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Executive Order Regarding Domestic Production and Purchase of Essential Medicines: A Lot to Unpack and More Than Meets the Eye

By Merle M. DeLancey Jr. and John M. Clerici*

The authors of this article discuss a recent Executive Order designed to eliminate United States dependence on foreign countries for "Essential Medicines" by ensuring that such medicines are made in the United States.

President Trump recently issued another Executive Order ("EO") that will likely have dramatic and long-lasting effects on the pharmaceutical industry. The impact of the EO may be far greater than currently anticipated. It is well-considered, well drafted, and structured in a way that is likely to survive if there is a change in Administration. The EO will have a greater and immediate impact on Medical Counter Measures ("MCMs") for chemical, biological, radiological, and nuclear threats, and emerging infectious diseases than on Essential Medicines. The inclusion of "Critical Inputs" (i.e., active pharmaceutical ingredients ("API")) and starting materials potentially makes the impact far reaching, especially when coupled with the significant funding from the federal government to support onshoring efforts as a result of the COVID-19 pandemic.

The key information regarding the EO is below.

PURPOSE

Eliminate United States dependence on foreign countries for Essential Medicines by ensuring that such medicines are made in the United States.

SCOPE

Applies to "Essential Medicines" to be determined by the Food and Drug Administration ("FDA"); MCMs, defined to include personal protective equipment ("PPE"), determined based on Project BioShield and Strategic National Stockpile ("SNS") procedures; and Critical Inputs, defined as key API

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and starting materials for Essential Medicines and MCMs including raw or intermediate materials used in manufacturing an API, incorporated as a significant structural fragment into an API, or used as an API ingredient that the FDA "determines to be critical in assessing the safety and effectiveness" of an Essential Medicine or MCM.

STEPS NECESSARY TO ACHIEVE PURPOSE

The EO focuses on:

- "cost-effective and efficient domestic production";
- "adequate redundancy built into the domestic supply chain";
- ensuring "long-term demand" for Essential Medicines and MCMs; and
- "creat(ing), maintain(ing), and maximiz(ing) production capabilities."

REQUIREMENTS

The EO requires all federal agencies "to the maximum extent permitted" to procure Essential Medicines, MCMs, and Critical Inputs that are produced in the United States. To do this, the EO limits competition to domestic sources and splits procurements among two or more domestic sources.

IMPLEMENTATION TIMELINES

- The Environmental Protect Agency ("EPA") shall immediately identify relevant requirements that can be streamlined for development of advanced manufacturing with respect to Critical Inputs by accelerating permitting/approvals.
- The Department of Health and Human Services ("HHS") shall immediately use the Defense Production Act to prioritize federal agency orders for Essential Medicines, MCMs, and Critical Inputs over other contracts if considered necessary for national defense.
- By November 11, 2020, the FDA, in consultation with the Office of Management and Budget ("OMB"), the HHS office for the Assistant Secretary for Preparedness and Response ("ASPR"), the Assistant to the President of Economic Policy, and the Director of Trade and Manufacturing Policy, shall identify the list of Essential Medicines, MCMs, and Critical Inputs.
    - 30 days thereafter, the U.S. Trade Representative ("USTR") shall take action to modify all trade agreements to exclude these products.
    - 60 days thereafter, the Department of Defense ("DoD") shall limit, to the maximum extent possible, procurement of these

items to domestic sources. Notably, the domestic production requirements do not apply if an agency head determines: (i) application of these requirements is inconsistent with Pubic Interest; (ii) the products are not produced in sufficient quantities domestically; (iii) the cost of procuring U.S.-made drugs would be 25 percent higher than foreign-sourced drugs (50 percent for DoD); or (iv) the procurement is for items necessary to respond to public health emergencies or major disasters. "Inconsistent with Public Interest" is undefined, and thus gives a fair amount of discretion for agency heads to grant an exemption, however, given that exemptions must be reported to Congress, as a practical matter, exemptions are likely to be granted judiciously.

- Also by November 11, 2020, OMB shall:
  - Review authority of agencies to limit online procurement of Essential Medicines to e-commerce platforms that adopt best practices to combat counterfeiting and intellectual property; and
  - In consultation with the FDA, develop procurement strategies to mobilize the Public Health Industrial Base.
- By February 9, 2021, in consultation with the FDA and OMB, HHS shall identify vulnerabilities in the supply chain for Essential Medicines, MCMs, and Critical Inputs and mitigate these vulnerabilities by:
  - Considering proposing regulations and/or guidance to include these vulnerabilities as part of the FDA application and regulatory approval process;
  - Entering into written agreements with the Department of State, DoD, the Veterans Administration, and other interested agencies to disclose records regarding these vulnerabilities;
  - Recommending to the president any need changes in applicable laws;
  - Reviewing FDA regulations to determine if any should be repealed or amended;
  - Accelerating FDA approval of domestic producers of Essential Medicines, MCMs, and Critical Inputs;
  - Issuing guidance for Advanced Manufacturing techniques; and
  - Refusing admission to the United States of imports of Essential Medicines, MCMs, and Critical Inputs from locations that delay FDA inspection of the ex-U.S. facility.

- Also by February 9, 2021, DoD, in consultation with OMB, shall identify vulnerabilities in the supply chain for Essential Medicines, MCMs, and Critical Inputs that are unique to DoD and shall provide this input to HHS, FDA, and the Director of Trade and Manufacturing Policy to ensure these items for defense use are available in adequate amounts/dosage forms.

CONCLUDING THOUGHTS

- For drugs and PPE already defined by Project Bioshield, the EO has an immediate impact. Providers of MCMs should immediately determine whether they can comply with the EO or seek exemption.
- Even if there is an Administration change, the EO will likely survive because:
    - Most of the critical work implementing the EO will be done before January 20, 2021; and
    - The EO is constructed in a way that will make it very difficult, politically, to be reversed by a new Administration, especially given the reference to the Defense Production Act. Since the EO focuses on supply chain vulnerabilities that are determined to threaten National Security, any deviation from its requirements is likely to meet political opposition.
- The EO includes provisions that both restrict and expedite FDA approval based on where a product is made.
- The EO appears to downplay or overlook what is required for the USTR to modify all trade agreements to exclude Essential Medicines, MCMs, and Critical Inputs. Such agreements cannot be unilaterally modified. They must be negotiated, which takes time.
- The EO creates a potentially huge competitive advantage for domestic products. However, because the EO contemplates implementation through procurement regulations, it is unclear when this potential advantage will become effective. Further, it is equally unclear how many drugs will satisfy the Order's "produced in the United States" requirements—Critical Input must be produced in the United States and the final product must be manufactured in the United States. These standards are more demanding than current Buy American Act and Trade Agreements Act requirements, especially given recent case law that has substantially weakened the impact of the Trade Agreements Act.
- The EO incentivizes new domestic facilities that use advanced manufacturing techniques and, given CARES Act funding and International

Development Finance Corporation ("DFC") loan programs, creates the huge potential for federal government assistance with onshoring efforts.

- Waivers to domestic production requirements will likely be difficult to obtain since an agency will be required to report to Congress when it issues a waiver.
- HHS' desire to have two manufacturers ("Rule of 2") of MSNs will require clarification regarding whether it means by drug (e.g., two sources of a specific antibiotic or antiviral) or by class (e.g., two sources of anthrax monoclonal antibodies, smallpox vaccines, etc.).
- The prohibition on the import of products from locations where FDA inspections have been inhibited could impact many more products than just those coming from China and India.
- Arguably, this EO could result in higher prices for domestically produced drugs, which seems at odds with previous recent EOs, the aim of which was to reduce prescription drug prices. However, agency heads must consider price impact in determining whether a waiver may be appropriate.
- The EO will test whether the federal government's market share is large enough to cause manufacturers to make dramatic changes to manufacturing and sourcing (e.g., moving foreign-based manufacturing to the United States or establishing dual-sourced (foreign and domestic) manufacturing facilities).