." (Sec. 7(k)).
- **Limitation on Online Procurement to e-Commerce Platforms Compliant with DHS Anti-counterfeiting Best Practices**. OMB, in consultation with appropriate agency heads: shall review the authority of each agency to limit the online procurement of Essential Medicines and Medical Countermeasures to e-commerce platforms that have adopted and certified their compliance with the applicable best practices published by DHS in its report to the President on "Combatting Trafficking in Counterfeit and Pirated Goods," dated January 24, 2020; agreed to permit DHS to evaluate and confirm their compliance with such best practices; and will report its findings to the President. (Sec. 2(b)).

Within 120 Days

- **Modification of Free Trade Agreements, the World Trade Organization (WTO) Government Procurement Agreement, and Section 301 Waivers to Reflect Modified Procurement Coverage of EMMCCI**. The United States Trade Representative shall take all appropriate action to modify U.S. federal procurement product coverage under all relevant free trade agreements and the WTO Agreement on Government Procurement, to exclude coverage of EMMCCI and make any necessary, corresponding modifications of existing waivers under section 301 of the Trade Agreements Act of 1979. (Sec. 2(d)).

Within 150 Days

- **Department of Defense (DOD) Procurement Limited to Domestic Sources.** The Secretary of Defense shall use the authority under DFARS 225.871-1(c) to restrict the procurement of EMMCCI to domestic sources and to reject otherwise acceptable offers of such products from sources in Qualifying Countries where considered necessary for national defense reasons. (Sec. 2(e)).

Within 180 Days

- HHS/FDA Identification and Mitigation of EMMCCI Supply Chain Vulnerabilities. The EO directs the Secretary of HHS, through the FDA Commissioner and in consultation with the Director of OMB, to take all necessary and appropriate action to identify vulnerabilities in the supply chain of EMMCCI and to mitigate those vulnerabilities, including:

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1. Consider proposing regulation or revising guidance on the collection of certain information from manufacturers of EMMCCI as part of the application and regulatory approval process, including: (i) the sources of Finished Drug Products, Finished Devices and Critical Inputs; (ii) the use of any scarce Critical Inputs; and (iii) the date of the last FDA inspection of the manufacturer's regulated facilities and the inspection results.
2. Entering into written agreements with the National Security Council, Department of State, DOD, Department of Veterans Affairs and other interested agencies to disclose records regarding the security and vulnerabilities of the supply chains for EMMCCI.
3. Recommending to the President any changes in applicable law that may be necessary to accomplish the supply chain security objectives.
4. Reviewing FDA regulations to determine whether any of those regulations may be a barrier to domestic production of EMMCCI and advising the President whether such regulation should be repealed or amended. (Sec. 3(a)).

- **DOD Identification of Defense-specific EMMCCI**. The Secretary of Defense, in consultation with the Director of OMB, shall take all necessary and appropriate action to identify vulnerabilities in the supply chain for EMMCCI necessary to meet the unique needs of the U.S. Armed Forces and to mitigate such vulnerabilities. The Secretary of Defense shall provide a list of defense-specific EMMCCI that are medically necessary to have available for defense use in adequate amounts and in appropriate dosage forms. The Secretary of Defense shall periodically update this list as appropriate. (Sec. 3(d)).
- **Commerce Department Assessment of Public Health Industrial Base**. The EO directs the Secretary of Commerce to submit a report describing any change in the status of the Public Health Industrial Base and recommending initiatives to strengthen the Public Health Industrial Base.

Other Significant Provisions

- **HHS/FDA Actions**. The EO directs the Secretary of HHS, through the FDA Commissioner, to take all appropriate action to: (1) accelerate FDA approval or clearance, as appropriate, for domestic producers of EMMCCI, including those needed for infectious disease and CBRN threat preparedness and response; (2) issue guidance with recommendations regarding the development of Advanced Manufacturing techniques; (3) negotiate with countries to increase site inspections and increase the number of unannounced inspections of regulated facilities manufacturing EMMCCI; and (4) refuse admission, as appropriate, to imports of EMMCCI if the facilities in which they are produced refuse or unreasonably delay an inspection. (Sec. 3(b)).
- **Federal Procurement Limited to Domestically Produced EMMCCI from Two or More U.S. Manufacturers**. Under the EO, agencies should procure EMMCCI using procedures that limit competition to only EMMCCI produced in the United States and divide procurement requirements among two or more manufacturers located in the United States. (Sec. 2(a)i-ii). The timing of this action is not clear but will presumably take place after the FDA publishes its list of EMMCCI.
- **Federal Contracts Given Priority**. The EO directs the Secretary of HHS to use the authority under the Defense Production Act to prioritize the performance of federal

government contracts or orders for EMMCCI over performance of any other contracts or orders, and to allocate such materials, services and facilities as the Secretary deems necessary or appropriate to promote the national defense. (Sec. 5).

- **Streamlining Environmental Regulations**. The Environmental Protection Agency Administrator is directed by the EO to take all appropriate action to identify relevant requirements and guidance documents that can be streamlined to provide for the development of Advanced Manufacturing facilities and the expeditious domestic production of Critical Inputs, including by accelerating siting and permitting approvals. (Sec. 4).
- **Reporting Requirements**. No later than December 15, 2021, and annually thereafter, the head of each agency is required to submit a publicly available report detailing, for the preceding three fiscal years, (1) the EMMCCI procured by the agency; (2) the agency's annual itemized and aggregated expenditures for all EMMCCI; (3) the sources of these products and inputs; and (4) the agency's plan to support domestic production of such products and inputs in the next fiscal year. (Sec. 6).

Key Exemptions

The EO provides an exemption to requirements related to procurement and procurement product coverage under modified free trade agreements and the WTO Government Procurement Agreement in two cases:

- An exemption would apply where an agency head determines in writing, with respect to a specific contract or order, that: (1) the limitations would be inconsistent with the public interest, (2) the relevant EMMCCI are not produced in the United States in sufficient and reasonably available commercial quantities and of a satisfactory quality or (3) the restrictions would cause the cost of the procurement to increase by more than 25 percent.
- Further, an exemption would apply 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, any major disaster or emergency declared under the Stafford Disaster Relief and Emergency Assistance Act, or any national emergency declared under the National Emergencies Act. (Sec. 2(f)).

Defined Terms (Sec. 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."
- **"'API Starting Material'** means a raw or intermediate material that is used in the manufacturing of an Active Pharmaceutical Ingredient (API), that is incorporated as a significant structural fragment into the structure of the API, and that is determined by the FDA Commissioner to be relevant in assessing the safety and effectiveness of Essential Medicines and Medical Countermeasures."
- **"'Critical Inputs'** means 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."

- **“Essential Medicine”** means those Essential Medicines deemed necessary by the FDA Commissioner for the United States pursuant to the EO. It is possible that the FDA begins with the World Health Organization list for Essential Medicines.
- **“Medical Countermeasures”** generally means certain FDA-regulated drugs, biologics and devices that can be used in the event of chemical, biological, radiological or nuclear threats, or emerging infectious diseases, as well as personal protective equipment described within Occupational Safety and Health Administration regulations.
- **“‘Produced in the United States.’** An Essential Medicine or Medical Countermeasure is ‘produced in the United States’ if the Critical Inputs used to produce the Essential Medicine or Medical Countermeasures are produced in the United States and if the Finished Drug Product or Finished Device, are manufactured, prepared, propagated, compounded, or processed, as those terms are defined in section 360(a)(1) of title 21, United States Code, in the United States.” It is important to note that the description of what is produced in the United States departs from the definitions found in the government’s procurement regulations so manufacturers will be required to review whether products qualify under the EO.
- **“‘Public Health Industrial Base’** means the facilities and associated workforces within the United States, including research and development facilities that help produce Essential Medicines, Medical Countermeasures, and Critical Inputs for the Healthcare and Public Health Sector.”
- **Other Definitions**. API, Finished Device, Finished Drug Product, Healthcare and Public Health Sector, Medical Countermeasures, and Qualifying Countries all have meanings set forth in statute, regulation or other Presidential Directive.

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