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ASIA EDITION

President Trump announces the U.S. strategy to boost domestic pharmaceutical manufacturing and reduce regulatory barriers

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A robust domestic manufacturing base for prescription drugs, including key APIs needed for manufacturing prescription drugs.



President Donald J. Trump signed an Executive Order to facilitate the restoration of a robust domestic manufacturing base for prescription drugs, including key ingredients and materials necessary to manufacture prescription drugs.

- The Order directs the U.S. Food and Drug Administration (FDA) to reduce the amount of time it takes to approve domestic pharmaceutical manufacturing plants by eliminating duplicative and unnecessary requirements, streamlining reviews, and working with domestic manufacturers to provide early support before facilities come online.
    - The Order directs the FDA to increase fees for and inspections of foreign manufacturing plants.
    - President Trump is directing the FDA to improve enforcement of active pharmaceutical ingredient source reporting by foreign drug producers and consider publicly displaying a list of facilities that do not comply.
- The Order directs the Environmental Protection Agency (EPA) to accelerate the construction of facilities designed to manufacture prescription drugs, active pharmaceutical ingredients, and other necessary raw materials.
- The Order ensures that federal agencies issuing permits for a domestic pharmaceutical manufacturing facility designate a single point-of-contact to coordinate permit applications with interagency support from the White House Office of Management and Budget (OMB) to ensure an efficient and coordinated process.

The Trump administration is removing administrative barriers to critical domestic pharmaceutical manufacturing, enabling Americans to have access to medicines they need.

- Critical barriers and gaps still exist in establishing a domestic, resilient, and affordable pharmaceutical supply chain for American patients.
    - New construction must navigate myriad Federal, State, and local requirements ranging from building standards and zoning restrictions to environmental protocols that together diminish the certainty needed to generate investment for large manufacturing projects.
- Estimates suggest that building new manufacturing capacity for pharmaceuticals and critical inputs may take as long as five to ten years, which is unacceptable from a national-security standpoint.
- This Order will speed up timelines for building domestic pharmaceutical manufacturing site by reducing regulatory barriers to construction.

Some of the statements from President Trump ensuring the FDA prioritizes American manufacturing facilities over foreign facilities:

- President Trump: “We don’t want to be buying our pharmaceuticals from other countries because if we’re in a war, we’re in a problem, we want to be able to make our own.”
- President Trump: “As we invest in the future, we will permanently bring our medical supply chains back home. We will produce our medical supplies, pharmaceuticals, and treatments right here in the United States.”
- This Order builds on actions from President Trump’s first term to re-shore production of essential medicines and cut down our reliance on foreign producers.