



Building geographic diversity in the medicines supply chain

USP White Paper





What is Geographic Diversification?

Geographic diversification is investing in business across multiple countries and various regions with the primary aim of limiting losses, spreading risk, and securing multiple sources for manufacturing and production.

Leveraging geographic diversification for a more resilient medicines supply chain

The globalization of commerce and supply chains over the past century has led to vast reductions in poverty and reduced cost for many goods. But, in many cases, globalization has also led to concentration of the production of some goods to a limited set of geographies—or even a single country—when downward pricing pressure requires producers to seek economies of scale, less regulation, and lower costs. This has been the dynamic facing the generic medicines industry.

While the globalization of the medicines supply chain has generally facilitated access to medicines at a lower cost, geographical concentration has increased the risk of unreliable supply following sudden or unexpected shocks in specific locations, including those caused by natural disasters, trade wars, domestic or geopolitical strife, or global public health emergencies. [USP's Medicine Supply Map](#)¹ data show that geographic concentration anywhere—including within the United States—increases the risk of drug shortages.

Promoting geographic diversification of the manufacturing base for U.S. drug products can help reduce supply chain vulnerabilities. Supply chain stakeholders, including governments and regulatory authorities and industry, are reassessing their strategies to determine the best path forward.

Geographic concentration increases supply chain vulnerability

Over the past decades, global medicines supply chains have moved from being vertically integrated—where a drug manufacturer owns or controls most aspects of production (including suppliers)—to horizontally distributed, where many functions in the supply chain, such as the production of both active pharmaceutical ingredients (APIs) and inactive ingredients, are often outsourced to multiple firms around the world. In many cases, these companies are concentrated in certain geographical areas because of lower costs and relaxed regulatory or environmental requirements in overseas facilities.²

An overreliance on a single region for the sourcing and procurement of raw materials and development of drug products can lead to drug shortages. A disruption in a single region can rupture multiple elements of the supply chain should it impact the reliable supply of APIs and the starting materials essential for their synthesis, excipients, packaging materials, and other supplies.³ A 2021 White House report⁴ found that 87 percent of U.S. Food and Drug Administration (FDA) registered API manufacturing facilities for generic medicines were located outside the United States. Many countries, including the United States, are reliant on China and India for the manufacturing of many APIs used in generic medicines, such as antibiotics and analgesics. A recent analysis reported that 67 percent of all active antimicrobial API Drug Master Files (DMFs)—



submissions to FDA used to provide confidential, detailed information about facilities—originate from manufacturing facilities in China and India.⁵ India, a U.S. trade ally, has itself recognized that API concentration in China poses a risk to supply chain resilience. To address this concern, the Government of India recently announced multiple initiatives to onshore more API manufacturing in India.⁶

Geographic diversification is important for a reliable supply of quality medicines

Few supply chains emerged unscathed from COVID-19 pandemic disruptions, including those of the pharmaceutical and healthcare industries. Challenges from these disruptions uncovered the limits of overseas manufacturing dependency and exposed vulnerability to exogenous shocks. The reality of today is not *if* the next crisis will occur—but *when*. To prepare for inevitable disruptions, geographic diversification of the supply chain is recognized as a method to rebalance supply chains and reduce risk. Importers and exporters, for instance, seek to diminish their risk by shortening the supply chain. Health plans are seeking more medicine sources, from more places, to mitigate the risk of shortages to their members. Policymakers are increasingly concerned about a fragmenting global trade network that could further accelerate drug shortages. To ameliorate these risks, stakeholders must diversify where products are manufactured.

Multiple strategies can enable geographic diversity of the supply chain

Current stakeholder conversations focus on various strategies to diversify geographically, such as onshoring, nearshoring, and friendshoring.⁷ To reduce supply chain vulnerabilities, these conversations cannot focus solely on implementing one strategy alone. To inject resilience and reliability into the medicines supply chain, several concurrent tactics should be considered. The solution to this complex situation must leverage a multifaceted approach.

- **Friendshoring or Allyshoring** is a growing trade practice where supply chain networks are focused on countries regarded as political and economic allies where the risk of disruption from political turmoil is low. However, there are concerns that the move toward friendshoring risks exacerbating geopolitical fragmentation and what has been described as ‘deglobalization.’
- **Nearshoring** is a business strategy that involves a company shifting some or all its supply chain operations to a location geographically closer to its main market. The proximity can bring several advantages including rapid transit from manufacturers to customers.
- **Onshoring** is the process of sourcing a company’s production operations within domestic national borders.
- **Offshoring** is the practice of basing portions of a company’s processes or services overseas, often to take advantage of lower costs.

- **Reshoring** is the process of returning product manufacturing from a foreign country back to the home country where a company's products are sold.

To improve supply chain resilience in the post-COVID world, a rebalancing of the supply chain can occur using these shoring approaches to unwind consolidation in heavily geographically concentrated areas and create a more distributed manufacturing footprint. Shoring strategies drive redistribution of capacity, create more flexibility for product manufacturing, open the potential to shift capacity away from regions that are suddenly impacted, and decrease over exposure in any one region. Enacting a multi-shoring approach allows for multi-sourcing from a mix of local, regional, and global sites. For both suppliers and production, multi-sourcing must be considered as a potential path to supply chain resiliency.

Geographic diversification can help ensure essential medicines security

A multifaceted shoring approach can de-risk production of goods, particularly those considered essential to national security, such as medicines. Drug shortages—especially shortages of essential medicines—create national security risks; building risk-resistant supply chains that anticipate uncertainty can support domestic security. The security of domestic drug supplies is contingent on multi-sourcing. To secure additional suppliers, geographic diversification can include onboarding secondary suppliers in the North American region while maintaining established partners overseas.

As governments, particularly the U.S. Government, are interested in fortifying the medical supply chain as a matter of national security interests, efforts to identify essential medicines are a focus of policy actions and initiatives to improve medicines supply chain resiliency. USP supports the establishment of a vulnerable medicines list to complement those medicines deemed essential that specifically addresses supply chain vulnerabilities. Such a list can help prioritize medicines and properly target policy interventions and finite resources to improve medicines supply chain resiliency and preserve patient access to necessary medicines.

For an increasing number of companies, shoring tactics are evolving into critical business objectives. As these companies accelerate the implementation of strategies to ensure that finite resources and investments are maximized and have substantial public health impact, investing in locations near their target market can facilitate integration and production of final products nearer to the end consumer. From a financial perspective, the benefits of this approach include less expensive shipping costs and avoidance of import tariffs on goods.

Cost is the biggest consideration for geographic diversification and shoring efforts

Financial incentives for manufacturers to accelerate geographic diversification opportunities are inadequate for many generic drug producers. For common medications, especially generic drugs or those drugs that are not produced in large quantities, economic margins are small and returns on any investments are limited and not guaranteed.⁸ A complex calculus is needed to evaluate the business case for shoring strategies; many find costs outweigh any benefits. The increasingly low prices of some generic medicines undermine the economic case for investing in geographic diversification of manufacturing.

Additionally, the “switching costs”⁹⁻¹⁰ and economic resources needed to establish new facilities are often too high for the low return on the required investment. Manufacturers cite differential manufacturing costs as a consideration for and barrier to implementing shoring strategies. Typically, the cost of manufacturing in the United States is, on average, 30 to 50 percent higher than in China, India, or Mexico.¹¹

Pricing models and government policies related to manufacturing can influence pharmaceutical industry decision-making about the best locations for business. Some factors include the available tax incentives for shoring initiatives, generic drug manufacturer collaboration and participation in public-benefit corporations, and more. Deciding when, where, and how to take advantage of geographically diverse sourcing options will require effort, significant time, and increased up-front costs.

Additional considerations exist for geographic diversification of medicines supply chains

In addition to cost, many considerations contribute to a company's assessment of moving operations and production, including:

- **Strategic Locations:** Geographic diversification allows suppliers and manufacturers to optimize supply chains through multi-sourcing. Additional partners in regions closer to the final end-users and near target markets allow for more integration from diversification of manufacturing and distribution partners, easier flow of goods, and potential and current multinational trade agreements.
- **Operational Considerations:** Identifying who will provide infrastructure investment is a key consideration for geographic diversification. Using traditional pharmaceutical manufacturing technology, many domestic companies are unable to offset labor and other cost advantages that foreign nations can provide. However, infrastructure deficiencies and uncertainty in the electricity and water sectors in some existing manufacturing locations may contribute to supply chain instability. Investment in new infrastructure, including advanced manufacturing technologies (AMTs), could enable domestic pharmaceutical manufacturing to regain its competitiveness and potentially ensure a stable supply of medicines.
- **Crawl-Walk-Run Approach:** Some companies and sectors may not have the infrastructure necessary to support immediate geographic diversification and may not be incentivized to consider long-term geographic diversification planning efforts. Manufacturers and suppliers can consider a stepwise approach beginning with trial projects to test feasibility, learning from the experience, building relationships with local and national regulators, communicating and exchanging information and capabilities from industry and other sectors, and then scaling production accordingly.
- **Economic Opportunities:** Several economic considerations exist when exploring shoring initiatives closer to end-user markets, such as competitive labor costs, potential tax exemptions, faster time to market, reductions in logistics costs, and more effective planning cycles to free up working capital tied to suppliers and inventory in transit.¹⁰
- **Structural Risks:** Lack of public and legal security, as well as corruption, fraud, weak rule of law, perceptions of insecurity, cargo risks, theft, and extortion can exist in some locations.
- **Regulatory Risks:** Challenges in filing for market authorizations, import permits, and manufacturing certifications—including administrative delays—can deter plans to move operations.
- **Wide Variation in Environmental Regulations for Drug Manufacturing:** The cost of meeting environmental regulations has been a factor in driving production into a few specific countries. In response to the very low prices of some generic drugs and drugs produced in small quantities, manufacturers have sought to reduce the costs associated with environmental compliance.
- **Workforce Considerations:** Manufacturing operations are increasingly more automated and leverage new technologies, which require specialized personnel. Training the workforce takes time and is an added expense. The technical skills of a workforce, the ability to integrate automation into production processes and operate them efficiently, and the ability to provide continuous training will be a source of competitive advantage.⁴
- **Advanced Manufacturing Considerations:** AMTs can increase future flexibility and help to strengthen supply chain resilience by reducing some of the vulnerabilities posed by geographic concentration. AMTs can also improve time to market and help bring manufacturing to more regions, allowing economies that are new to pharmaceutical manufacturing to establish production plants of quality medicines and APIs. Numerous technical challenges and regulatory considerations play into decisions to adopt AMTs, including understanding the impact of the technology and how to best implement it. Some potential benefits of AMTs include smaller facility footprints, reductions in operating costs, reductions in waste, and increased efficiencies for many medicines and



their ingredients, all of which may be appealing incentives to manufacturers.

Looking ahead and leading the way to a more resilient and reliable medicines supply chain

As outlined in a recent [USP Global Policy Position Statement](#),¹² USP urges that policy reforms to promote geographic diversification in medicines manufacturing should include but not be limited to onshoring and reshoring initiatives, as geographic concentration—even within the United States—can serve as a significant risk factor for drug shortages. USP supports and encourages:

- Economic or other incentive measures that will encourage multiple suppliers for key drugs, geographic diversification of manufacturing facilities, and manufacturing location and component supply redundancies.
- Economic incentives to encourage increased domestic manufacturing of APIs and finished drug products in the United States, prioritizing specific medicines or ingredients that are most vulnerable to supply disruptions.
- Market-based incentives that encourage utilization of excess domestic manufacturing capacity. Up to 50 percent of manufacturing capacity in the United States is currently unutilized.
- Financial incentives to provide manufacturers with the necessary funding to build facilities supporting advanced manufacturing technologies on U.S. soil; currently, manufacturers of low-margin drug products that have a higher likelihood of shortage have insufficient profitability to invest in AMTs.
- The development of tools and standards to help reduce the technical barriers to wider adoption of AMTs.

About USP

The U.S. Pharmacopeia (USP) is an independent, scientific nonprofit organization focused on building trust in the supply of safe, quality medicines, dietary supplements, and foods, through setting public quality standards in its various compendia. A core pillar of USP's work is to help strengthen the global supply chain so that the medicines, dietary supplements, and foods that people rely on for their health are available when needed and meet quality standards as expected and required.



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