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Strengthening the US-Mexico Pharmaceutical Supply Chain

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During the 2025 Milken Institute Global Investors' Symposium in Mexico City, the Milken Institute Public Health team convened an invite-only roundtable titled "Strengthening the US-Mexico Pharmaceutical Supply Chain." The roundtable was composed of North American pharmaceutical industry leaders, investors, and current and former government officials. The summary below presents key insights from the roundtable discussion, conducted under the Chatham House Rule.

Strategic Opportunity to Expand Mexico's Pharmaceutical Manufacturing Capacity

The pharmaceutical supply chain is an intricate and interconnected system that plays a crucial role in ensuring that communities and individuals have access to medicines when they need them. The ready availability of pharmaceuticals enables people to protect their health, prevent disease, manage treatments, and improve overall health outcomes.

Ideally, these products should be available to anyone at any time needed. This means that supply chains in North America must operate efficiently and resiliently during both times of crisis and steady state. However, critical medicine shortages are increasingly threatening public health systems worldwide, and the North American pharmaceutical supply chain relies heavily on

countries outside of the Americas, namely China and India, which puts its resiliency and security at risk. This issue will only intensify as populations in North America age and increase demand for pharmaceuticals.

Nearshoring and onshoring can help to increase the safety, security, and resiliency of supply chains. Nearshoring refers to procuring pharmaceutical products from markets located closer to a country to shorten supply chains, reduce geopolitical risk, and improve resilience while maintaining cost advantages. Onshoring refers to bringing production—including active pharmaceutical ingredients (APIs), key starting materials (KSMs), and finished-dose drugs—within a country's borders to enhance domestic supply chain security. KSMs are the building blocks used in the early manufacturing process to make the API, which is the main active ingredient of the medicine. Through nearshoring and onshoring, North America can draw investment and jobs back to the region and exercise greater oversight of movement and utilization.

The US and Mexico are uniquely positioned to transform pharmaceutical supply chain resilience as joint strategic partners. Mexico is the 15th-largest market for pharmaceuticals in the world and the second-largest regional market, behind Brazil. About 400 laboratories manufacture pharmaceuticals in Mexico, as the country is home to 20 of the 25 largest companies worldwide.

Furthermore, the United States-Mexico-Canada Agreement (USMCA) created a legal foundation that supports both nearshoring and onshoring of pharmaceutical manufacturing to North America to reduce external dependence. This cross-border framework enables a diversified regional supply chain that could lead to improved supply chain security, shorter lead times for manufacturing products to move from manufacturing site to point of use, and more efficient drug approvals. Bringing supply chains closer to home offers the potential to enhance the region's health security, reduce vulnerabilities, and strengthen collaboration in research, manufacturing, and policy.

However, API production in places such as Mexico has decreased in recent years, in no small part due to competition from outside of the hemisphere. This competition, emanating largely from South and East Asia, has undercut North American production by benefiting from significant domestic demand for pharmaceuticals, coordinated local policies, and state-directed subsidies.

Role of Regulatory Environment to Advance North American Cooperation and Alignment

A predictable, transparent, and cooperative regulatory environment is a cornerstone of a successful biomedical innovation ecosystem and will be foundational to efforts aimed at strengthening regional pharmaceutical supply chains. As the United States and Mexico explore opportunities to enhance the production and integration of APIs within North America, deeper collaboration between the US Food and Drug Administration (US FDA) and Mexico's Federal Commission for the Protection against Sanitary Risk (COFEPRIS) becomes increasingly important.

Strengthening alignment between the two agencies would help streamline cross-border production, reduce regulatory uncertainty for manufacturers, and improve overall supply chain safety, security, and resilience. At the same time, any steps toward greater alignment must be grounded in mutual respect for national sovereignty, ensuring that cooperation enhances—rather than compromises—each country's regulatory authority.

US FDA recently launched the PreCheck Program, aimed at engaging early with manufacturers interested in domestic production through regulatory clarity and the streamlining of applications related to the construction of manufacturing sites, including for APIs. Although the initiative is promising, experts note that increasing domestic API production from its current 9 percent capacity to self-sufficiency is a long-term endeavor, which could potentially take 5 to 10 years or more. Thus, the United States' stated pursuit of ensuring pharmaceutical supply chain resilience will require tapping into production capacity beyond its own borders at a greater magnitude than has been achieved to date. Building blocks for doing so already exist; for example, the FDA's Office of Global Operations Latin America Office helps to ensure the quality and safety of exports to the United States.

In Mexico, many pharmaceutical companies already meet high regulatory standards. In addition to the domestic Mexican market, many multinational pharmaceutical companies with a presence in Mexico have been exporting to the European and broader North American marketplace for over a decade and possess experience navigating both the European Medicines Agency's (EMA) and US FDA's requirements. However, the degree to which manufacturers of generic drugs based in Mexico are ready and able to secure approval from the US FDA or EMA varies. Doing so can be a challenging process for many companies; it is time-consuming and expensive, and far from a guaranteed investment.

Regulatory and standards harmonization could, in part, help to ameliorate this challenge, and the situation is slowly improving, as evidenced by COFEPRIS joining the International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use (ICH) in 2021. COFEPRIS' efforts in 2025 toward modernizing applications through digitalization and streamlining procedural requirements are welcome developments that can help to accelerate existing processes. Additional resources and institutional strengthening would continue this progress.

During the roundtable, participants emphasized the urgency of strengthening coordination between US FDA and COFEPRIS to review and approve APIs of finished dosage products. With 3,000 to 4,000 APIs needed globally—and around 1,000 deemed critical—any delay in regulatory processes could have life-or-death consequences. Existing organizations in the United States have identified 200 drugs as most vulnerable to shortage. Developing a joint US-Mexico list of the most vulnerable finished dosage products and APIs is a necessary first step toward greater management of cross-border supply disruptions.

Roundtable participants also identified USMCA reauthorization in 2026 as a crucial opportunity to strengthen cross-border regulatory coordination while simultaneously incentivizing manufacturing and infrastructure investment. Consideration of the inclusion of special treatment for APIs within the framework, whether through special tariff rates or rules of origin, was strongly recommended.

The Case for Economies of Scale

For new investment in North American API production to be viable, economies of scale must be achievable. API manufacturing requires significant volume and a sufficiently large market to justify the capital, operational, and compliance costs. A coordinated North American pharmaceutical supply chain—rather than one fragmented across multiple countries—can aggregate demand, attract investment, and strengthen the region's ability to maintain a safe and secure supply of critical medicines. Over time, such capacity could position North America as a competitive producer not only within the region but also for South America, Europe, and other global markets.

China and India dominate KSM and API production today in part because their large populations and consolidated manufacturing ecosystems create the conditions that make achieving economies of scale easier. North America can replicate this advantage only by aligning its market, reducing duplication, and building sufficiently large production capacity anchored in regional cooperation.

Current tariff-related policies in the United States create an interesting tension. On the one hand, if narrowly tailored, tariff-related policies could help to set a price floor on imports of APIs and KSMs sourced from geographies where governments subsidize the cost of their manufacturing. This approach could allow for production of these goods in North America to more readily compete on price. On the other hand, the economies of scale already achieved by incumbent producers make it more likely that these inputs are employed as a bargaining chip in broader economic negotiations. Consequently, the rapid application of tariffs without a concurrent, coordinated ramping up of North American production capacity could lead to shortages of APIs and KSMs, reducing the availability of critical medicines.

Although a high-risk approach, temporary tariffs may help jumpstart API production in North America, particularly when combined with the establishment of the United States' Strategic Active Pharmaceutical Ingredients Reserve (SAPIR). SAPIR was created as a stockpile of APIs to insulate the United States from foreign manipulation of API supply levels. If employed effectively, it could help ensure a degree of appropriately priced demand for local production. A sustainable solution, however, must be built upon market-based principles, select application of incentives from governments in the United States and Mexico, and broad support of public–private partnerships.

Mexico's Infrastructure Investment Needs

To build an efficient, transparent, and resilient pharmaceutical supply chain in Mexico, several pivotal infrastructure needs must be addressed. Robust infrastructure is essential for the production of APIs, their movement to manufacturers, and the reliable export of finished products. Critical areas such as workforce development, transportation networks, water treatment, and energy capacity all require targeted investment to strengthen Mexico's ability to support large-scale API manufacturing.

Workforce Development

Mexico's workforce is well positioned to support expanded manufacturing, pharmaceutical production, and biochemistry operations. Currently, Mexico City has about 40,000 students focusing their education in relevant fields, providing a strong pipeline of talent capable of meeting industry needs. In addition, Mexico has demonstrated a consistent track record of respecting intellectual property, an important factor that can help to attract global pharmaceutical companies seeking reliable partners for API and finished-dose manufacturing.

Transportation Networks

Improving Mexico's transportation infrastructure could strengthen operational efficiency and help Mexican producers compete more effectively. In recent years, ports and other logistical infrastructure have greatly improved, and plans to continue to enhance transportation networks are ongoing, but challenges remain. Additionally, the time required to transport APIs, KSMs, and finished-dose drugs is acutely important for medicines that must be handled using cold chain and maintained at certain temperatures.

Furthermore, safety and security are important factors to consider across the supply chain. Considered high-value substances, pharmaceuticals can be subject to organized crime. Ensuring higher levels of security across Mexico's roads for both drivers and pharmaceutical products is essential to guarantee the reliable and safe movement of medicines across Mexico.

Water Treatment and Energy Capacity

Reliable sourcing of both energy and water is a necessary predicate to API production. The roundtable identified opportunities and challenges related to sourcing these inputs in Mexico. Investments in water- and energy-related infrastructure are critical to the creation of any new API manufacturing hubs and the expansion of existing facilities. Much of Mexico's considerable technology and manufacturing capacity is concentrated in northern and central regions, some of which are grappling with the possibility of a water-stressed future. Regions with more abundant water resources are concentrated in certain coastal and southern regions; while some manufacturing is present, more can and is being done through government policies to build capacity in these areas.

As with water, reliable and competitively priced energy is a necessity. Although energy rates in Mexico are generally low, they have been increasing in recent years. To multinational companies and investors, the perceived lower cost when compared to other locations globally still represents a competitive advantage for Mexico.

Role of Capital Investment

Mobilizing capital at scale will be necessary to achieve increased API production in Mexico. Government(s) and public spending alone cannot fully finance the investments needed; public–private partnerships incorporating all levels of government, development banks, and private capital are critical. The good news is that the challenge of mobilizing capital through public–private partnerships is not insurmountable.

The growth of the private retirement system through the Administradoras de Fondos para el Retiro (AFORES) over the past two decades has created another key conduit for allocating domestic capital to longer-term projects, including infrastructure and key sectors. International investors, including private equity and venture capital, continue to view Mexico with keen interest. However, inefficiencies in the regulatory space, particularly uncertainty related to COFEPRIS, remain a concern for many investors, ultimately impeding potential investments. Solving some of the regulatory, USMCA, and infrastructure-related questions discussed above would go a long way toward assuaging hesitation from these investors.

Recent government initiatives, notably Plan Mexico, have been designed to promote inclusive, sustainable economic growth while strengthening Mexican competitiveness through investment mobilization in infrastructure, including energy and water, and key sectors, including pharmaceuticals. Plan Mexico includes certain policies and tax incentives, such as accelerated depreciation for investment in new fixed assets and tax deductions for investments in innovation that results in new patents. When combined with a broader program of infrastructure investment and regulatory reform, these tax-based incentives may help to spur the investments needed to expand existing pharmaceutical manufacturing capacity in Mexico.

Conclusion

During this roundtable discussion, the Milken Institute uncovered important regulatory, infrastructure, and financing considerations for Mexico to strengthen the North American pharmaceutical supply chain by becoming a trusted global supplier of APIs, KSMs, and finished-dose drugs. With a forward-looking lens, efforts to form public–private partnerships, invest in Mexico's infrastructure, and create enticing opportunities for capital investments are pivotal to strengthening the pharmaceutical supply chain in North America. The Milken Institute looks forward to continuing research and facilitating conversations with senior leaders across government and industry and to catalyzing actionable solutions.

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