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What the "Essential Medicines" Executive Order Means for Federal Contractors and the FDA

By James W. Kim, Brian J. Malkin, Peter M. Routh, and Gugan Kaur*

The Executive Order on Ensuring Essential Medicines, Medical Countermeasures, and Critical Inputs Are Made in the United States directs the Food and Drug Administration and other federal agencies to take actions that could expand future procurement opportunities for pharmaceutical manufacturers and members of the medical supply chain, while restricting opportunities for others. The authors of this article discuss the Order.

President Donald Trump has issued the Executive Order on Ensuring Essential Medicines, Medical Countermeasures, and Critical Inputs Are Made in the United States (the "Order"). The Order is aimed at ensuring that there is an adequate supply in the United States of Essential Medicines, Medical Countermeasures, and Critical Inputs (i.e., the ingredients and components used to make essential medicines and medical countermeasures) (collectively, "Products") in the face of chemical, biological, radiological and nuclear threats and public health emergencies, such as infectious disease outbreaks. The Order establishes a policy of decreasing reliance on foreign manufacturers for Products by:

- Increasing the development of domestic production of Products and developing an adequate redundancy in the domestic supply chain;
- Ensuring long-term demand for U.S.-made Products;
- Focusing on domestic production capabilities for critical inputs, finished drug products and finished devices essential for public safety and national defense; and
- Combating counterfeit Products on e-commerce platforms and third-party online sellers involved in government procurement.

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To achieve these goals, the Order sets forth requirements for executive departments and agencies involved in the procurement of Products, as described below.

WHAT DOES THE ORDER MEAN FOR FEDERAL CONTRACTORS?

The Order requires various federal agencies to take actions that could significantly boost future procurement opportunities for certain federal contractors, while restricting opportunities for others. While the Order is likely to have near-term impacts on federal contractors, its impact will likely continue to evolve as the relevant federal agencies carry out the Order's directives and issue the required recommendations and reports.

Federal contractors that are domestic producers of Products could see increased opportunities due to the Order's directive to federal agencies to limit competition to Products produced in the United States, as well as the Order's directive that agencies divide procurement requirements among two or more manufacturers. This could have significant competitive ramifications for existing contractors that can meet the Order's requirements related to domestic manufacturing. Further, the Secretary of Health and Human Services, through the U.S. Food and Drug Administration ("FDA") Commissioner, is directed to accelerate FDA approval or clearance for such domestic producers of Products.

On the other hand, these same directives could significantly limit opportunities for contractors that do not produce Products domestically and have traditionally relied upon existing statutory guidance that permits compliance with ordinary Buy American Act requirements through the Trade Agreement Act. The Order's directive to the U.S. Trade Representative to exclude coverage of products from the U.S. federal procurement under all relevant Free Trade Agreements and the World Trade Organization Agreement on Government Procurement could further reduce opportunities for federal contractors that are not domestic producers.

Additionally, when considered necessary for national defense reasons, the Secretary of Defense is directed to use his authority under the Defense Federal Acquisition Regulation Supplement ("DFARS") to restrict procurement of Products to domestic sources and reject otherwise acceptable offers from Qualifying Countries. A trend towards this activity has been evident in certain procurements and is worth examining when planning for manufacturing capabilities and engagement with subcontractors for manufacturing needs.

HOW WILL FDA MODIFY ITS PROCEDURES?

On its face, the Order is an unfunded mandate for the FDA, requiring the agency to engage in at least some activities that it normally does not, and which fall within the practice of medicine or more traditionally with other public

health agencies such as the Centers for Disease Control and Prevention or medicine manufacturers themselves. For instance, the FDA does not normally identify "essential" medicines and countermeasures, but it does identify products that would qualify for a priority review to fill an unmet treatment need.

The FDA can help accelerate the review or clearance of products by providing increased input during development and by placing priority on the review cycles, but it is not accustomed to prioritizing a "made in the USA" approach. Given that many medicines sold in the United States currently are made with ingredients or components from overseas, it will take time for companies to develop economically viable capacities to make all of those ingredients and components domestically. Just as the FDA does not normally identify products made solely with domestic ingredients and components, the agency does not usually identify supply chain issues for manufacturers. This responsibility is expected to fall to the manufacturers themselves.

The Order further requires the FDA to increase the frequency of foreign inspections, where the agency has been implementing a prioritization process to inspect facilities with more deficiencies more often. Together, these new requirements may place a further strain on the FDA's tight resources, which have been constrained by COVID-19, and could reduce, or in many cases eliminate, the FDA's ability to conduct routine or for-cause inspections. The FDA therefore will likely require more resources to take on these new responsibilities, a factor that the Order does not seem to have contemplated.

IMMEDIATE AGENCY ACTIONS REQUESTED

- *Agencies procuring products*: In consultation with the FDA, use procedures to limit competition to only those products produced in the United States and divide procurement requirements among two or more U.S. manufacturers.
- *The Secretary of Health and Human Services, through the FDA Commissioner*: Accelerate FDA approval or clearance. Issue guidance regarding the development of "Advanced Manufacturing" techniques. Negotiate with countries to increase site inspections of regulated facilities manufacturing Products and refuse to admit imports of Products if the manufacturing facilities refuse or unreasonably delay an inspection.
- *The Administrator of the Environmental Protection Agency*: Identify relevant requirements and guidance documents that can help in the development of Advanced Manufacturing facilities and increase domestic production of critical inputs.

WITHIN 90 DAYS OF THE DATE OF THE ORDER (BY NOVEMBER 4, 2020)

- *The Director of the Office of Management and Budget*: "[R]eview the authority of each agency to limit online procurement of Essential Medicines and Medical Countermeasures" to e-commerce platforms that meet certain requirements and report findings to the president.
- *Each head of agency*: In consultation with the FDA, "develop and implement procurement strategies, including long-term contracts."
- *FDA Commissioner:* In consultation with various offices and agencies identified in the Order, identify the list of medically necessary Products. After the FDA Commissioner has identified this list:
    - *No later than 30 days*, the *U.S. Trade Representative* must "modify United States Federal procurement product coverage under all relevant Free Trade Agreements and the World Trade Organization Agreement on Government Procurement" to exclude the listed Products and to reflect updates by the FDA Commissioner, must make any necessary corresponding modifications to relevant existing waivers, and must notify the president.
    - *No later than 60 days,* the *Secretary of Defense* must restrict the procurement of Products on the list to domestic sources and reject offers for these products from Qualified Countries, as defined in the DFARS, when considered necessary for national defense.

EXCEPTIONS

The requirements above do not apply where the head of agency determines the following:

- Their application would be inconsistent with the public interest.
- The relevant Products are not produced in the United States in sufficient quantities and of a satisfactory quality.
- Their application would cause cost of procurement to increase by more than 25 percent (unless applicable law requires a higher percentage, in which case that percentage would apply).

If the head of agency makes any of the determinations above, she must submit an annual report to the president describing the justification for the determination.

The requirements also do not apply if the Products are necessary to respond to any public health emergency, major disaster, or national emergency.

WITHIN 180 DAYS OF THE DATE OF THE ORDER (BY FEBRUARY 2, 2021)

- *The Secretary of Health and Human Services, through the FDA Commissioner and in consultation with the Director of OMB*, must identify vulnerabilities in the supply chain for Products. They must also mitigate the vulnerabilities by:
    - Proposing regulations or revising guidelines on the collection of certain information from manufacturers of Products as part of the application and regulatory approval process;
    - Entering into written agreements with appropriate agencies to disclose records regarding the security and vulnerabilities of the supply chains for Products;
    - Recommending to the president any changes in applicable law that may be necessary to accomplish these objectives; and
    - Reviewing FDA regulations to determine whether any may be a barrier to the domestic production of these Products and advising the president about whether such regulations should be repealed or amended.
- *The Secretary of Defense, in consultation with the Director of OMB*, must identify vulnerabilities in the supply chain for Products necessary to meet the needs of the U.S. Armed Forces and to mitigate the vulnerabilities and prepare a list of defense-specific Products that are medically necessary.
- *The Secretary of Commerce* must submit a report to the agencies outlined in the Order describing any change in the status of the Public Health Industrial Base and providing recommendations for strengthening it.

NO LATER THAN DECEMBER 15, 2021 AND ANNUALLY THEREAFTER

- *Each head of agency, through the Director of OMB and the Assistant to the President for Trade and Manufacturing Policy*, must submit a report to the president for the preceding three fiscal years containing the following information:
    - The Products procured by the agency;
    - The agency's annual itemized and aggregated expenditures for all Products;
    - The sources of the Products; and

- The agency's plan to support domestic production of the Products in the next fiscal year.