After a 100-day review of longstanding vulnerabilities in the US pharmaceutical supply chain, the Biden administration released key findings from this effort last week and described actions needed to address these weaknesses.

Such vulnerabilities became especially apparent during the COVID-19 pandemic, federal officials noted.

“Last year the American people experienced a widespread and significant shortage of N95 respirators for healthcare workers and masks to protect essential workers and others, and year after year we see shortages of medicines and medical supplies like saline,” said US Food and Drug Administration (FDA) Acting Commissioner Janet Woodcock, MD, in a press statement. “Pharmaceutical supply chains are essential for the national and health security and economic prosperity of the United States, yet the COVID-19 pandemic revealed just how vulnerable the supply chain is in this country.”

The review was mandated by an executive order issued by President Biden on February 24, which called for a government-wide assessment of vulnerabilities in critical supply chains, as well as recommendation for approaches to address problems and decrease reliance on other countries for key products and materials.

The government published its findings on the supply chain for pharmaceuticals and their active ingredients in a 250-page report, which also assessed supply chains for other key areas, including semiconductors, high-capacity batteries, and critical minerals and strategic materials.

“The drive toward lower costs as well as unfair trade practices have led to a hollowing out of domestic production,” notes a White House fact sheet on the report. “A new approach is needed to ensure more resilient supply chains that includes improving transparency, building emergency capacity, and investing in domestic production.”

The Department of Health and Human Services (HHS), which wrote the portion of the report specifically addressing the pharmaceutical products and ingredients, is taking immediate steps to address the pharmaceutical supply chain issue. For example, the department has committed approximately $60 million from the Defense Production Act appropriation in the $1.9 trillion coronavirus relief bill (the American Rescue Plan) to develop new technologies to increase active pharmaceutical ingredient (API) manufacturing capacity.

In addition, HHS will host a “high-level summit” on drug supply chain resilience and assemble a public-private consortium of public health experts (including in critical care and emergency medicine). The consortium will review the FDA’s essential medicines list, recommend up to 100 drugs that are most critical to have on hand at all times for US patients, and determine a potential volume that might be needed, “using the surges during [the] COVID-19 pandemic as one metric for that analysis.”

An analysis by HHS of 120 medications—118 of them from the FDA’s 2020 list of essential medicines—found that domestic facilities produce only 60 of these critical drugs. For 50 of these drugs, 70% of the facilities that produce the active ingredients are based in Asia.

The report also notes that HHS will examine the shortages of essential medicines in the past year “to determine major drivers, including mapping their supply chains to characterize their redundancy, diversity, and manufacturing quality.” The agency also will leverage the Defense
Production Act process to determine the financial incentives needed to boost pharmaceutical production capacity within the United States or “nearshore” in a nearby country.

The report also focused on the supply chain issues related to generic medications, which represent 90% of all prescription medications filled in the United States. About 87% of API facilities for such drugs are overseas, in part because of the influential role played by market factors.

“While the United States does not need to make every drug itself, it does need increased domestic production capacity for key drugs,” the report says. “Policy tools to increase the economic sustainability of US and allied drug manufacturing include providing predictability in production costs, pricing, and volume sold; increasing government and private sector flexibility in contracting and sourcing of finished drugs and raw materials; and studying whether the current market for finished drugs supports a diversification of supply instead of relying on one or two suppliers through preferred contractual arrangements.”

In addition, the review says better transparency is needed throughout the supply chain, such as transparency about the source of APIs used in the manufacture of generic drugs. Currently, a generic manufacturer outside the United States might rely on ingredients from another non-US source, particularly in China, making it harder for the FDA to anticipate potential issues.

Other countries are also working to address pharmaceutical supply chain issues. The report notes that the Canadian Generic Pharmaceutical Association is calling for investment in domestic manufacturing and an enhanced international role, whereas in Europe, Sanofi is creating an API manufacturer, EUROAPI.