DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Strategic Preparedness and Response

2024 Report to Congress on Increased Manufacturing Capacity for Certain Critical Antibiotic Drugs

Dawn O'Connell
Administrator and Assistant Secretary for Preparedness and Response

January 17, 2025
Date

Introduction

Section 2411 of the Consolidated Appropriations Act, 2023 (P.L. 117-73-22) requires an annual report on the use of the authority, granted in the section, to award contracts to increase the domestic manufacturing capacity of certain antibiotic drugs with identified supply chain vulnerabilities, or the active pharmaceutical ingredients or key starting material of such antibiotic. Specifically:

> *Report.--Not later than 2 years after the date of enactment of this Act and every year thereafter until the termination or expiration of all such contracts, the Secretary shall submit to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives a report on any activities supported under subsection (a), including--*
>
> *(1) the antibiotic drugs for which the Secretary prioritized awards under subsection (a), including a description of how the Secretary consulted with stakeholders to inform such prioritization;*
>
> *(2) information regarding each contract awarded pursuant to subsection (a), including—*
>
> *(A) the recipient of each such contract, including any recipients of a subaward;*
>
> *(B) the milestone and performance requirements pursuant to each such contract;*
>
> *(C) the duration of each such contract;*
>
> *(D) the amount of funding provided by the Secretary pursuant to each such contract, including any advanced or partial payments;*
>
> *(E) the antibiotic drugs supported through each such contract, including a description of the medical necessity of each such antibiotic drug and any supply chain vulnerabilities, limitations, and related characteristics identified pursuant to subsection(a)(2)(B)(iv for each such antibiotic drug; and*
>
> *(F) the amount of increased manufacturing capacity for such antibiotic drug that each such contract supports; and*
>
> *(3) a description of how such contracts address supply chain vulnerabilities, including increasing manufacturing capacity of antibiotic drugs in the United States; and*
>
> *(4) a description of the strategic plan submitted pursuant to subsection (a)(2)(B)(vi) by each recipient of an award under subsection (a).*

The following report has been prepared by the Administration for Strategic Preparedness and Response (ASPR) in response to this request.

Presential Directive

On August 6, 2020, the President issued the Executive Order on Ensuring Essential Medicines, Medical Countermeasures, and Critical Inputs Are Made in the United States[1]. This executive order directed the U.S. Food and Drug Administration (FDA) to identify a 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 and in the appropriate dosage forms[2]. The goal of the EO is to ensure sufficient and reliable, long-term domestic production of these products, and to minimize potential shortages by reducing our dependence on foreign manufacturers of these products.

The executive order also directed the FDA to coordinate with other federal partners on a number of additional issues, including strategies for acquiring the products on the list, accelerating domestic manufacturing, and identifying and addressing supply chain vulnerabilities. Through this effort, FDA identified that companies should consider adopting advanced manufacturing technologies to enhance competitiveness with global partners in this space.

Background on Domestic Manufacturing of API

Concentration of API production in China is the result of Chinese actions to increase market share. For example, per 2019 testimony before the U.S.-China Economic and Security Review Commission[3], penicillin has not been made in the United States since 2004, which has been attributed to a broader active strategy by Chinese companies to sell product on the global market at below-market price, which drove U.S., European, and Indian producers out of the business. Once the Chinese companies gained dominant global market share, prices increased. As a result of this strategy, not only have prices risen, but the United States does not have current domestic production capacity for many generic antibiotics for children's ear infections, strep throat, pneumonia, urinary tract infections, sexually transmitted diseases, Lyme disease, superbugs, and other infections that are threats to human life.

This consolidation of production to low-cost countries is also driven by increasing pressure to acquire products at the lowest cost possible, which for drugs like antibiotics has led to companies focusing production on products that have higher profit potential. When profit margins are lower on patented products, there are fewer incentives for multiple generic companies to enter the market. Additionally, shortages of products like antibiotics can have effects beyond patient access; doctors may use inferior products that are not as effective, leading to longer hospital stays, greater burdens on the health care system, and in the case of antibiotics, potentially additions to growing antimicrobial resistance globally.

---

[1] Available online at https://trumpwhitehouse.archives.gov/presidential-actions/executive-order-ensuring-essential-medicines-medical-countermeasures-critical-inputs-made-united-states/

[2] The FDA list is available online at https://www.fda.gov/about-fda/reports/executive-order-13944-list-essential-medicines-medical-countermeasures-and-critical-inputs

[3] Hearing available online at https://www.uscc.gov/hearings/exploring-growing-us-reliance-chinas-biotech-and-pharmaceutical-products

Current Efforts to Address Domestic Manufacturing Capacity of Certain Antibiotic Drugs

As a first step in API production domestically, ASPR, in consultation with the FDA, began a development effort with Phlow Pharmaceuticals for Ciprofloxacin HCL (Ciprofloxacin is on the FDA essential medicines list) in February of 2021. Ciprofloxacin HCL is an antibacterial prescription medicine approved by the FDA for the treatment and prevention of several infections caused by certain types of bacteria, for example, certain urinary tract infections, lower respiratory tract infections, and skin infections. ASPR awarded $583 million toward a 5-year base with Phlow and included milestones for Pre-Development, Process Research, Process Development, Production Development, as well as Validation and Commercialization. As of the date of this report, Phlow has completed the pre-development, process research and process development milestones and is working towards production development, validation, and commercialization in FY2025.

During the current validation campaign, Phlow is on contract to produce 9 kg of ciprofloxacin HCL. This is representative of 36,000 doses per campaign produced in their Kilo-scale facility. They are also constructing a hybrid manufacturing facility that will be capable of producing 240M doses per year, more than enough to meet US Demands of 13,100 kg/year (52.4M doses/year). This contract reduces supply chain reliabilities on API that is currently being produced in China.

Future Considerations

Congress should be aware that without additional funding, the U.S. government will be unable to support additional rounds of domestic production, including maintaining and expanding current investments in API. Included in the FY 25 President's Budget was a request for $95 million to continue to support ASPR investment in domestic manufacturing. We look forward to working with Congress on solutions to sustain investments in building domestic manufacturing and production capacity.