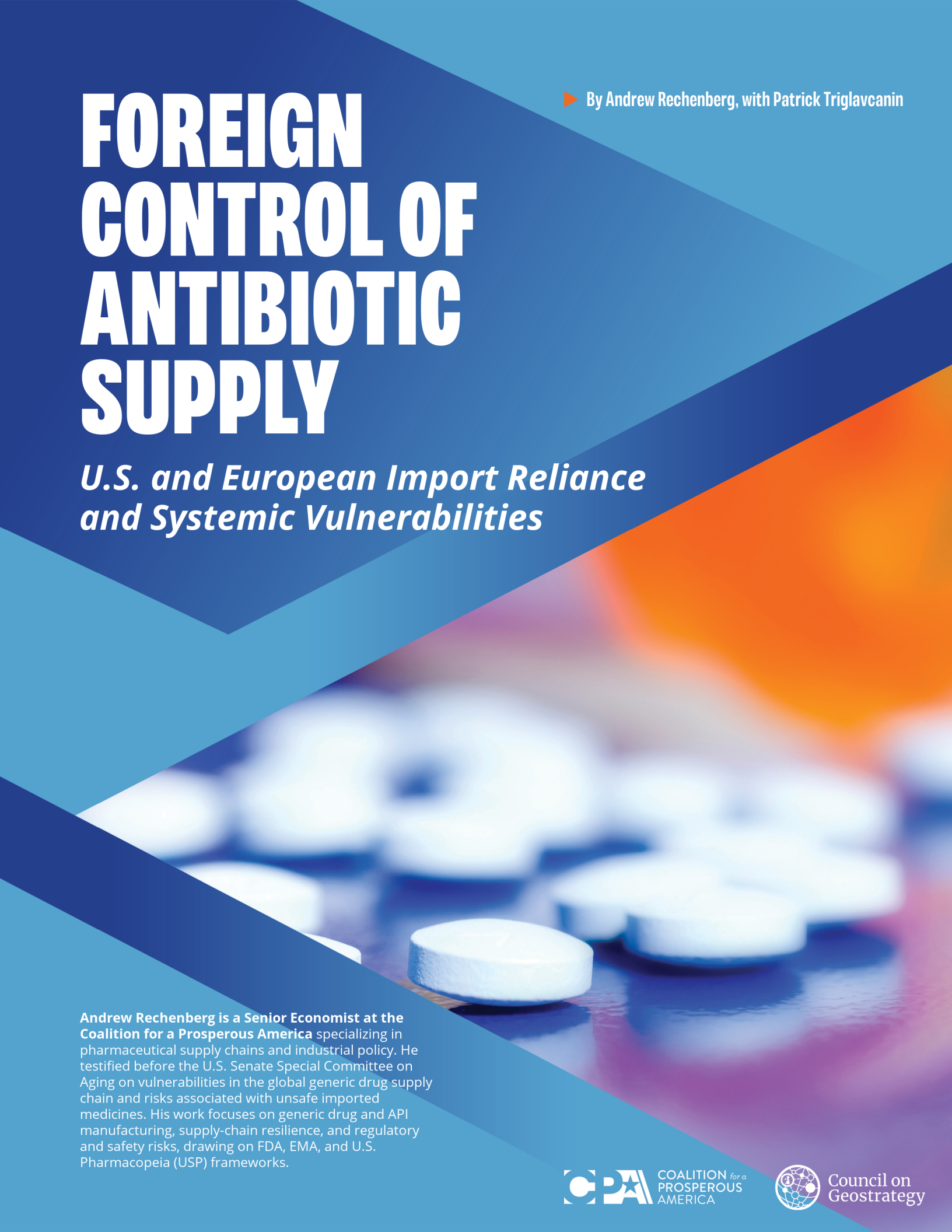
FOREIGN CONTROL OF ANTIBIOTIC SUPPLY

U.S. and European Import Reliance and Systemic Vulnerabilities

By Andrew Rechenberg, with Patrick Triglavcanin



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I. Executive Summary

The United States and countries in Europe now depend overwhelmingly on foreign suppliers for the antibiotics that modern medicine requires. Nowhere is this dependence more acute than in the upstream stage of production: both rely almost entirely on China for the active pharmaceutical ingredients (APIs) that form the molecular foundation of all antibiotics. Without these inputs, no finished-dosage form (FDF) antibiotics can be manufactured—whether in India, Europe, or the United States. This extreme upstream reliance means that the stability of U.S. and European health systems is tied directly to the continuity of Chinese industrial operations, regulatory decisions, and geopolitical posture.

This vulnerability is amplified by the architecture of the global supply chain. China controls the upstream API stage; India formulates the downstream FDF antibiotics; and the United States and Europe import the result. What appears to be a multi-country supply network is, in practice, a single chokepoint with minimal redundancy and heavy firm-level concentration. This system operates through four reinforcing layers of vulnerability.

- **Layer 1:** The United States and Europe rely on India and China for finished-dosage antibiotics.
- **Layer 2:** Downstream supply is concentrated among a small number of Indian manufacturers.
- **Layer 3:** These manufacturers depend almost entirely on China for upstream antibiotic APIs.
- **Layer 4:** Within China, production itself is concentrated among a limited set of firms responsible for the majority of global API output.

Each layer compounds the risk, leaving the global antibiotic supply chain highly concentrated and fragile. A shutdown, contamination event, or export interruption at even a small number of Chinese API facilities could disrupt entire antibiotic classes worldwide. Downstream disruptions in India would compound the impact. The United States and European countries are thus exposed not only to changes in foreign output, but also to the potentially unforeseen regulatory and industrial shifts of a handful of companies thousands of miles away. This exposure includes drug quality and safety risks, as Food and Drug Administration enforcement actions have shown that major exporters have supplied adulterated or improperly tested medicines into U.S. and European markets, including the Ranbaxy case discussed in this report.

Despite this fragility, the United States and European countries still retain critical industrial footholds—particularly a small number of facilities capable of fermentation, chemical synthesis, and sterile-injectable production, including the last major fully vertically integrated production site for penicillin-class antibiotics in Europe—that is, a facility that performs the complete production chain from fermentation of Penicillin-G through conversion to 6-aminopenicillanic acid (6-APA), synthesis of finished APIs, and formulation and packaging of FDF antibiotics. While the United States no longer has any vertically integrated penicillin production sites or upstream penicillin-class API producers, it does maintain an important downstream foothold in amoxicillin finished-dose manufacturing through USAntibiotics.

These remaining assets are strategically irreplaceable. They form the industrial core from which upstream antibiotic sovereignty can be rebuilt. With the right policies and market signals, these facilities can anchor renewed API capacity, restore domestic production, and expand downstream formulation capabilities. The U.S. and European nations face a profound strategic vulnerability, but also a clear opportunity to rebuild leadership in the essential stages of antibiotic manufacturing.

Addressing this vulnerability requires a coordinated policy framework that strengthens domestic and allied producers, corrects distorted market dynamics, and ensures that U.S. and European manufacturers can operate viably at scale. This includes targeted trade tools to counter persistent price suppression, procurement reforms that reward reliability over lowest cost, stronger oversight and transparency requirements for foreign supply, and joint U.S.–European Union (EU) investment in fermentation, synthesis, and formulation infrastructure. Fermentation underpins the production of core antibiotic APIs and intermediates and is both capital-intensive and highly concentrated. As this report demonstrates, approximately 90% of global 6-APA production capacity is located in China, making this stage the primary upstream chokepoint in the modern antibiotic supply chain. Together, this coordinated policy framework would restore the upstream resilience both the U.S. and several European countries have lost and reduce their structural dependence on foreign-controlled supply.

U.S. and European reliance on China for antibiotic APIs is the product of past decisions—but this can be corrected. Rebuilding API capacity within allied jurisdictions is both possible and necessary. This requires preserving strategic penicillin manufacturing, particularly the Sandoz Kundl plant in Austria, the last remaining large-scale vertically integrated penicillin production site in Europe and the foundation for rebuilding secure antibiotic API capacity. By capitalizing on the capabilities that remain, the United States and European countries can regain control of the antibiotic supply chain and secure the foundations of modern medicine and national security.

Key Supply-Chain Concentration Indicators

- China accounts for an estimated 80–90% of global antibiotic API production, reflecting dominance in large-scale, fermentation-based upstream manufacturing.
- China accounts for 87% of U.S. antibiotic API imports, and 67% for the EU and European Free Trade Association (EFTA).
- Approximately 90% of global 6-APA production capacity is located in China, making penicillin-class antibiotics uniquely exposed to upstream conditions.
- Only seven 6-APA manufacturing sites exist worldwide, five of which are located in China, creating a severe, facility-level chokepoint in the global penicillin supply chain.
- India and China together supply 77% of all FDF antibiotic imports into the EU+EFTA, and nearly 40% of U.S. imports.
- China supplies 91.3% of all antibiotic APIs imported into India, tying global FDF antibiotic production to Chinese upstream inputs.
- Upstream dependence is further concentrated at the firm-level: the top four Chinese API suppliers—North China Pharma, Sinobright Pharma, MS, and Centrient Pharma—account for 54% of India's antibiotic API imports, leaving global supply dependent on a small number of individual companies.
- Downstream supply is likewise concentrated, with Aurobindo Pharma supplying 32% of all FDF antibiotics imported into the United States. Aurobindo (27.2%) and Micro Labs (25.4%) together supply 52.6% of FDF antibiotics imported into the EU+EFTA.

II. Introduction: Why Antibiotics Are Strategic Infrastructure

Antibiotics are essential medical infrastructure. They make surgeries safe, protect immunocompromised patients, enable cancer treatment, and prevent routine infections from becoming life-threatening. When their supply is unstable, entire health systems are at risk.

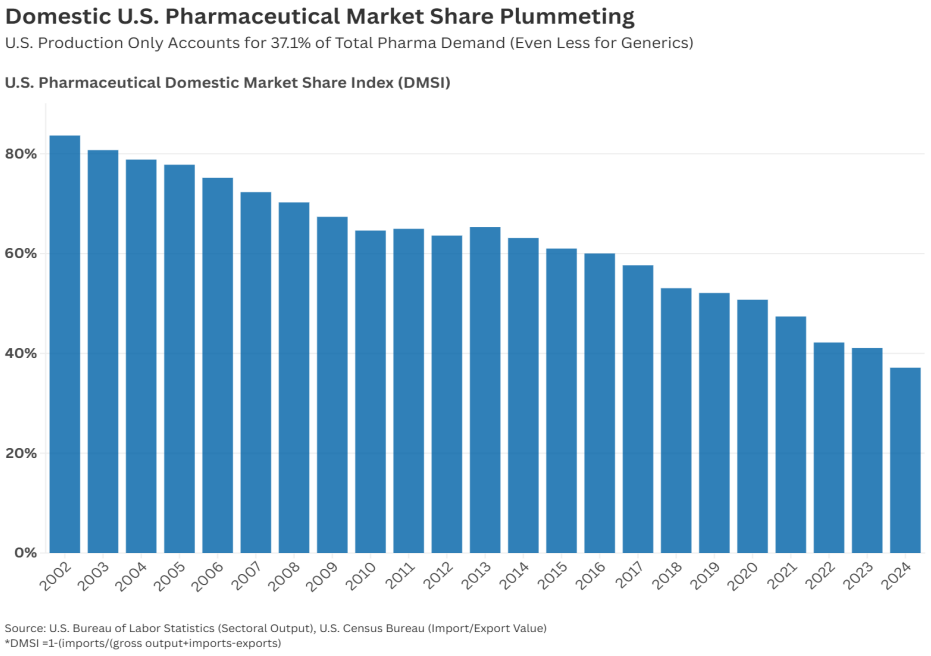
Over the last two decades, American and European antibiotic manufacturing has contracted—not because the U.S. and European countries lack technical capability, but because global price distortions and foreign industrial consolidation shifted production abroad. China now dominates upstream production of active pharmaceutical ingredients (APIs), and India formulates much of the world's finished-dosage form (FDF) antibiotics.

Nearly 70% of manufacturing sites for a representative set of antibiotic APIs are located in China and India [1], reflecting geographic consolidation at the facility level. This concentration is not incidental; it reflects decades of foreign industrial scaling and American and European divestment from fermentation and chemical-synthesis capacity. This structure has left the U.S. and many European countries dependent on a narrow set of foreign suppliers for medicines central to inpatient and outpatient care.

This report maps that dependence with country- and firm-level precision. It identifies where the U.S. and EU+European Free Trade Association (EFTA) rely on foreign APIs and finished drugs, which companies control these flows, and where single-source exposure creates systemic vulnerability.

The collapse in American and European antibiotic manufacturing occurred within a much broader contraction of the pharmaceutical industrial base. The figure below illustrates how domestic producers today supply only 37% of total U.S. pharmaceutical demand—an unprecedented decline that leaves even basic generic drugs increasingly foreign-controlled. U.S. market share has eroded steadily since the early 2000s, reflecting the global price dynamics and foreign consolidation that hollowed out antibiotic production.

Figure 1:



Across both the United States and Europe, the antibiotic supply chain is now overwhelmingly import-dependent and anchored in Asia. This reflects the large scale of Chinese fermentation-based production and its dominance in upstream API manufacturing. According to recent analyses in JAMA Health Forum [2], nearly all U.S. supplies of penicillin-class active ingredients are sourced from China. Furthermore, European health authorities estimate that China contributes to 80–90% of global antibiotic API production [3]. These conditions translate directly into systemic vulnerability for the U.S. and many European countries, reflected in import exposure, supplier concentration, and the geographic dominance of a small set of Asian producers.

III. Capturing the Two-Country Global System: China (APIs) → India (FDFs)

The modern antibiotic supply chain is built on a highly concentrated two-country structure: China produces the active pharmaceutical ingredients (APIs), and India converts those inputs into finished-dosage form (FDF) antibiotics. Nearly every major antibiotic class now moves through this sequence.

Over decades, global fermentation capacity—the foundational step for producing intermediates such as 6-aminopenicillanic acid (6-APA)—collapsed across the U.S. and Europe, leaving only a handful of surviving facilities. China now anchors the upstream stage with large-scale fermentation and chemical-synthesis capability, making it the dominant source of antibiotic ingredients worldwide. The only remaining large-scale producer in Europe or the United States is Sandoz's Kundl facility in Austria, which maintains a fully vertically integrated penicillin-production base.

India, for its part, controls much of the downstream formulation stage through export-oriented plants that supply both hospital and outpatient antibiotics. But India's strength depends almost entirely on uninterrupted access to Chinese APIs; without Chinese upstream inputs, Indian FDF production cannot operate at scale.

In practice, the system functions as a single linear chain: China manufactures the inputs → India manufactures the finished products → America and Europe import them. This is not a diversified network; it is a concentrated structure with minimal redundancy and high systemic risk.

IV. Analytical Purpose and Research Questions

This study examines the structure and resilience of the U.S. and European antibiotic supply chain by identifying where production, processing, and critical intermediates are geographically and firm-level concentrated. The analysis asks how dependence differs across manufacturing stages—including both upstream active pharmaceutical ingredient (API) production and downstream finished-dosage form antibiotics manufacturing—and which origin countries, firms, and facilities could constitute single points of failure with systemic implications. These questions are addressed using harmonized U.S.–EU+EFTA trade data, firm-level shipment records, and molecule-specific analysis consistent with established pharmaceutical supply-chain and health-economics methodologies.

V. Methodology, Scope, and Harmonized Tariff Schedule (HTS) Framework

This analysis isolates antibiotic-specific trade flows to distinguish upstream dependence on active pharmaceutical ingredients (APIs) from downstream dependence on finished-dosage form (FDF) antibiotics.

Antibiotic Classes Included

The study covers the major therapeutic classes used in U.S. and EU+EFTA clinical settings, including penicillins, cephalosporins, tetracyclines, macrolides, fluoroquinolones, carbapenems, glycopeptides, β-lactam/β-lactamase inhibitor combinations, and key adjunct agents (e.g., clindamycin, linezolid, metronidazole). These capture both high-volume outpatient drugs and hospital-critical sterile injectables.

HTS Codes

The following HTS codes cleanly correspond to antibiotic APIs and FDFs, enabling clear separation of manufacturing stages:

- **2941.10, 2941.20, 2941.30, 2941.40, 2941.50, 2941.90**—Antibiotic APIs (bulk powders).
- **3004.10, 3004.20**—FDF antibiotics (tablets, capsules, sterile vials).

This structure allows consistent comparison across U.S. Census, Eurostat, and bill-of-lading datasets.

Table 1. Antibiotic HTS Codes and Molecule Classes

HTS Code	Description	Stage	Antibiotic Classes Included	Representative Molecules
2941.10	Penicillins and derivatives (bulk pharmaceuticals)	API	Penicillins (β-lactams)	Amoxicillin, Ampicillin, Penicillin G/V; inputs for Amoxicillin-Clavulanate and Ampicillin-Sulbactam
2941.20	Streptomycins and derivatives (bulk pharmaceuticals)	API	Aminoglycosides (streptomycin class)	Streptomycin, Dihydrostreptomycin
2941.30	Tetracyclines and derivatives (bulk pharmaceuticals)	API	Tetracyclines	Tetracycline, Doxycycline
2941.40	Chloramphenicol and derivatives (bulk pharmaceuticals)	API	Amphenicols	Chloramphenicol, Thiamphenicol, Florfenicol
2941.50	Cephalosporins and derivatives (bulk pharmaceuticals)	API	Cephalosporins (β-lactams)	Ceftriaxone, Cefazolin, Cefuroxime, Cefotaxime, Ceftazidime
2941.90	Other antibiotics (bulk pharmaceuticals)	API	Macrolides, Carbapenems, Glycopeptides, Lincosamides, others	Azithromycin, Clarithromycin, Vancomycin, Clindamycin, Meropenem, Imipenem; components used in combination antibiotics
3004.10	Medicaments containing penicillins or derivatives, in measured doses	FDF	Penicillins and combinations	Amoxicillin tablets/capsules, Amoxicillin–Clavulanate, Ampicillin products
3004.20	Medicaments containing other antibiotics, in measured doses	FDF	Cephalosporins, Carbapenems, Macrolides, Glycopeptides, Tetracyclines, others	Ceftriaxone vials, Cefazolin vials, Meropenem vials, Vancomycin vials, Azithromycin tablets, Doxycycline, Piperacillin–Tazobactam

Data Sources

- **U.S. Census Bureau (USA Trade Online):** U.S. imports of APIs and FDFs;
- **Eurostat:** EU-27 and EFTA imports under identical HTS classifications; and,
- **Bill of Lading / Customs Shipment Records:** Company-level supply patterns.

Different estimates of antibiotic dependence measure different layers of the supply chain. Import shares reflect where finished APIs are shipped from; production-share estimates reflect where APIs are manufactured globally; facility counts measure site location rather than output volume; and molecule-specific data capture dependence on critical upstream intermediates. These metrics are complementary, not contradictory; import statistics alone understate true systemic dependence when upstream production and key intermediates are highly concentrated.

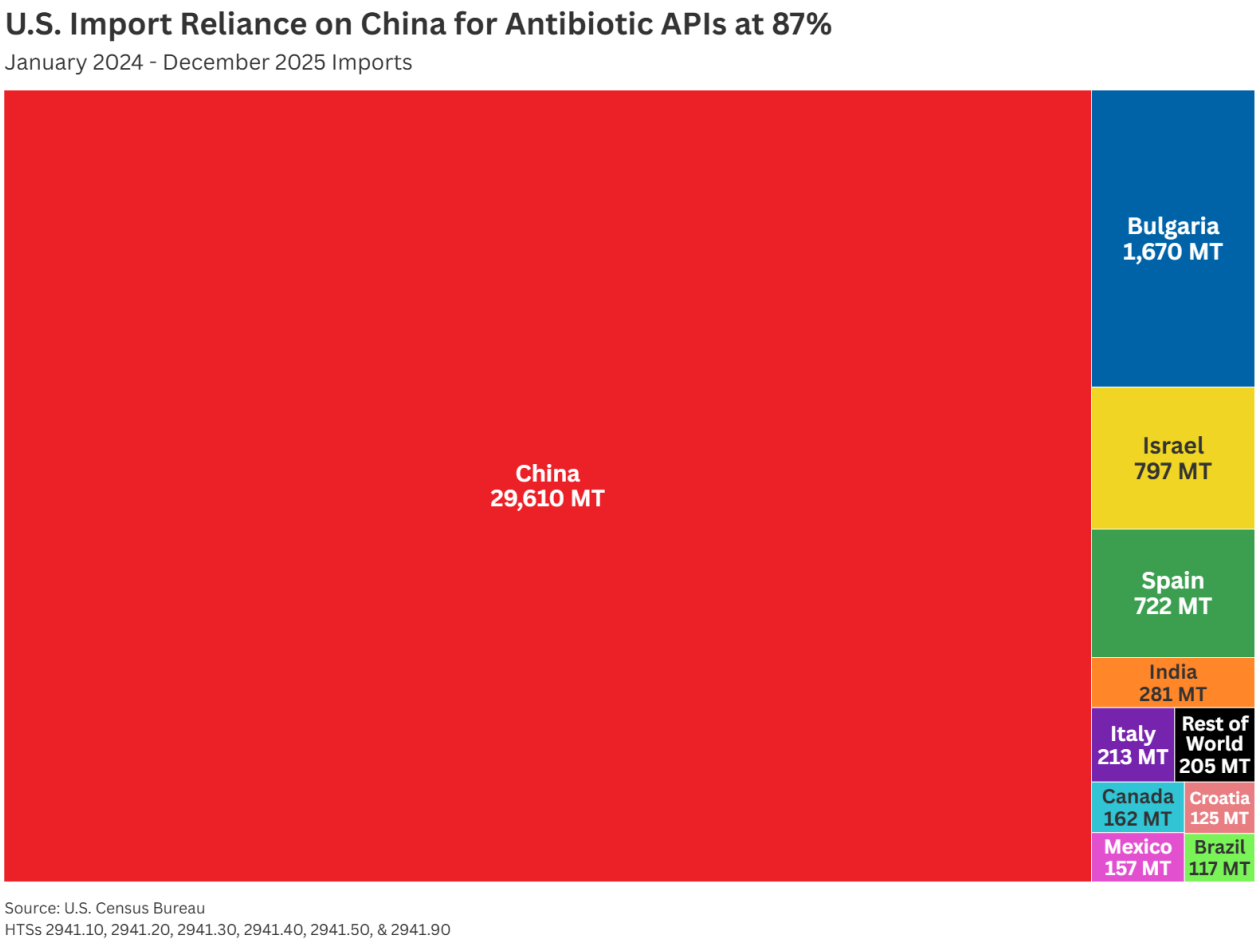
VI. U.S. Antibiotic Dependence

The United States retains some fill-and-finish antibiotic production, including USAntibiotics' Bristol, Tennessee facility, which manufactures amoxicillin finished-dose products [1]. However, the United States no longer has active pharmaceutical ingredient (API) or 6-aminopenicillanic acid (6-APA) production capability [1]. As a result, domestic finished-dose production remains important but incomplete. Although USAntibiotics sources its upstream API from Europe, the broader U.S. antibiotic supply remains overwhelmingly reliant on Chinese API.

U.S. API Imports: China as the Upstream Bottleneck

The API stage is where supply-chain fragility is deepest. APIs determine whether antibiotics can be produced at all, and the U.S. is overwhelmingly dependent on China for these critical ingredients. The following figure illustrates the distribution of U.S. antibiotic API imports by country.

Figure 2:



China supplies about 87% of all U.S. antibiotic API imports—effectively controlling the upstream import supply of critical antibiotic inputs. The next highest country, Bulgaria, supplies less than 5% of all U.S. antibiotic API imports. This means China dominates the APIs for the antibiotic classes most essential to hospitals: cephalosporins (e.g., ceftriaxone, cefazolin), macrolides (azithromycin), tetracyclines (doxycycline), and carbapenems (meropenem). These drugs are cornerstones of inpatient care, and their availability hinges on uninterrupted Chinese production.

Even antibiotics manufactured in the United States rely on these Chinese APIs. Domestic finished-dosage form (FDF) manufacturing only partially mitigates dependence when the foundational inputs still come from abroad, and from China, an adversarial country no less. This means the U.S. lacks true manufacturing sovereignty over its antibiotic supply. A production slowdown, export restriction, environmental crackdown, or contamination event at even a handful of Chinese plants could disrupt American hospitals quickly.

The following table provides a detailed breakdown of U.S. API and FDF import shares.

Table 2. U.S. Antibiotic Dependence by Country (API vs FDF)

Country	Antibiotic API Imports (MT)	API Import Share		Country	FDF Imports (MT)	Final Drug Import Share
China	29,610	86.9%		**India**	11,903	27.1%
Bulgaria	1,670	4.9%		**China**	4,809	11.0%
Israel	797	2.3%		**Italy**	4,794	10.9%
Spain	722	2.1%		**Jordan**	4,433	10.1%
India	281	0.8%		**Switzerland**	4,395	10.0%
Italy	213	0.6%		**Canada**	3,498	8.0%
Canada	162	0.5%		**Austria**	2,144	4.9%
Mexico	157	0.5%		**Portugal**	1,944	4.4%
Croatia	125	0.4%		**Ireland**	1,131	2.6%
Brazil	117	0.3%		**Spain**	1,043	2.4%
Rest of World	205	0.6%		**Rest of World**	3,785	8.6%

Source: U.S. Census Bureau
January 2024 – December 2025
Final Antibiotic Drugs: HTSs 3004.10 and 3004.20
Antibiotic APIs: HTSs 2941.10, 2941.20, 2941.30, 2941.40, 2941.50, and 2941.90

At 29,610 metric tons, China supplies over six times the volume of all other import sources combined. Bulgaria, Israel, and Spain contribute minor shares. India supplies only 0.8% of U.S. APIs, underscoring its own reliance on imported ingredients even as it supplies large volumes of finished drugs.

Limited U.S.–EU+EFTA trade in antibiotic active pharmaceutical ingredients reflects specialization in particular molecules and production processes, not surplus or interchangeable upstream capacity. Due to their unique reliance on imports for high-volume APIs from China, bilateral transatlantic API flows do not indicate resilience at scale, instead reflecting a narrow but real base of remaining American and European production that could be expanded through coordinated U.S.–EU industrial policy as part of a broader effort to diversify away from dominant Asian suppliers. This concentration means the U.S. has little diversified fallback strategy for API sourcing. Europe offers the next best import diversification with trusted suppliers in countries such as Bulgaria, Spain, Italy, and Croatia, but these countries also cannot compete with the market dominance of China without drastic policy changes. When a system depends so heavily on one upstream producer, the entire downstream market—domestic or imported—becomes a point of vulnerability.

B. U.S. FDF Antibiotic Imports: India's Downstream Dominance

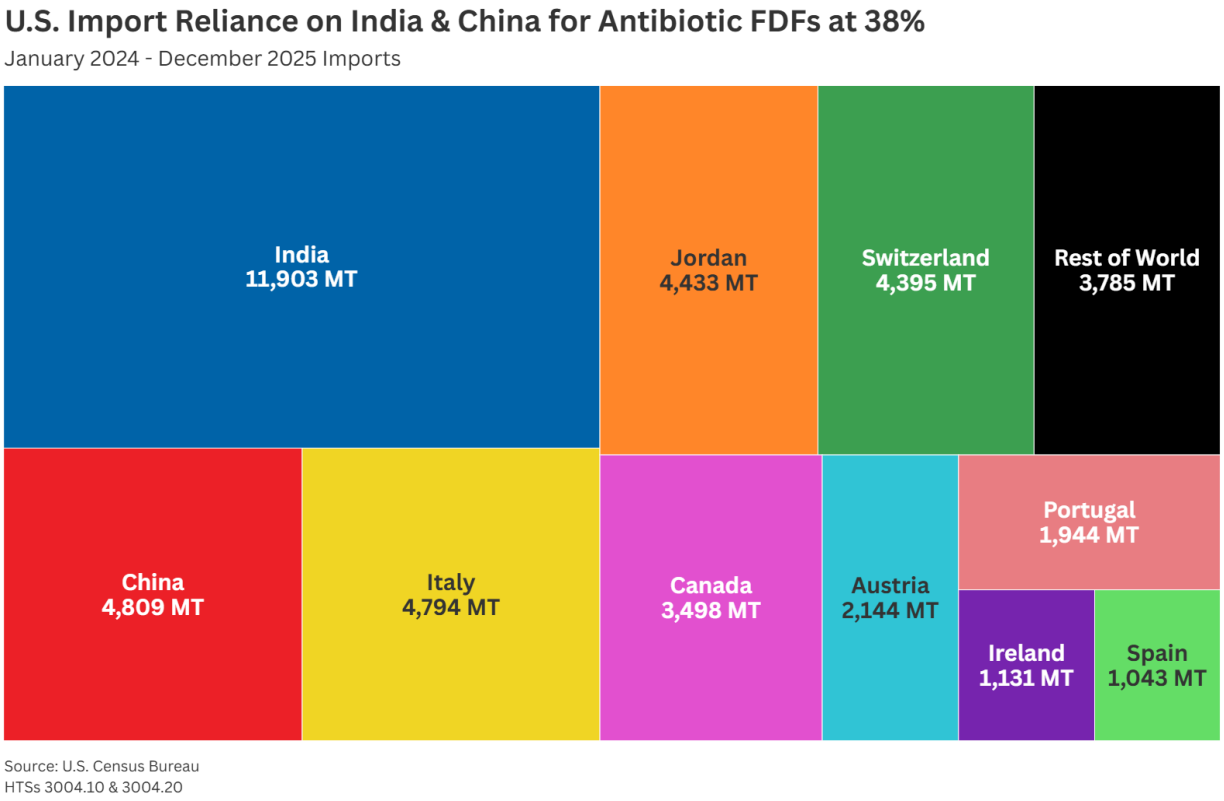
Finished-dosage antibiotics (FDFs) include tablets, capsules, suspensions, and sterile injectables. The U.S. relies on foreign FDF antibiotics not because it cannot formulate drugs, but because protracted low-cost competition has driven domestic prices to unsustainable levels. India has gained a dominant share of U.S. FDF imports through an optimized cost-efficiency model which is supported by leveraging subsidies, low production costs, and greater access to Chinese APIs.

In parallel, generic purchasing and reimbursement structures have driven prices to unsustainable levels, particularly sterile injectables, pushing manufacturers out of the market and magnifying reliance on a handful of foreign suppliers. The U.S. Food and Drug Administration (FDA) has identified this dynamic as a core driver of drug shortages, noting [4]:

> *"Root Cause 1: Lack of Incentives to Produce Less Profitable Drugs. When market conditions limit manufacturers' profitability, they reduce a firm's motivation to maintain a presence in, or enter the market for older prescription drugs, and to invest in manufacturing quality and redundant capacity. Manufacturers of older generic drugs, in particular, face intense price competition, uncertain revenue streams, and high investment requirements, all of which limit potential returns. Current contracting practices contribute to a "race to the bottom" in pricing." [4]*

The next figure shows the top supplier countries for U.S. FDF antibiotics.

Figure 3:



India supplies 27% of all U.S. FDF antibiotic imports—by far the largest share. Combined with China's 11% share, nearly 40% of the U.S. market is anchored in this two-country pipeline. European countries, by contrast, appear at first to offer another option: suppliers in Italy, Switzerland, Austria, Portugal, Spain, and Ireland contribute a meaningful share of U.S. imports (35%) and still maintain credible antibiotic formulation capacity. But nearly all these producers are increasingly confined to niche or higher-value formulations. They no longer participate meaningfully in the lowest-cost, highest-volume products, most notably amoxicillin, which has become one of the most vulnerable molecules in the antibiotic supply chain precisely because neither the United States nor European nations can compete with Chinese API price suppression or India's high-volume, low-cost manufacturing base.

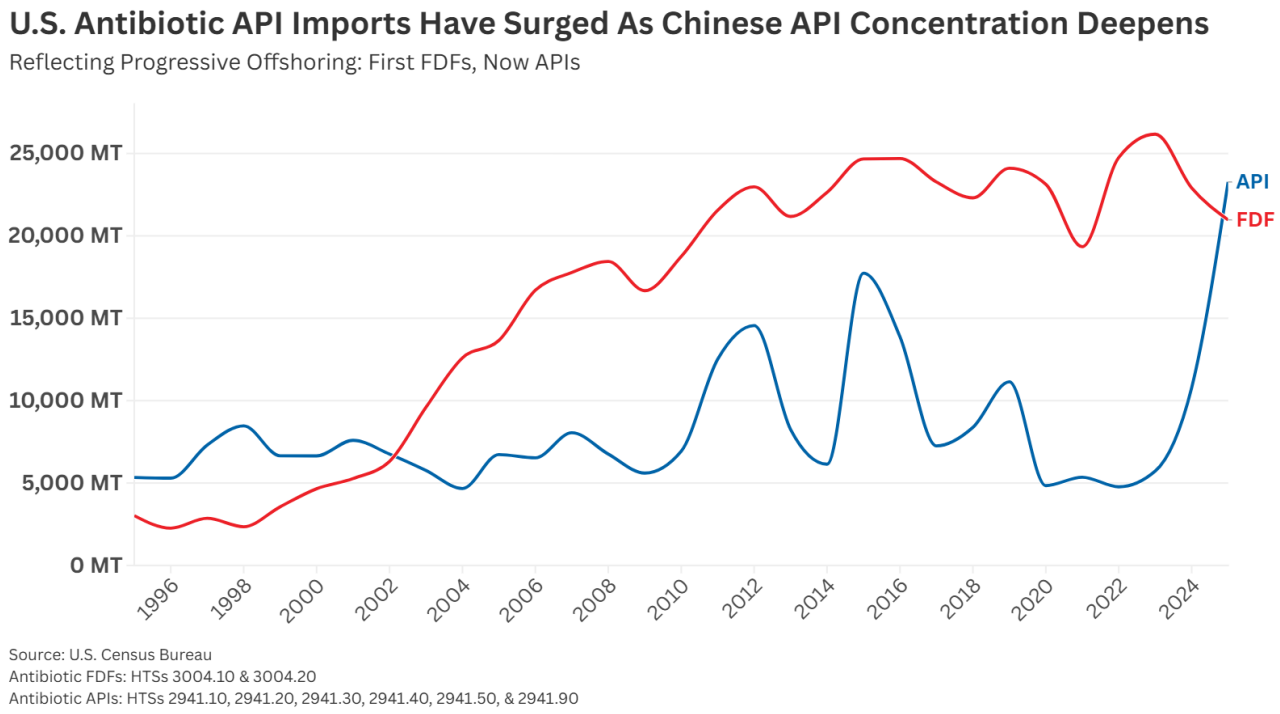
Sustained price suppression from Chinese intermediates and Indian mass-production platforms has undercut the viability of American and European producers' cost structures for more than a decade. As a result, Europe's remaining upstream capabilities survive, but they no longer shape—or stabilize—the broader U.S. antibiotic market. Since COVID, Indian suppliers have further expanded their share of U.S. amoxicillin and amoxicillin–clavulanate supply [5], intensifying price pressure on remaining U.S. FDF producers and deepening downstream dependence. And because nearly all Indian manufacturers and most American and European formulators outside the Sandoz Kundl network in Austria rely on Chinese APIs, the U.S. market is functionally tied to a single upstream source regardless of where final dosage production occurs.

Long-Term Import Trends: Evidence of Domestic Erosion

The deeper pattern underlying the API and FDF data is the long-term erosion of U.S. formulation capacity. As foreign competitors—benefiting from lower costs and state-backed industrial strategy—gained market share, U.S.-based formulation lines were forced to downscale or shut down.

The following figure illustrates the long-running trend in U.S. FDF and API antibiotic imports.

Figure 4:



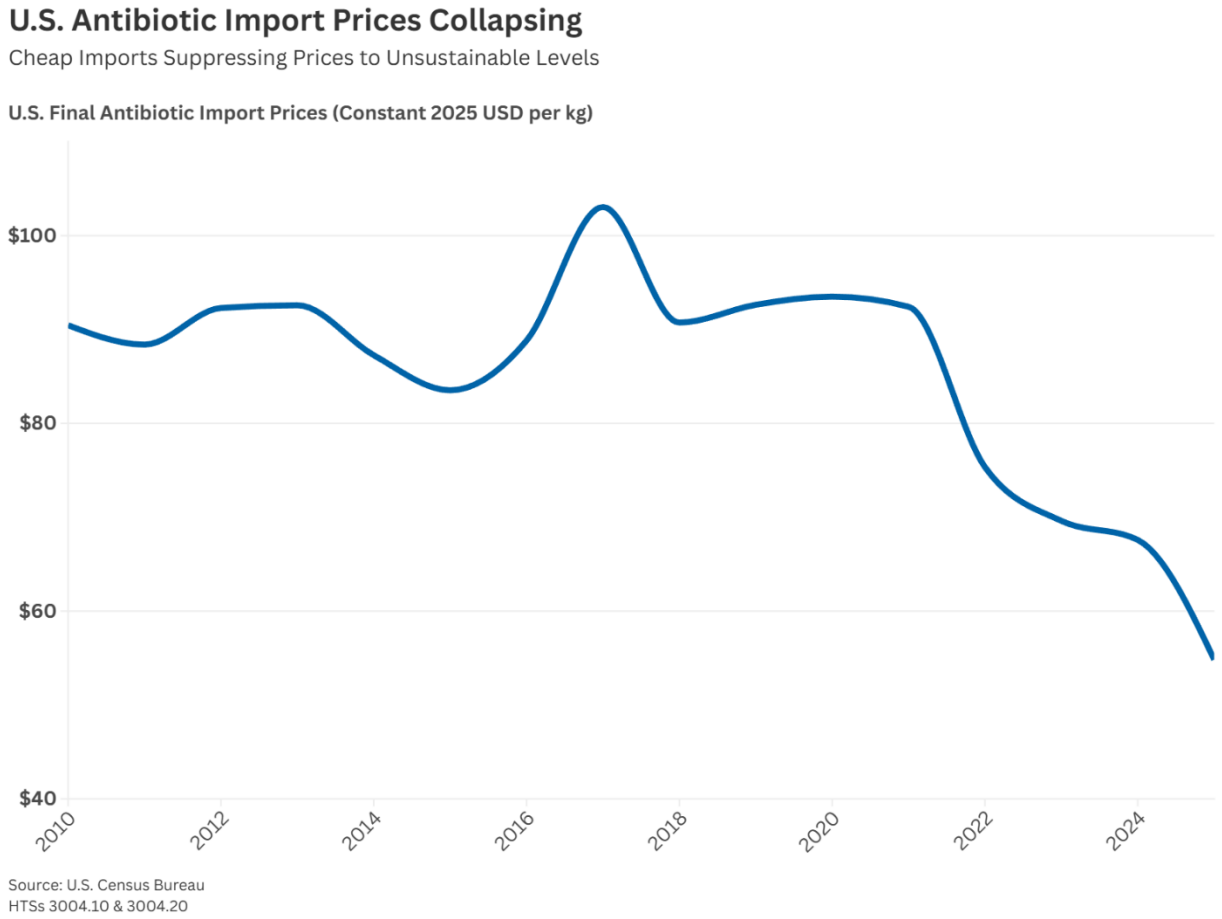
The trendline shows a marked and persistent rise in FDF imports over time, with the steepest increases occurring post-2002 after China received permanent Most Favored Nation trade status in 2001, granting it access to the lowest general U.S. tariff rates and accelerating its integration into the U.S. market. Lower tariff rates accelerated China's industrial rise and unleashed a wave of low-priced antibiotic imports into global markets. That shift intensified foreign price competition and expedited China's consolidation of antibiotic production.

A key feature of this pattern is how U.S. API imports did not rise in parallel with FDF imports at first. API volumes remained comparatively flat, as pharmaceutical manufacturers in countries such as China and India initially focused on the technologically less complex stage of FDF manufacturing. However, over the past two years, China in particular has consolidated its dominance in global antibiotic API production, and U.S. API import dependence has increased sharply. This collapse of U.S. FDF and API manufacturing and the surge in import reliance is visible in real production losses. For example, the Bristol-Myers Squibb antibiotic fermentation plant in East Syracuse (later acquired by Pfizer)—the last industrial-scale

U.S. penicillin producer at the time—shut down penicillin production in 2004, leaving the United States entirely dependent on foreign-made penicillin thereafter [6]. Similarly, other widely used antibiotics—such as doxycycline—are no longer produced domestically, reflecting how essential generic medicines have migrated entirely offshore.

As FDF imports surged, domestic formulation facilities either reduced output or exited entirely as margins collapsed. The next figure shows the direct economic mechanism driving this collapse. As import volumes accelerated, import prices for FDF antibiotics fell sharply—dropping from roughly $100 per kilogram a decade ago to nearly $55 per kilogram as of late 2025. Since 1992, import prices have fallen by over 90% for FDFs and about 80% for APIs [2]. No U.S. or European producer can sustain industrial-scale operations under these collapsing price conditions primarily driven by subsidized Chinese API output and India's ultra–low-cost formulation platforms.

Figure 5:



This precipitous decline in import prices illustrates why domestic formulation capacity withered among American and European producers: producers were competing not in an open market but against state-supported cost structures they could not match. The economic floor collapsed beneath U.S. formulators long before demand for antibiotics did, driving FDF imports sharply upward while API import demand remained flat. This was not a technological failure, but the predictable

outcome of an environment in which American manufacturers were priced out by subsidized Chinese production operating under free trade access and by foreign competitors facing far lower regulatory and compliance costs. Sustained price suppression has already driven competing producers out of the market, raising the risk that future supply disruptions or price shocks could occur once alternative capacity is eliminated, unless deliberate action is taken to preserve diversified U.S. and European supply.

This trajectory reveals a troubling dynamic:

- As the U.S. became more reliant on FDF imports, domestic capability atrophied.
- As domestic capability declined, import dependence became harder to reverse.
- As import dependence grew, foreign suppliers gained structural leverage without bearing the same safety or reliability standards.

The end result is a brittle system in which U.S. antibiotic supply is tightly coupled to foreign production decisions, foreign regulatory systems, and foreign industrial policies. In particular, the geopolitical posture and foreign policy decisions of key supplier states such as China and India can shape export availability and therefore directly affect U.S. and European access to essential antibiotics.

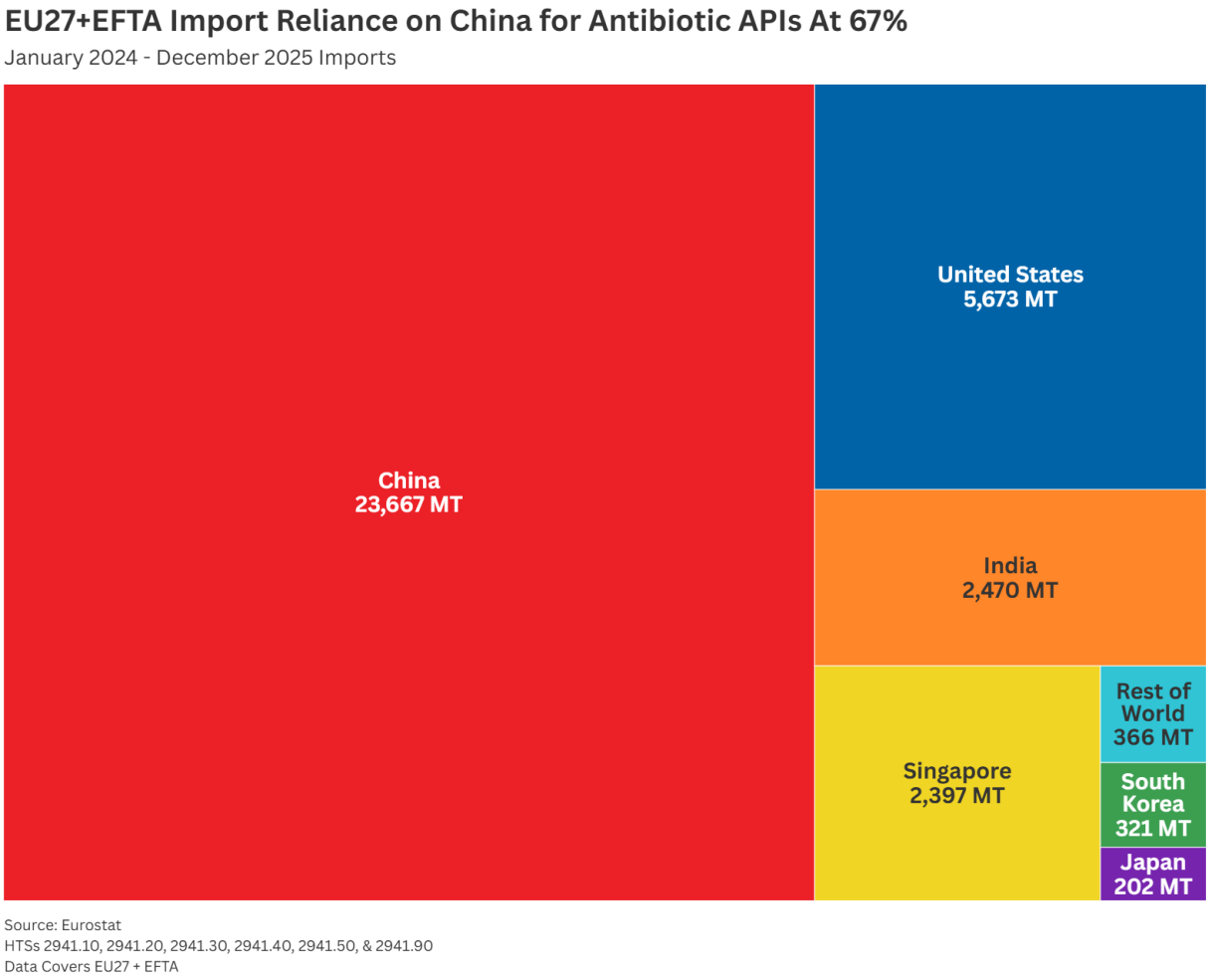
VII. EU+EFTA Antibiotic Dependence

Pockets of antibiotic manufacturing capability remain in Europe, but like the United States, Europe now relies heavily on foreign suppliers for both active ingredients and finished-dosage form (FDF) antibiotics. The EU+EFTA's dependence is less acute upstream compared to the U.S. However, China still supplies the overwhelming majority of Europe's antibiotic active pharmaceutical ingredients (APIs) imports. The remaining fermentation plants in Europe operate at a fraction of global scale, leaving many countries exposed to the same two-country supply chain that shapes U.S. vulnerability.

EU+EFTA API Imports: Extreme Upstream Dependence on China

The EU+EFTA's antibiotic vulnerability begins with API sourcing. Like the United States, European countries are also highly reliant on Chinese antibiotic API supply. The next figure shows the distribution of EU+EFTA antibiotic API imports by source country.

Figure 6:



China supplies 67% of all EU+EFTA antibiotic API imports. The next-largest supplier, the United States, provides only 16%, and this category includes intermediates and specialized products rather than large-scale fermentation output. Singapore and India account for minor additional volumes, though Singapore's role is largely that of a transit and re-export hub rather than a true manufacturing source. Neither approaches the breadth, scale, or cost structure of Chinese production.

Historically, antibiotic APIs in European nations were supplied by domestic pharmaceutical producers. In the post-war period, penicillin production expanded across Western Europe, with manufacturing plants operating in countries such as Italy, France, and Spain [7]. Yet, as China scaled production and made many global pricing models unsustainable, many European facilities either contracted, shifted to niche products, or closed altogether. This transformation is visible in the dominance of Chinese suppliers where Europe once held significant market share.

European Commission policy analyses note that pharmaceutical supply chains are highly integrated globally and that production of generic APIs is increasingly concentrated in China and India, creating upstream supply dependencies [8]. With current market conditions, this makes it nearly impossible for European producers to expand output without relying on the very same Chinese firms that dominate the global supply chain.

EU+EFTA API and FDF Import Breakdown

The following table provides a detailed breakdown of EU+EFTA API and FDF import shares, highlighting the geographic structure of European dependence.

Table 3. EU+EFTA Antibiotic Dependence by Country (API vs FDF)

Country	Antibiotic API Imports (MT)	API Import Share		Country	FDF Imports (MT)	Final Drug Import Share
China	23,667	67.4%		**India**	7,367	45.5%
United States	5,673	16.2%		**China**	5,110	31.6%
India	2,470	7.0%		**United States**	1,152	7.1%
Singapore	2,397	6.8%		**Turkey**	468	2.9%
South Korea	321	0.9%		**North Macedonia**	456	2.8%
Japan	202	0.6%		**New Zealand**	366	2.3%
Rest of World	366	1.0%		**Rest of World**	1,272	7.9%

Source: Eurostat
January 2024 – December 2025
Final Antibiotic Drugs: HTSs 3004.10 and 3004.20
Antibiotic APIs: HTSs 2941.10, 2941.20, 2941.30, 2941.40, 2941.50, and 2941.90

The API side of the table confirms the central finding of Figure 6: China's over 23,000 metric ton supply of APIs dwarfs contributions from every other country. On the finished-dosage side, India supplies 46% of EU+EFTA FDFs, while China supplies 32%. Together, these two countries provide 77% of all finished antibiotics entering the EU+EFTA. This mirrors the U.S.'s global supply chain described earlier: China produces the ingredients; India formulates the final drugs; and Europe imports them.

The table thus reinforces the structural dependence created by global consolidation. Europe's antibiotic supply is no more diversified than the U.S. supply—and in some respects, is more vulnerable.

EU+EFTA FDF Imports: India and China's Downstream Control

Taking a closer look at the finished-dosage side of Table 3, Figure 7 illustrates the geographic concentration of antibiotic drugs entering the EU+EFTA market. While multiple countries export finished antibiotics to Europe, the market is dominated by India and China.

Figure 7:

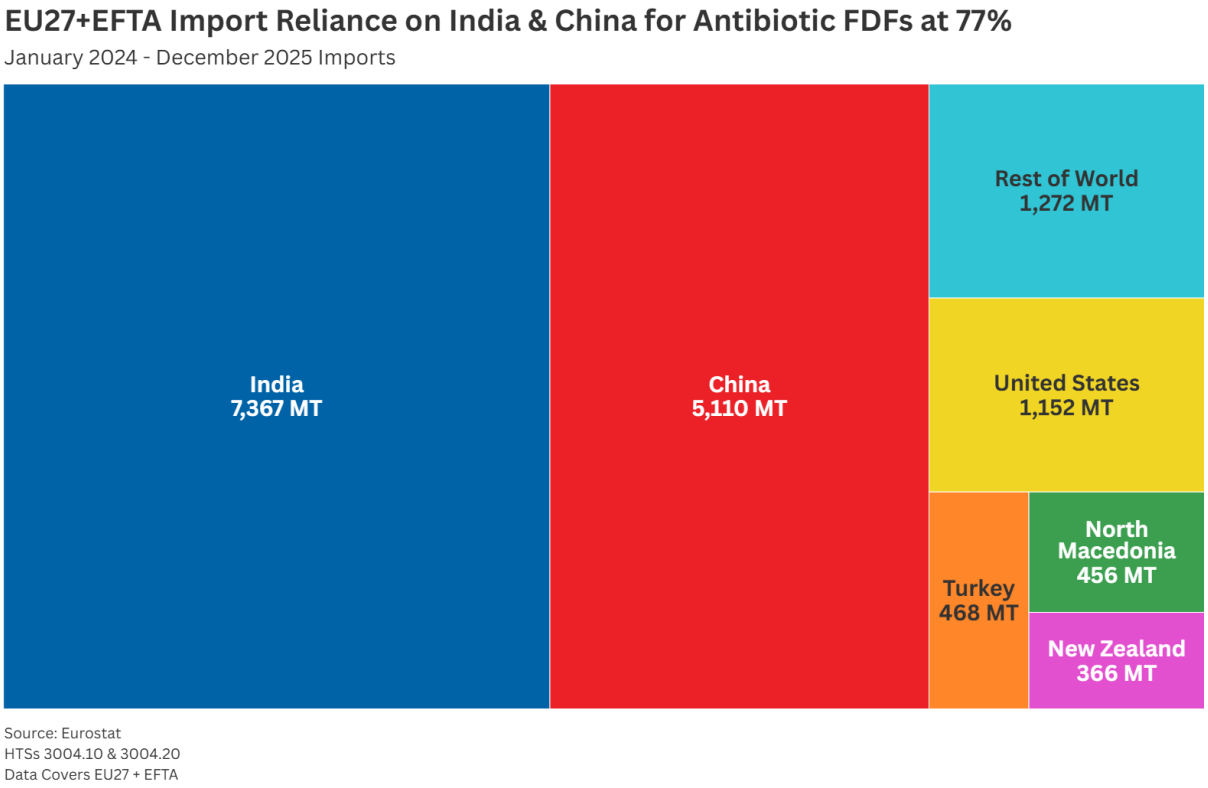


Figure 7 shows that India and China together supply over three-quarters of finished antibiotic imports entering the EU+EFTA market. The remaining suppliers—including the United States, Turkey, and several smaller exporters—account for only a small share of the market. This pattern reinforces the broader structure of the global antibiotic supply chain: China dominates upstream ingredient production while India serves as the primary formulation hub.

This overwhelming import share stands in stark contrast to the historical strength of European nations in pharmaceutical formulation. Several EU countries—Italy, Austria, Germany, Slovenia, Spain, and France—still maintain antibiotic formulation and sterile-injectable manufacturing capacity [9]. Yet this industrial base has been progressively displaced by lower-cost, higher-volume Indian producers. India now dominates EU+EFTA imports of oral-dose antibiotics—including amoxicillin, cefuroxime, and azithromycin—while China plays a growing role in sterile injectables such as ceftriaxone and meropenem through its upstream control of key APIs.

The consequences of this structural shift are visible across the continent. In 2025, Xellia announced the shutdown of its Copenhagen antibiotics complex [10]—one of Europe's largest remaining fermentation and injectable-antibiotics facilities for non-penicillin classes—after concluding that European production could no longer compete with Asian cost structures. With this closure, European countries were left with only a single major antibiotic fermentation base at scale for penicillin-class production—Sandoz's Kundl site in Austria—underscoring how little upstream capacity now remains.

Sandoz's Kundl facility in Austria anchors the only fully integrated penicillin-production network in Europe or the United States [11]—one that already supplies over a hundred countries and could be rapidly scaled further if supported by stable

market signals and aligned trade and industrial policy. Its continued operation demonstrates that American and European capacity can expand when the economic environment rewards resilience rather than the lowest-cost imports.

Yet even this remaining capability operates within market conditions that continue to place pressure on Europe's antibiotic manufacturing base. Across Europe, reference-pricing systems, tender-based purchasing, and strict reimbursement caps have driven generic prices down to levels that leave limited margin for manufacturers, particularly for injectable antibiotics. As in the United States, a "lowest-price wins" procurement model has reduced the number of economically viable producers and increased reliance on a small number of high-volume Asian suppliers for essential generics.

These outcomes reflect the same market dynamics described earlier: sustained downward pricing pressure has narrowed the pool of viable producers, leaving European nations dependent on a small number of foreign suppliers despite retaining technical manufacturing capability.

The broader structural position of European countries becomes clear when examining upstream and downstream data together. 67% of antibiotic API imports are sourced from China—a conservative trade-based measure that likely understates the EU+EFTA's dependence on Chinese-controlled upstream intermediates—leaving Europeans without the input resilience needed to sustain or expand their own formulation capacity. China's control of key intermediates and global-scale fermentation—including approximately 90% of global 6-APA production capacity [12]—means that even a short-term disruption would propagate rapidly through the supply chain. Downstream, European countries retain formulation plants, but their aggregate scale is increasingly overshadowed by the large volume of low-cost finished drugs imported from India and China, many of which themselves rely on Chinese-produced API.

This dual dependency is deeper than America's, reflecting the EU+EFTA's higher import concentration for both finished drugs and APIs. Yet these vulnerabilities remain reversible: European nations have the historic capability and industrial skill to produce both APIs and finished antibiotics. What they lack are the market conditions—distorted by foreign subsidies, global price pressure, and fragmented policymaking—that would allow those capabilities to operate at scale.

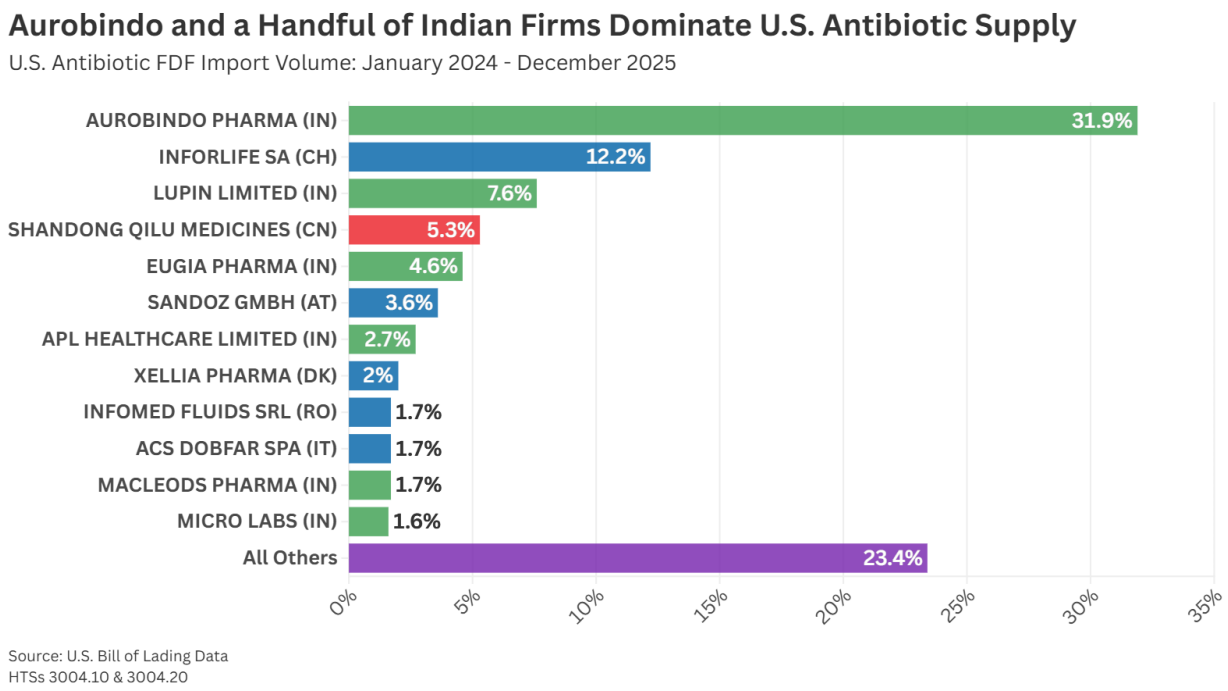
VIII. Company-Level Supply Concentration

Country-level import patterns reveal the geographic structure of antibiotic dependence, but firm-level concentration exposes the true operational chokepoints within global supply chains. A highly consolidated supplier base means that disruptions at individual companies—whether regulatory closures, contamination events, production shutdowns, logistics failures, or energy constraints—can trigger shortages across entire molecule classes. In such a concentrated system, the policy decisions of the governments overseeing these producers—including export restrictions, regulatory interventions, or broader geopolitical actions—can disrupt supply as easily as operational failures at the firms themselves. Antibiotics depend on a small number of exporters operating at industrial scale.

U.S. Finished-Dosage Form (FDF) Suppliers: Dominance by Indian Firms

The U.S. relies disproportionately on a handful of Indian manufacturers for FDF antibiotics, reflecting a market in which domestic formulators have been priced out by concentrated lower-cost offshore competitors.

Figure 8:



Aurobindo Pharma alone supplies over 30% of all finished-dosage antibiotics imported into the United States—a high level of single-firm reliance for such a critical category of medicines. Several other Indian firms—Lupin, Eugia Pharma, APL Healthcare, Macleods, and Micro Labs—add smaller but meaningful shares, collectively pushing India's footprint to cover a substantial portion of U.S. FDF imports.

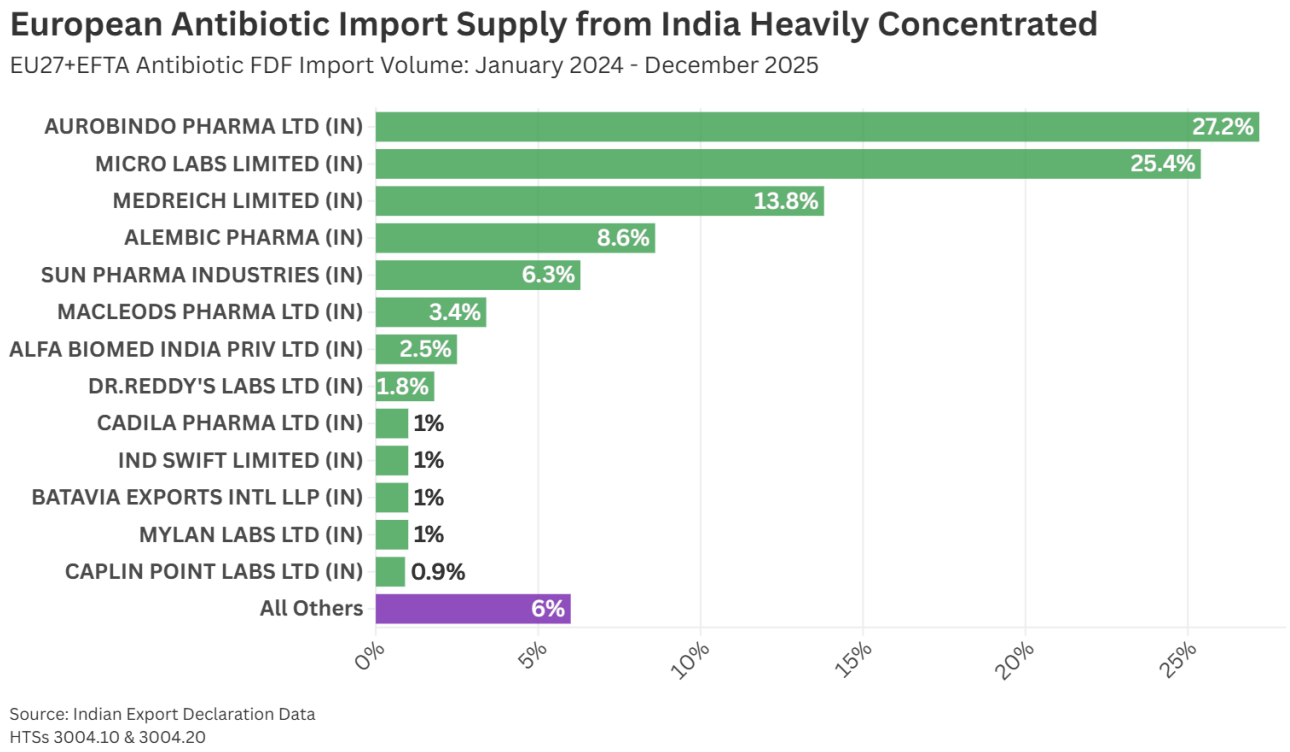
European suppliers such as Sandoz and Inforlife demonstrate that some formulation capability still exists in allied jurisdictions. But the European supply is not currently at the same scale or sustainability as the Indian supply. European manufacturers cannot scale or compete against the low-cost, high-volume platforms of China and India, whose structure has steadily priced out American and European producers for decades.

This means that a disruption at any major Indian plant—or at Chinese API facilities supplying them—would immediately reverberate and impact U.S. hospital and outpatient care supply.

EU+EFTA FDF Suppliers from India Heavily Concentrated

European dependence on Indian suppliers is even more concentrated than in the United States, as the distribution of EU+EFTA antibiotic imports shows.

Figure 9:



Source: Indian Export Declaration Data
HTSs 3004.10 & 3004.20

Aurobindo (27.2%) and Micro Labs (25.4%) together supply 52.6% of all Indian-origin FDF antibiotics imported into the EU+EFTA market. The concentration is so sharp that the top five Indian exporters collectively supply 81% of all Indian-origin FDF imports. This means that European countries do not merely rely on India as a country—they rely on a small cluster of Indian firms with outsized market share.

The implication is clear: a shutdown, recall, quality warning letter, or export disruption affecting Micro Labs or Aurobindo would have immediate, systemwide consequences across multiple European states.

Firm-Level Dynamics as the Hidden Source of Systemic Fragility

Country-level data shows where antibiotics originate, but company-level concentration reveals how vulnerable the system truly is. The U.S. and EU+EFTA antibiotic supply depends on a very small number of firms. There are only a few foreign-subsidized firms that can easily maintain sustainable, large-scale capacity in the current market conditions. This geographic concentration gives continued regulatory compliance and production output an outsized impact on whether antibiotics remain available in the U.S. and across Europe.

Import surges, thin margins, and volatile global prices have driven many U.S. and European firms out of the market, leaving only a narrow band of high-output producers in China and India.

As a result, most antibiotic molecule classes—especially key APIs and intermediates—are produced by only a handful of firms worldwide. Only four companies globally manufacture the API for penicillin [13], reflecting extreme supply concentration in critical ingredients. In such a fragile system, a single regulatory or quality failure can disrupt entire drug families, persistent price suppression erodes surge capacity and reduces resilience, and failures at upstream intermediate producers cascade across multiple downstream formulators.

Crucially, company failures are a frequent occurrence—contamination events, shutdowns, and supply interruptions are routine in global antibiotic production. This fragility shows up in patient access: antibiotics are 42% more likely to experience shortages than the average drug [14], reflecting how concentrated global production has become.

This risk is not hypothetical—it has already happened in India's own finished-dosage sector. In 2013, Ranbaxy—then one of India's largest antibiotic and generic drug exporters—pleaded guilty to felony charges in the U.S. after admitting it manufactured adulterated medicines, falsified stability data, and hid failed quality results from regulators [15]. FDA investigators found that the company had released substandard products into the U.S. market, including essential antibiotics, based on fabricated test results and false statements to the FDA [15]. When a dominant Indian formulator collapses in this way, it exposes how a single downstream failure can jeopardize drug supply and patient safety across multiple countries.

When so few firms anchor antibiotic production, disruptions propagate instantly across borders, leaving hospitals with no alternatives. Each breakdown—whether caused by fraud, contamination, or operational failure—reverberates through the U.S. and European countries because domestic redundancy has declined.

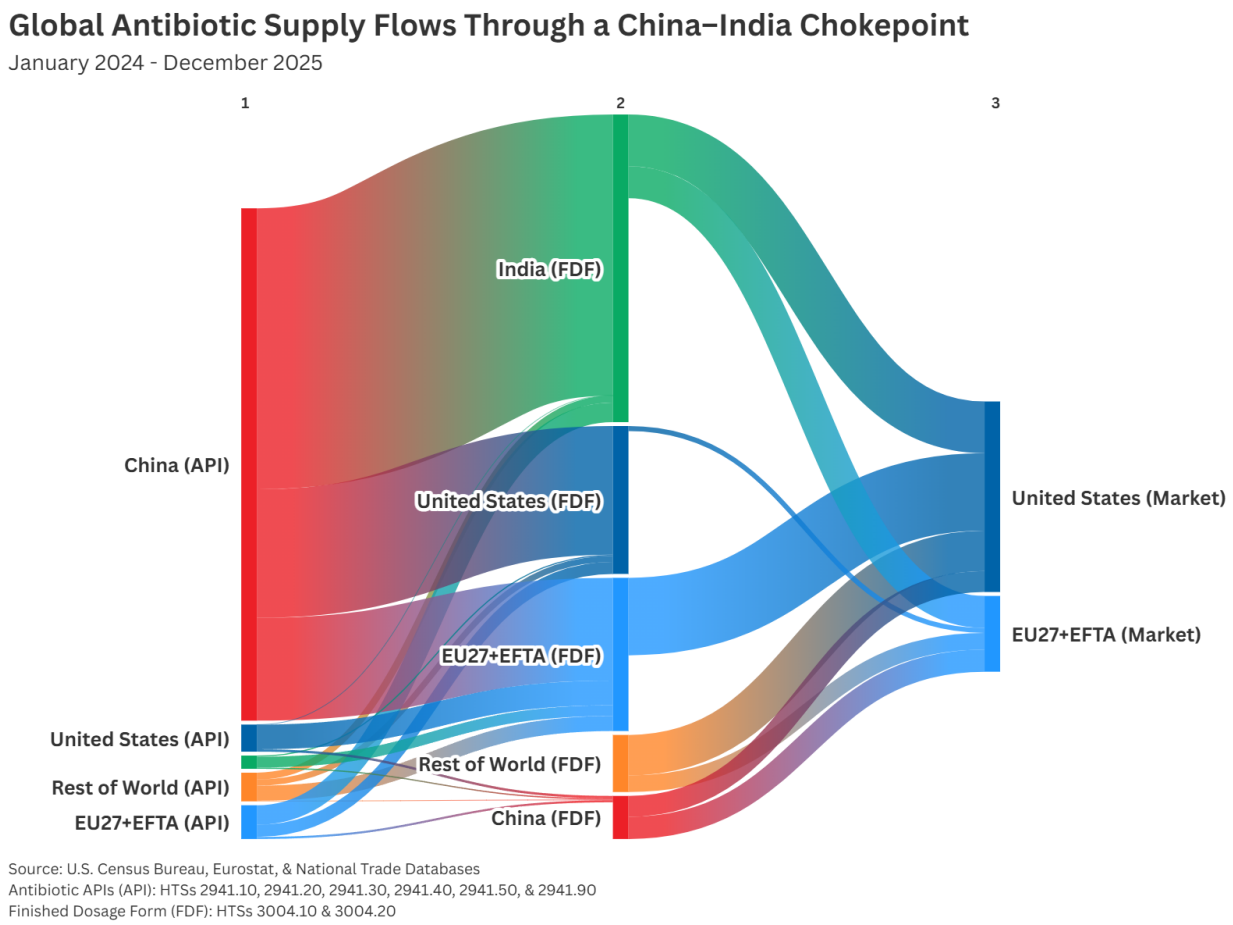
This firm-level fragility is the true chokepoint in the antibiotic system. Upstream concentration in China reinforces downstream dependence on India, leaving American and European health systems exposed to a supply chain with too few firms, too little redundancy, and too many single points of failure.

IX. China's Upstream Control: India's Reliance on Chinese APIs

While India is the world's dominant exporter of finished-dosage antibiotics, that position is entirely dependent on uninterrupted access to Chinese-made active pharmaceutical ingredients. API production is the true "source code" of antibiotic manufacturing; without Chinese inputs, downstream formulation halts. India cannot meet global antibiotic demand without China—and therefore neither can the United States nor European countries. Together, China's upstream concentration and India's downstream dominance create a single global chokepoint.

China sits at the center of nearly every major antibiotic API stream, while India serves as the primary formulation hub that converts those APIs into finished medicines. The vast majority of global supply flows along this China–India spine before reaching American and European markets. The following figure maps these flows and makes the chokepoint structure unmistakable.

Figure 10:



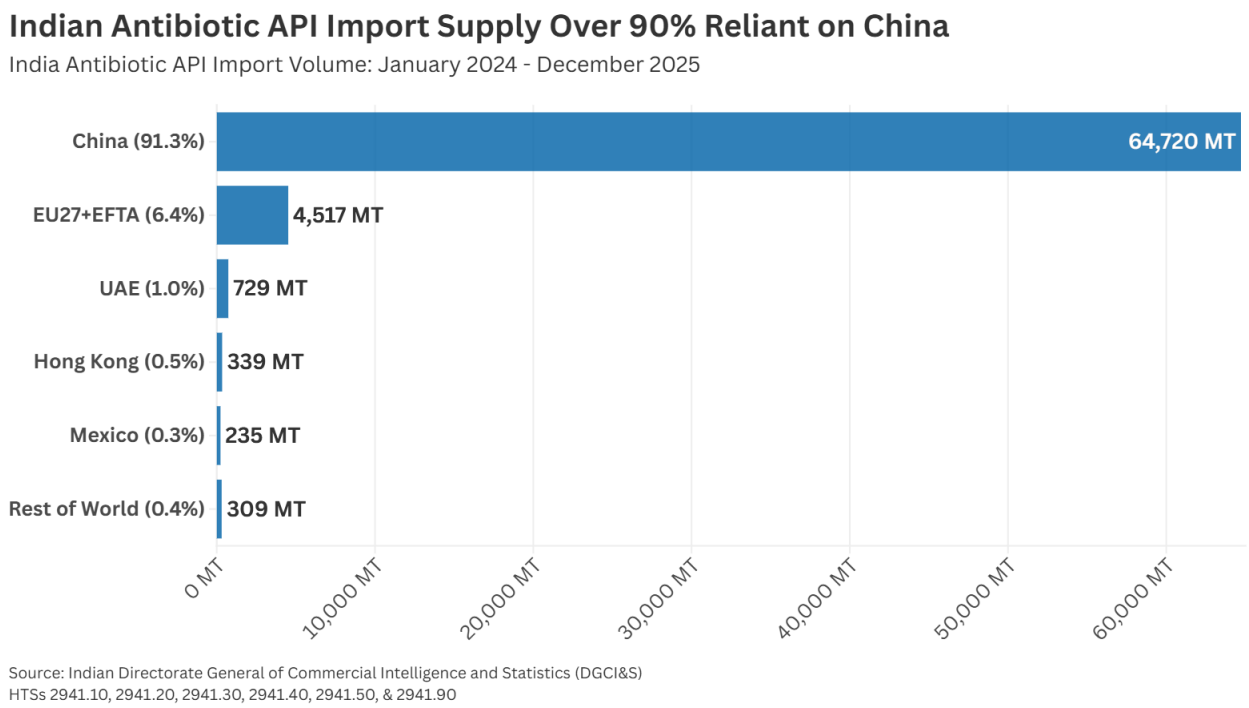
The Sankey diagram shows two key structural dynamics:

1. **China has clear upstream dominance.** The majority of all antibiotic API streams originate in China, regardless of where the finished drug is ultimately formulated. India's own API production is dwarfed by its API imports from China.
2. **India converts Chinese APIs into FDF exports for the U.S. and EU+EFTA.** The majority of FDF antibiotic flows into American and European markets trace backward to Chinese API. The single largest API importer and FDF exporter is India, but the rest of the world also heavily relies on Chinese API supply as well. India's role is not independent of China but entirely tied to Chinese supply.

India's API Imports: Over 90% Dependence on China

Because India formulates such a large share of the world's antibiotics, its API sourcing patterns become a proxy for global vulnerability. Commercial formulators have shifted toward near-universal dependence on Chinese-origin 6-APA for penicillin-class production. The following figure shows India's antibiotic API import volume and origin.

Figure 11:



This figure reveals a staggering degree of upstream dependence. China supplies 91.3% of all antibiotic APIs imported into India. By contrast, the EU+EFTA supply just 6.4% and the rest of the world combined supply just over 2%.

India's efforts to reestablish penicillin-class API capacity—supported by substantial government subsidies—reflect a clear recognition of upstream vulnerability but also underscore the economic difficulty of competing with entrenched Chinese incumbents. In 2024, Aurobindo commissioned a new 6-APA fermentation and conversion facility [16]—the first major attempt in years to establish a penicillin-class intermediate plant designed to operate independently of Chinese supply. The project moved forward only because of substantial support from the Indian government through production-linked incentives and other subsidies, reflecting the economic impossibility of competing with Chinese prices on a market basis alone. Yet even this highly subsidized plant proved vulnerable: shortly after opening, the facility was forced to shut down following a fire in an electrical unit, underscoring how easily global supply can be destabilized when a single upstream site goes offline [16].

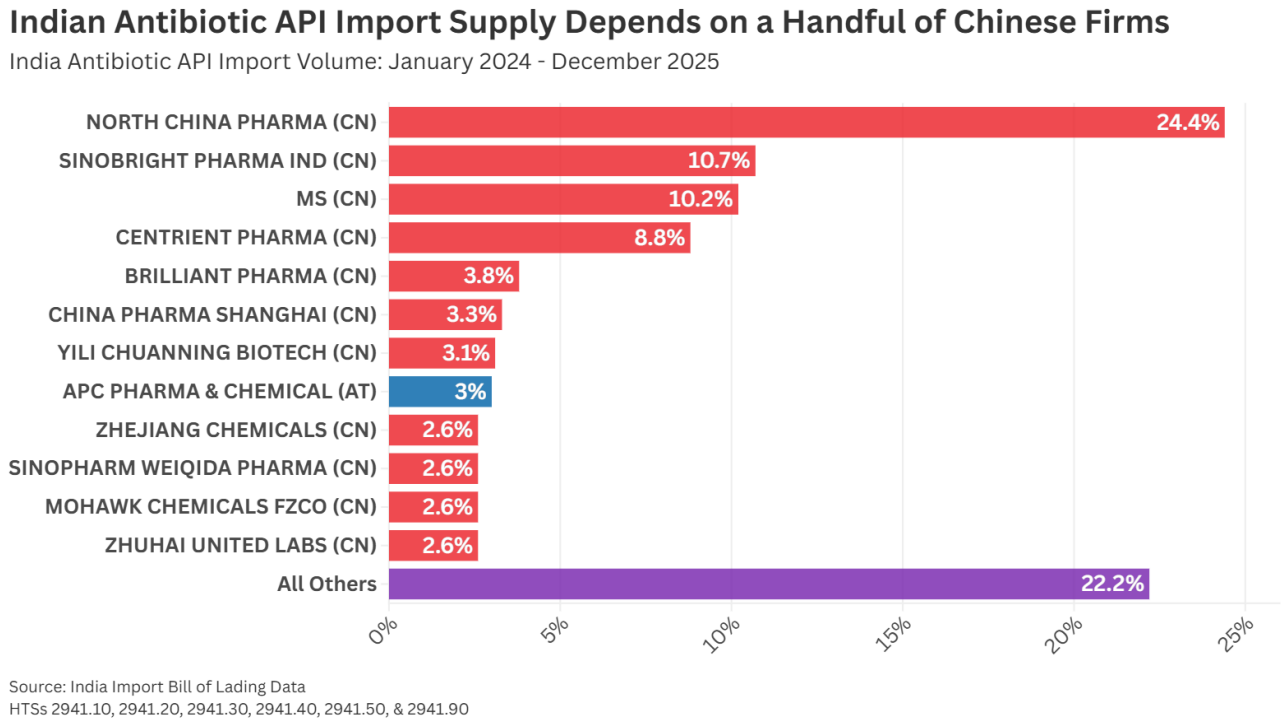
India's experience illustrates how difficult it is to rebuild upstream capacity once global pricing and scale advantages have consolidated elsewhere, as sustained price suppression—whether directed at established producers or emerging competitors—systematically inhibits alternative capacity from reaching scale absent comprehensive government policy support for domestic production.

It is clear that the vast majority of antibiotic tablets and injectables manufactured in India—and later exported to the U.S. or EU+EFTA—still rely on Chinese-produced ingredients. If Chinese API exports are reduced, Indian formulation volume collapses. This is not a theoretical risk—COVID-19 lockdowns in China's Hubei province disrupted API supplies to India, prompting the Indian government to restrict exports of several medicines [17].

Concentration Among India's Chinese API Suppliers

India's near-total reliance on Chinese APIs is compounded by the fact that this supply comes from a very small group of Chinese companies, creating a third and deeper layer of concentration atop the China–India chokepoint. The next figure identifies the leading Chinese firms supplying antibiotic APIs to India.

Figure 12:



Source: India Import Bill of Lading Data
HTSs 2941.10, 2941.20, 2941.30, 2941.40, 2941.50, & 2941.90

Several detailed insights emerge from Figure 12. The top four API suppliers to India by volume—North China Pharma, Sinobright Pharma, MS, and Centrient Pharma together account for 54% of India's total antibiotic API imports. North China Pharmaceutical Group (24.4%) was a major construction initiative under China's First Five-Year Plan and today is among China's largest pharmaceutical giants. Centrient Pharma (8.8%), though Dutch-owned, operates its major API facilities in China, illustrating how antibiotic production that was once largely based in the U.S. and Europe has been offshored. Sinobright Pharma (10.7%) is a Chinese exporter specializing in high-volume penicillins and cephalosporins. The remaining major suppliers are also predominantly Chinese-based producers, reinforcing a structural pattern in which China controls much of the upstream supply of ingredients used to produce antibiotics globally.

This concentration represents the fourth and deepest layer of global antibiotic vulnerability:

- **Layer 1:** U.S. and European reliance on India and China for finished-dosage antibiotics;
- **Layer 2:** Heavy firm-level concentration among Indian FDF manufacturers;
- **Layer 3:** India's near-total dependence on China for antibiotic APIs; and,
- **Layer 4:** Within China, reliance on a small cluster of firms responsible for the majority of global API output.

The global antibiotic supply chain is not merely dependent on China—it is dependent on a handful of individual facilities and production clusters within China. The fragility of this arrangement is already evident. In 2016, an explosion at a single Chinese API plant wiped out the world's supply of piperacillin–tazobactam, a frontline hospital antibiotic [18]. Because China was the sole global API source, this one accident triggered worldwide shortages and forced hospitals across multiple continents to ration care [18]. This was not an anomaly; it was a preview of how the entire system reacts when a single upstream plant goes offline.

Any disruption at a major Chinese API facility could ripple outward through the entire global chain—halting India's finished-dosage production, constraining U.S. hospital formularies, destabilizing European health systems, and draining global emergency stockpiles. When so much of the world depends on so few upstream producers, a single failure can become a systemic shock, with no redundancy to absorb the impact.

Together, upstream concentration and the erosion of alternative capacity elsewhere transform what began as price competition into a structural dependency with limited resilience.

X. Case Study: Penicillin and Amoxicillin—A Molecule-Level View of Systemic Dependency

To distinguish general import exposure from system-critical chokepoint risk, this report treats penicillin-class intermediates—particularly 6-APA—as a separate dependence metric. Because 6-APA sits upstream of all major penicillin-derived antibiotics, concentration at this stage represents the decisive vulnerability in the broader antibiotic supply chain.

Penicillin-class antibiotics, and amoxicillin in particular, are central to both outpatient and hospital-based care. They are the most widely used antibiotics globally, with amoxicillin frequently ranking as the single most prescribed agent in many health systems. In the United States, penicillin-derived antibiotics account for 45% of all outpatient antibiotic prescriptions [19]. Amoxicillin alone represents 28% of all outpatient prescriptions [19], making it the single most widely used antibiotic in the country.

Its role as a first-line treatment for respiratory infections, otitis media, and other community-acquired conditions is well established [20]. Penicillin-derived β-lactams also anchor modern surgical prophylaxis—cefazolin remains the standard preventive antibiotic used across U.S. operating rooms [21].

Yet despite their ubiquity and clinical importance, the upstream production of penicillin-class active pharmaceutical ingredients (APIs)—including Penicillin-G and its key derivative 6-APA, the essential intermediate used to produce amoxicillin—has become highly concentrated in China. As has been demonstrated previously, approximately 90% of global 6-APA production capacity is located in China [12], reflecting the near-monopolization of a critical intermediate for penicillin-class antibiotics, which account for approximately 47% of total antibiotic consumption across the EU+EFTA [22]. This concentration is reinforced by structural evidence: only seven 6-APA manufacturing sites exist worldwide, five of which are located in China, underscoring a severe chokepoint in the global penicillin supply chain [23].

Only four companies globally manufacture the API for penicillin [13], adding a firm-level bottleneck on top of China's geographic dominance and leaving the world dependent on a vanishingly small number of upstream producers. This extreme concentration extends to the key intermediate itself. Many historic penicillin and 6-APA fermentation sites across Europe and the U.S. have shut down permanently over the past two decades, leaving only a limited number of active facilities worldwide. Without 6-APA, neither penicillin V nor amoxicillin can be produced, leaving control over this single upstream molecule as influential over the resilience of the entire penicillin class.

Analysis from the U.S. Pharmacopeia's (USP) Medicine Supply Map further underscores this fragility. USP examined the geographic origin of key starting materials (KSMs) and APIs across dozens of critical antibiotics, including amoxicillin, and demonstrated that even when India manufactures finished amoxicillin, the underlying chemistry originates in China. Penicillin-class KSMs and intermediates are overwhelmingly sourced from Chinese producers, making India's downstream formulation step dependent on Chinese upstream control. India formulates a large share of global amoxicillin finished-dosage forms, but imports more than 90% of its 6-APA from China [24]. This structure can obscure true dependency: finished drugs may appear Indian in origin, yet their molecular foundation is Chinese.

This pattern exemplifies the broader systemic design of the antibiotic supply chain: a tightly linked China → India → America/Europe pathway. China manufactures the API; India formulates the finished-dosage product; and the United States and Europe import the result. Even when formulation occurs domestically, the critical API inputs typically remain Chinese, erasing any presumed resilience from local production.

This structure of dependency was not incidental. It emerged from a decades-long market collapse triggered by China's massive expansion of penicillin fermentation capacity. Beginning in the late 1990s, Chinese firms scaled up Penicillin-G production dramatically, flooding global markets and driving prices well below American, European, and Indian production costs [25]. Within a few years, Penicillin-G and its derivative 6-APA became unprofitable to manufacture in the U.S. and Europe. 6-APA production requires large-scale fermentation and enzymatic cleavage infrastructure—capital-intensive, energy-intensive assets that were dismantled in the U.S. and European countries after China's price suppression, making domestic operations uneconomic. By 2004, the last U.S. facility producing the raw material for penicillin—located in East Syracuse, NY—had shut down, ending domestic penicillin API production [26].

European nations followed a similar trajectory: Germany closed its final penicillin API plant in 2017, leaving Sandoz's Kundl facility in Austria as the EU's sole vertically integrated penicillin producer, and the only site today that still manufactures Pen-G, converts it into 6-APA, and produces downstream semi-synthetic penicillin APIs. Recent European Commission actions were explicitly taken to prevent this capability from disappearing from Europe altogether [27] [28]. As a result, Kundl remains the last major fully vertically integrated penicillin production base in the U.S. or Europe, with no comparable upstream-to-downstream penicillin capacity elsewhere.

The scale of production already concentrated at Kundl demonstrates that this remaining capability is not marginal or symbolic, but industrially significant. Approximately one in three boxes of penicillin used in European countries is supplied directly or indirectly from Sandoz's Kundl plant, reflecting its central position in the continent's penicillin supply [28]. This

footprint illustrates that Kundl is not merely a legacy facility, but a functioning, high-volume production anchor that has already absorbed much of the capacity lost elsewhere in Europe. Its continued operation provides concrete evidence that large-scale penicillin manufacturing can be sustained outside China—and that there are existing facilities that can serve as viable platforms for further expansion and diversification away from Chinese-dominated upstream supply.

Yet the existence of a single remaining American or European production anchor does not offset the broader structure of global dependence. China's dominance extends beyond downstream penicillin and finished formulations to the upstream molecular precursors themselves. About 90 percent of the antibiotic APIs used in the U.S. final market now originate in China [29].

The JAMA Health Forum's 2024 analysis of U.S. antibiotic-API imports underscores how exposed the penicillin value chain has become. The study identifies upstream β-lactam intermediates—including 6-APA—as belonging to the highest-risk category of APIs [30], reflecting the extraordinary concentration of supply. The JAMA findings show that antibiotic APIs exhibit minimal geographic diversification, with China serving as the dominant globally scaled producer for key intermediates. This leaves the United States dependent on a supply chain that lacks redundancy outside a single country.

This chokehold enables Chinese firms to exert global pricing pressure: in 2024–2025, they slashed the price of Penicillin-G and related intermediates by 40–50%, threatening to bankrupt newly launched Indian fermentation facilities before they could scale up [31].

The penicillin case thus echoes every major risk documented in this report: global overdependence on a small group of upstream Chinese firms, downstream bottlenecking in India, and the erosion of American and European production capacity under sustained price suppression. It is a concrete example of how even the most fundamental, high-volume antibiotics now hinge on a fragile, foreign-controlled chain.

Any serious effort to restore American and European antibiotic resilience must begin by reestablishing penicillin-class API production in the United States and European nations. Until that is done, the supply of the world's most essential antibiotic remains structurally exposed to potential external disruption.

XI. Policy Implications

Antibiotic dependence in the U.S. and European countries is driven not by a loss of technical capability, but by distorted market conditions that favored concentrated, subsidized foreign supply. Rebuilding resilience requires reshaping these conditions so that domestic and allied producers can operate viably at scale. The policy actions below target the specific structural weaknesses identified in the antibiotic supply chain: upstream API concentration, downstream formulation dependence, firm-level chokepoints, and misaligned procurement incentives.

1. Use Targeted Tariff-Rate Quotas to Stabilize the Market and Counter Low-cost Foreign Pricing

Antibiotic APIs and finished products have been subject to persistent foreign suppression, primarily from China's subsidized fermentation complex and India's low-cost formulation platforms. A U.S.–EU tariff-rate quota (TRQ) system would establish a tariff wall against high-risk suppliers, while preserving tariff rates for generic drugs at Most Favored Nation (MFN) levels (effectively zero) between the United States and EU, which both operate under trusted, high-standard regulatory

environments. This coordinated TRQ would prevent protracted low-cost competition from destabilizing domestic and allied producers while maintaining adequate supply during the transition.

A TRQ designed for antibiotics would:

- Limit exposure to unsafe or unreliable suppliers;
- Distinguish allied production (U.S. and EU) from higher-risk imports;
- Create predictable market space for reshored and allied facilities; and,
- Counteract price suppression which has historically contributed to American and European plants going offline.

A TRQ is a calibrated mechanism that establishes U.S.–EU tariff protection, helps correct a distorted global market, and enables long-term investment in American and European antibiotic manufacturing.

2. Deploy Targeted Financial Incentives to Restart and Expand Antibiotic Manufacturing Capacity

Rebuilding meaningful American and European capacity requires lowering the barriers to entry for domestic API fermentation, chemical synthesis, and sterile-injectable formulation. These production stages are capital-intensive, low-margin, and highly sensitive to global price movements. Targeted incentives—production tax credits, investment credits, accelerated depreciation, or direct-pay mechanisms—can make domestic and allied production economically viable again.

These tools would support the construction and modernization of fermentation facilities, the reopening or expansion of chemical synthesis lines, new investment in sterile-injectable capacity for hospital-essential drugs, and the scaling of oral-solid antibiotic production for outpatient care. Taken together, this approach enables the U.S. and EU+EFTA to rebuild the industrial base that once anchored the global antibiotic supply.

3. Strengthen Oversight and Quality Assurance for Imported Antibiotics

As domestic and allied capacity is rebuilt, the U.S. and many European countries may continue relying on imports in the short-term—particularly from India, which in turn relies on Chinese APIs. Oversight mechanisms must therefore be strengthened to protect supply reliability and ensure quality.

Effective measures include:

- Unannounced, risk-based inspections of foreign plants;
- Independent laboratory testing for vulnerable molecule classes;
- Enforcement actions for repeated compliance failures; and,
- Mandatory disclosure of API origin throughout the supply chain.

These safeguards ensure imported antibiotics meet consistent standards, prevent unsafe drugs from displacing high-quality U.S. and European producers, and reduce the risk of quality-driven shortages or recalls.

4. Align Procurement with Supply-Security Goals

Government procurement is often the decisive force shaping antibiotic supply chain outcomes. When national programs and major public purchasers prioritize only the lowest-cost supplier, they unintentionally reinforce dependence on concentrated foreign producers and drive domestic firms out of the market. This "price-only" competition is exactly what has driven U.S. generic prices to unsustainably low levels, contributing to recurring shortages and a shrinking pool of manufacturers. By contrast, procurement reform can anchor demand for high-quality domestic antibiotics, creating the stable, long-term market signals that manufacturers need to invest, scale capacity, and reopen production lines. When the government commits to buying resilient, trusted supply, the industry follows.

Procurement reform should:

- Favor suppliers offering reliable domestic or allied production;
- Require API-origin transparency for all contracted antibiotics;
- Support dual-sourcing or multi-region sourcing where feasible;
- Use long-term volume commitments to anchor investment in reshored facilities; and,
- Integrate supply-chain risk criteria into government and national security purchasing decisions.

The fastest path to implementation runs through public health procurement. In the United States, that means major federal health systems such as the Department of Veterans Affairs and the Department of Defense. In the United Kingdom and Europe, it means the UK Department of Health and Social Care, NHS procurement structures, the European Commission's HERA-supported joint procurement mechanisms, and national health ministries and hospital purchasing bodies across EU member states. These systems are among the largest purchasers of antibiotics and already sit at the center of health security and medicines supply resilience. Aligning their procurement policies with supply-chain resilience through domestic and allied-country sourcing preferences, long-term contracts, and stronger API-origin transparency requirements would create immediate, durable demand for U.S., UK, EU, and allied production. In the United States, this would require targeted procurement reforms, including incorporating pharmaceutical supply security into Department of Defense purchasing criteria. In the United Kingdom and European Union, it should be embedded directly in essential-medicines procurement frameworks and anti-shortage planning.

American and European production cannot succeed if procurement systems continue rewarding the very vulnerabilities policymakers seek to reduce. But with aligned purchasing power, government procurement becomes an indispensable tool to rebuild domestic capacity and ensure a resilient antibiotic supply.

5. Integrate Antibiotic Supply Security Into NATO and Allied Force Readiness Planning

Modern military readiness depends not only on weapons systems and logistics but also on guaranteed access to essential medical countermeasures—including antibiotics. NATO allies cannot maintain credible force readiness if their medical systems rely on foreign-controlled supply chains for frontline antibiotics, particularly penicillin-class and hospital-essential agents. Ensuring uninterrupted availability of these medicines is as vital to operational resilience as secure fuel or munitions supply. NATO's planning frameworks should therefore include antibiotic supply-chain security as a core readiness requirement: identifying vulnerabilities, prioritizing allied production, and preventing dependence on Chinese-controlled API

sources that could be disrupted or weaponized during a crisis. A military alliance cannot project strength if its medical backbone depends on another's industrial decisions.

6. Build Coordinated U.S.–EU+EFTA Antibiotic Manufacturing and Supply Networks

Because the U.S. and European nations rely on the same foreign producers, fragmented national strategies cannot deliver the scale or stability needed to rebuild antibiotic manufacturing. A coordinated transatlantic approach would expand the market for high-quality American and European production, reduce duplicative regulatory burdens, and create the predictable demand environment that European and American firms need to invest and compete globally. Such cooperation not only strengthens supply security—it strengthens the position of allied manufacturers.

Joint initiatives could include:

- Shared investment in fermentation and synthesis facilities located in allied jurisdictions;
- Harmonized API-origin and quality standards that reward compliant, high-quality producers;
- Coordinated TRQ or tariff structures that support American and European manufacturers against unfairly priced imports;
- Shared surveillance of global antibiotic supply risks to ensure early warning and rapid response; and,
- Trusted-supplier corridors between the U.S. and EU+EFTA to streamline movement of intermediates and finished products.

This partnership-based approach strengthens the collective ability of American and European producers to reduce the risks emanating from concentrated foreign control, expand capacity, and rebuild a diversified, resilient antibiotic supply chain.

XII. Conclusion

The evidence in this report shows that the antibiotic supply serving the United States and Europe is structurally vulnerable, and sustained by a small set of foreign producers whose decisions and continuity directly determine American and European access to essential medicines. This dependence is already causing disruptions across U.S. and European antibiotic supply chains, and domestic producers are being pushed out of the market.

The primary vulnerability stems from a chain of dependencies across the supply system. The United States and European countries rely heavily on imports from India and China for finished medicines. Those medicines are produced by a small number of manufacturers, which themselves depend heavily on Chinese APIs—where production is further concentrated among a limited set of firms. At each step, the system becomes more fragile, leaving supply exposed not only to disruption, but also to documented drug quality, safety, and compliance failures among major foreign exporters.

Yet, the U.S. and EU+EFTA are fully capable of restoring control over this supply chain. U.S. and European antibiotic API and FDF manufacturers only need a policy environment that rewards reliability over lowest-cost sourcing. Strategic tools—tariff-rate quotas, targeted industrial incentives, stronger oversight of foreign production, and procurement reform—can rebuild upstream ingredients, downstream formulation, and a trusted network of allied manufacturers. Preserving and expanding

critical existing capacity, particularly the Sandoz Kundl plant in Austria, provides the foundation for rebuilding antibiotic API capacity in the United States and Europe.

Antibiotics are essential infrastructure. Reestablishing secure production is a national security imperative, and with coordinated action, the U.S. and Europe can replace today's precarious dependence with a resilient, sovereign foundation for modern medicine.

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ANNEX B. Methodological Transparency

This report relies on harmonized U.S.–EU+EFTA trade data and firm-level import/export records to quantify antibiotic import dependence, supplier concentration, and upstream/downstream vulnerabilities.

HTS Framework.

The following HS codes that exclusively capture human-use antibiotics were included:

- **2941.10, 2941.20, 2941.30, 2941.40, 2941.50, 2941.90** (bulk APIs)
- **3004.10, 3004.20** (FDF antibiotics)

Data Sources.

The analysis integrates:

- **U.S. Census (USA Trade Online)** for U.S. imports of API and FDF products;
- **Eurostat (EU and EFTA)** for parallel EU antibiotic import flows; and
- **Bill-of-lading and customs shipment record data for company-level concentration patterns, including Indian export data** and Chinese API exporters.

Scope Limitations.

Country-level import statistics necessarily capture all goods reported under each HTS code, which means they include both human and veterinary antibiotics. However, veterinary-only companies and veterinary-specific production lines were excluded from company-level concentration data to prevent distortion of human-medicine vulnerability analysis. Because veterinary and human antibiotics can share the same HS code, country-level aggregation may slightly overstate total market volumes and differ from company-level aggregates.

Timeframe and Comparability.

U.S. and EU+EFTA data was analyzed for January 2024 through December 2025.

ANNEX C. Glossary of Technical Terms

Active Pharmaceutical Ingredient (API).
The bulk chemical or fermented substance that gives a drug its therapeutic effect; the essential upstream input for antibiotic manufacturing.

Finished-Dosage Form (FDF).
A fully formulated, patient-ready medicine (e.g., tablets, capsules, sterile injectables). FDF production cannot occur without APIs.

β-lactam Antibiotics.
A major antibiotic class—including penicillins and cephalosporins—produced through fermentation and chemical synthesis and widely used in hospitals.

Fermentation Capacity.
Industrial-scale bioproduction used to manufacture many antibiotic APIs. Globally concentrated in China.

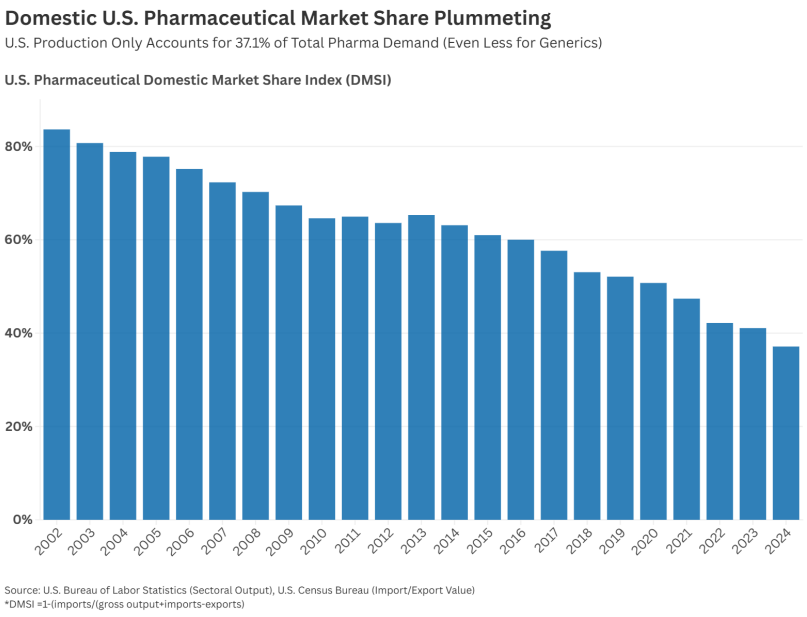
Intermediate (Chemical Intermediate).
A precursor substance required to synthesize APIs. China dominates global production of antibiotic intermediates.

MFN / PNTR Status.
"Most Favored Nation" (MFN), known in the U.S. as Permanent Normal Trade Relations (PNTR), grants low tariff rates. China's PNTR access after 2001 accelerated its rise in antibiotic API production.

Tariff-Rate Quota (TRQ).
A trade tool that allows a limited volume of imports at a low tariff while imposing high tariffs on imports above that threshold, used to stabilize domestic production.

ANNEX D. List of Figures and Tables

Figure 1:



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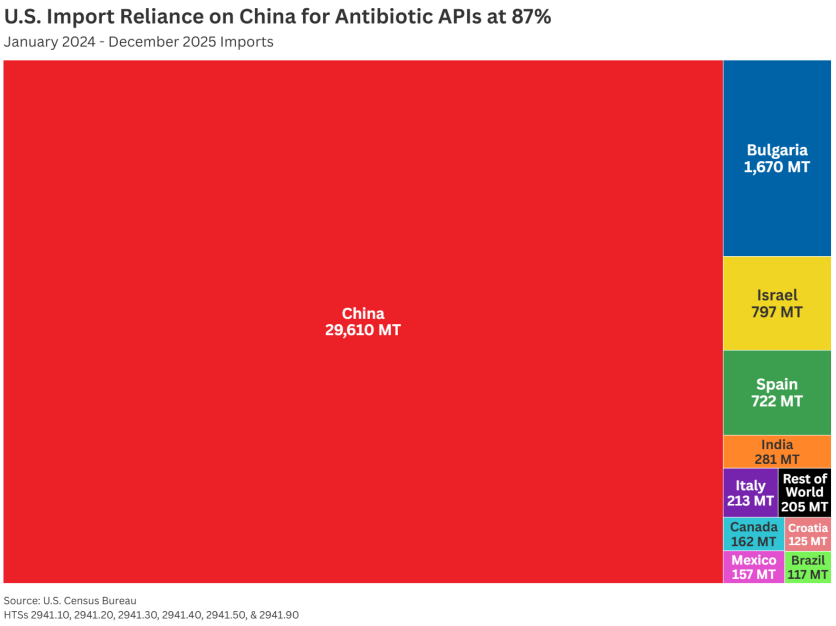

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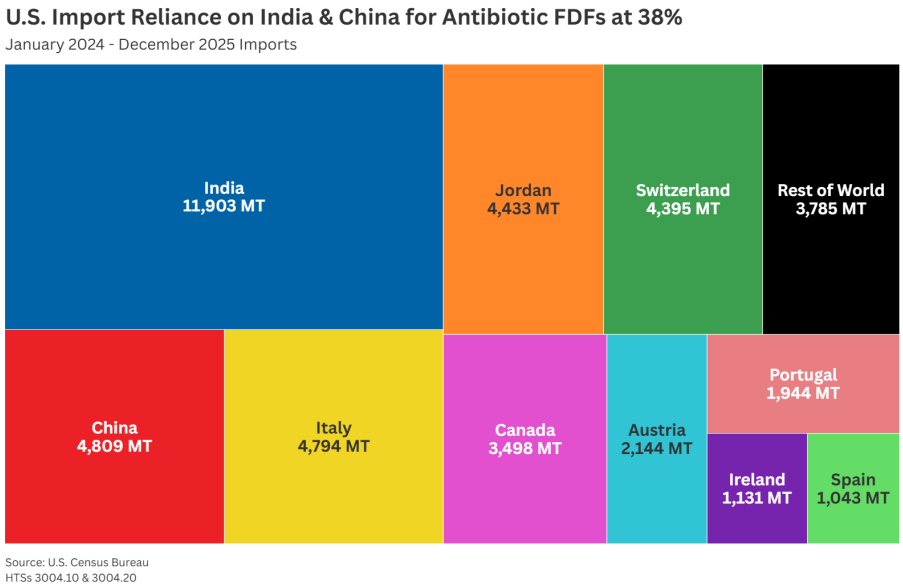

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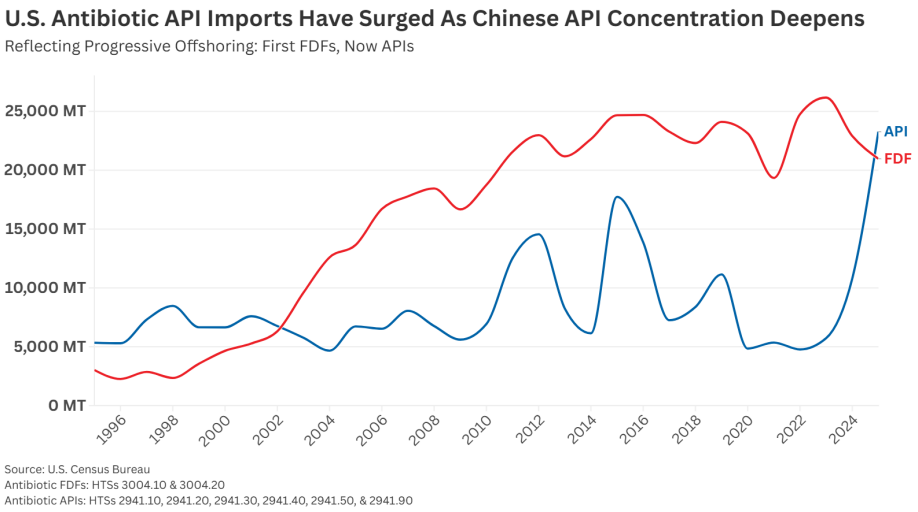

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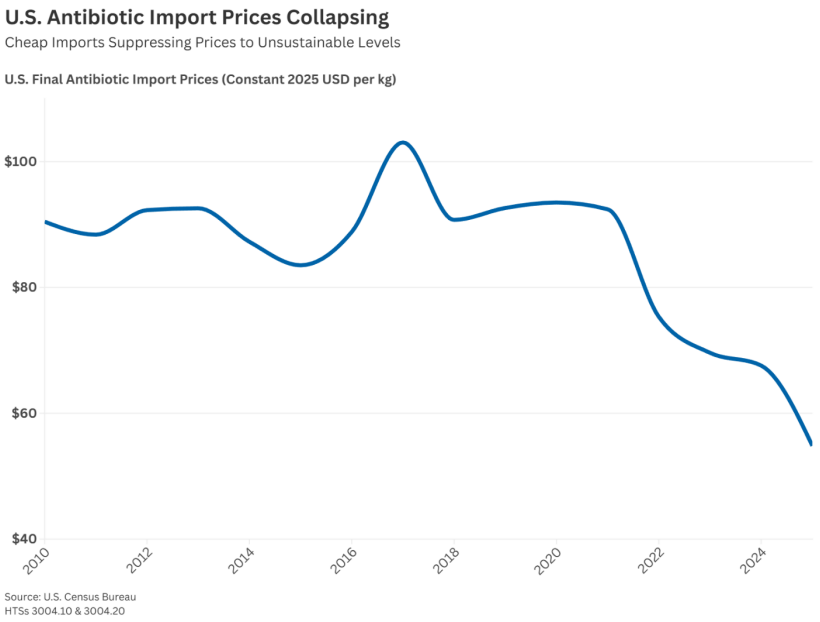

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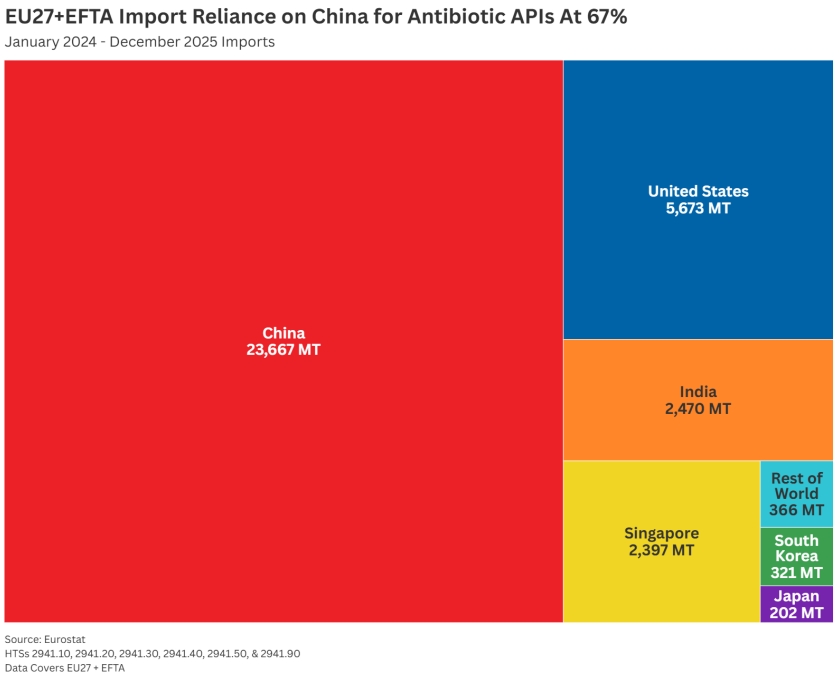

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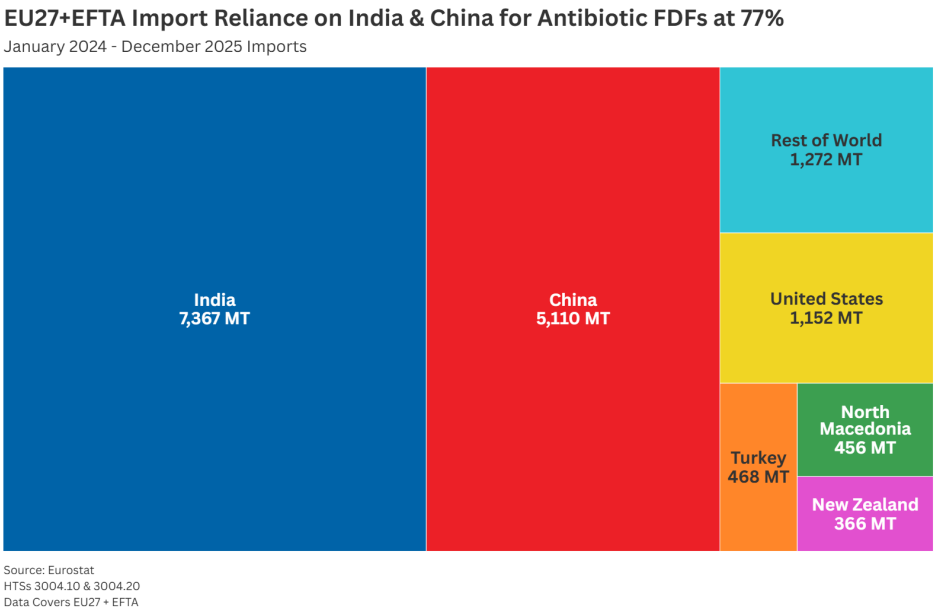

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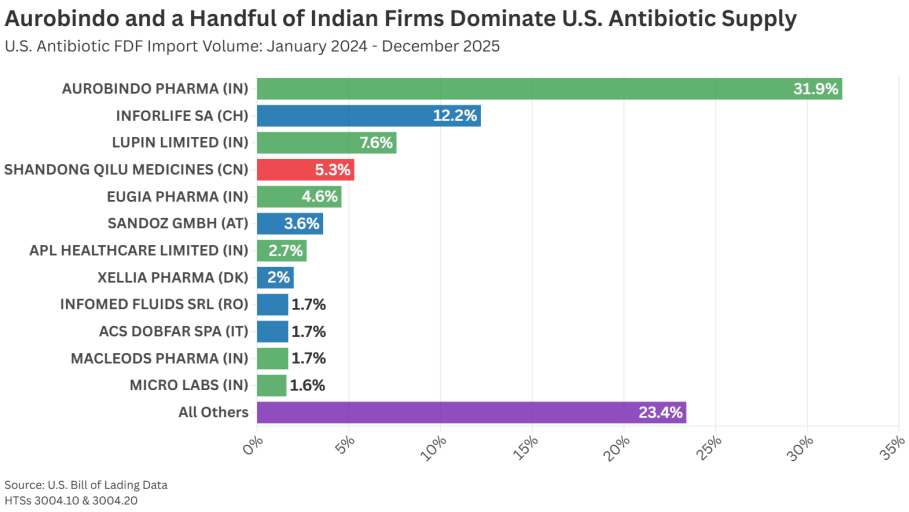

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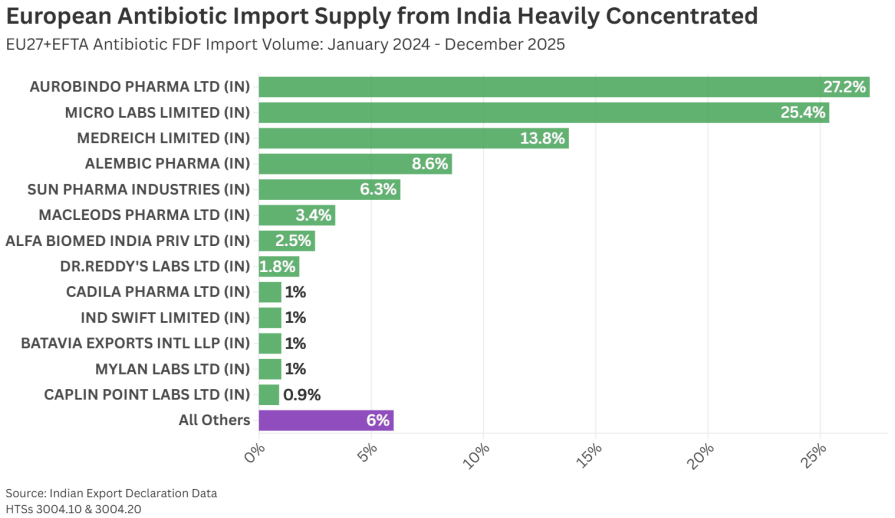

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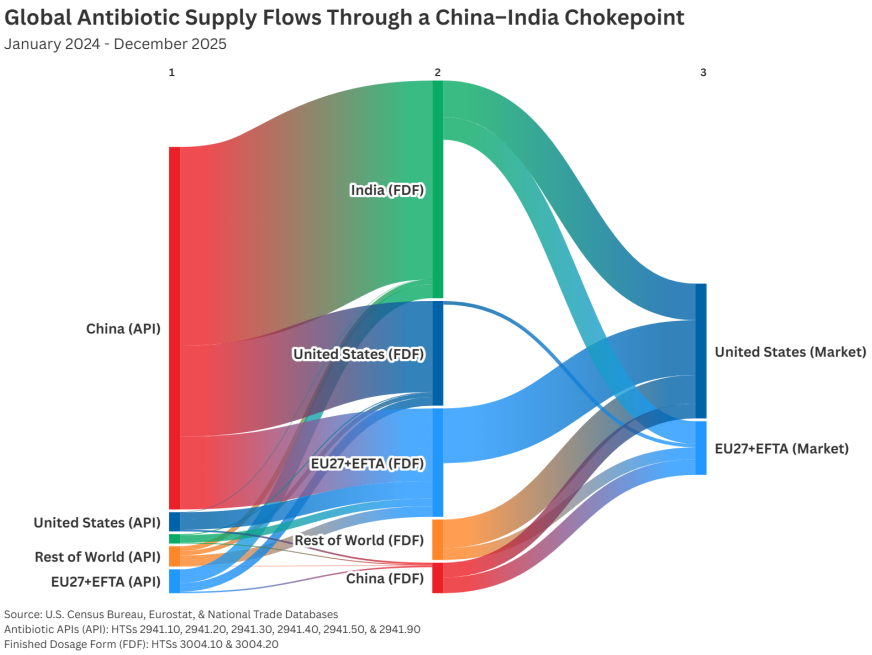

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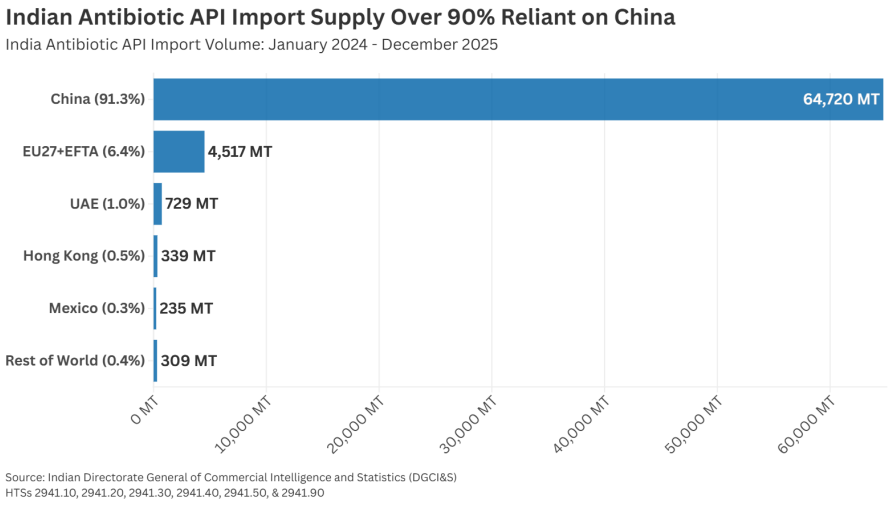

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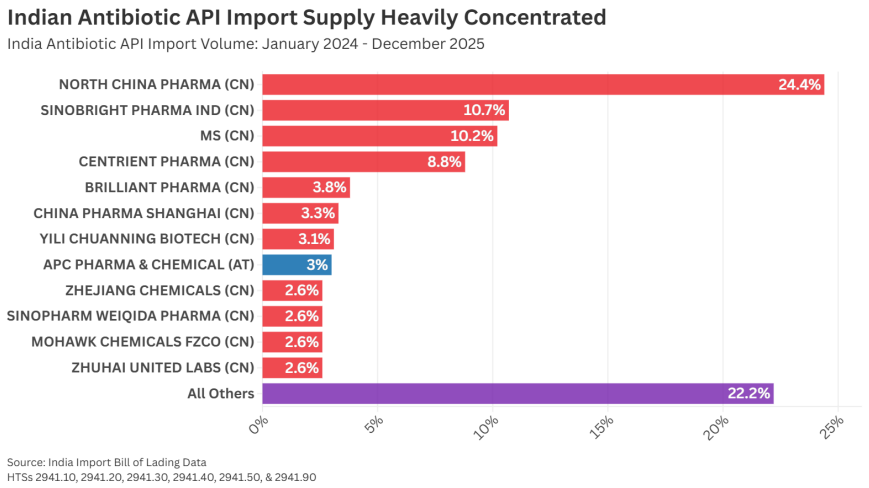

Table 1. Antibiotic HTS Codes and Molecule Classes

HTS Code	Description	Stage	Antibiotic Classes Included	Representative Molecules
2941.10	Penicillins and derivatives (bulk pharmaceuticals)	API	Penicillins (β-lactams)	Amoxicillin, Ampicillin, Penicillin G/V; inputs for Amoxicillin-Clavulanate and Ampicillin-Sulbactam
2941.20	Streptomycins and derivatives (bulk pharmaceuticals)	API	Aminoglycosides (streptomycin class)	Streptomycin, Dihydrostreptomycin
2941.30	Tetracyclines and derivatives (bulk pharmaceuticals)	API	Tetracyclines	Tetracycline, Doxycycline
2941.40	Chloramphenicol and derivatives (bulk pharmaceuticals)	API	Amphenicols	Chloramphenicol, Thiamphenicol, Florfenicol
2941.50	Cephalosporins and derivatives (bulk pharmaceuticals)	API	Cephalosporins (β-lactams)	Ceftriaxone, Cefazolin, Cefuroxime, Cefotaxime, Ceftazidime
2941.90	Other antibiotics (bulk pharmaceuticals)	API	Macrolides, Carbapenems, Glycopeptides, Lincosamides, others	Azithromycin, Clarithromycin, Vancomycin, Clindamycin, Meropenem, Imipenem; components used in combination antibiotics
3004.10	Medicaments containing penicillins or derivatives, in measured doses	FDF	Penicillins and combinations	Amoxicillin tablets/capsules, Amoxicillin–Clavulanate, Ampicillin products
3004.20	Medicaments containing other antibiotics, in measured doses	FDF	Cephalosporins, Carbapenems, Macrolides, Glycopeptides, Tetracyclines, others	Ceftriaxone vials, Cefazolin vials, Meropenem vials, Vancomycin vials, Azithromycin tablets, Doxycycline, Piperacillin–Tazobactam

Table 2. U.S. Antibiotic Dependence by Country (API vs FDF)

Country	Antibiotic API Imports (MT)	API Import Share		Country	FDF Imports (MT)	Final Drug Import Share
China	29,610	86.9%		**India**	11,903	27.1%
Bulgaria	1,670	4.9%		**China**	4,809	11.0%
Israel	797	2.3%		**Italy**	4,794	10.9%
Spain	722	2.1%		**Jordan**	4,433	10.1%
India	281	0.8%		**Switzerland**	4,395	10.0%
Italy	213	0.6%		**Canada**	3,498	8.0%
Canada	162	0.5%		**Austria**	2,144	4.9%
Mexico	157	0.5%		**Portugal**	1,944	4.4%
Croatia	125	0.4%		**Ireland**	1,131	2.6%
Brazil	117	0.3%		**Spain**	1,043	2.4%
Rest of World	205	0.6%		**Rest of World**	3,785	8.6%

Source: U.S. Census Bureau

January 2024 – December 2025
Final Antibiotic Drugs: HTSs 3004.10 and 3004.20
Antibiotic APIs: HTSs 2941.10, 2941.20, 2941.30, 2941.40, 2941.50, and 2941.90

Table 3. EU+EFTA Antibiotic Dependence by Country (API vs FDF)

Country	Antibiotic API Imports (MT)	API Import Share		Country	FDF Imports (MT)	Final Drug Import Share
China	23,667	67.4%		**India**	7,367	45.5%
United States	5,673	16.2%		**China**	5,110	31.6%
India	2,470	7.0%		**United States**	1,152	7.1%
Singapore	2,397	6.8%		**Turkey**	468	2.9%
South Korea	321	0.9%		**North Macedonia**	456	2.8%
Japan	202	0.6%		**New Zealand**	366	2.3%
Rest of World	366	1.0%		**Rest of World**	1,272	7.9%

Source: Eurostat

January 2024 – December 2025
Final Antibiotic Drugs: HTSs 3004.10 and 3004.20
Antibiotic APIs: HTSs 2941.10, 2941.20, 2941.30, 2941.40, 2941.50, and 2941.90