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From Molecules to Medicine: A Primer on the Pharmaceutical Supply Chain

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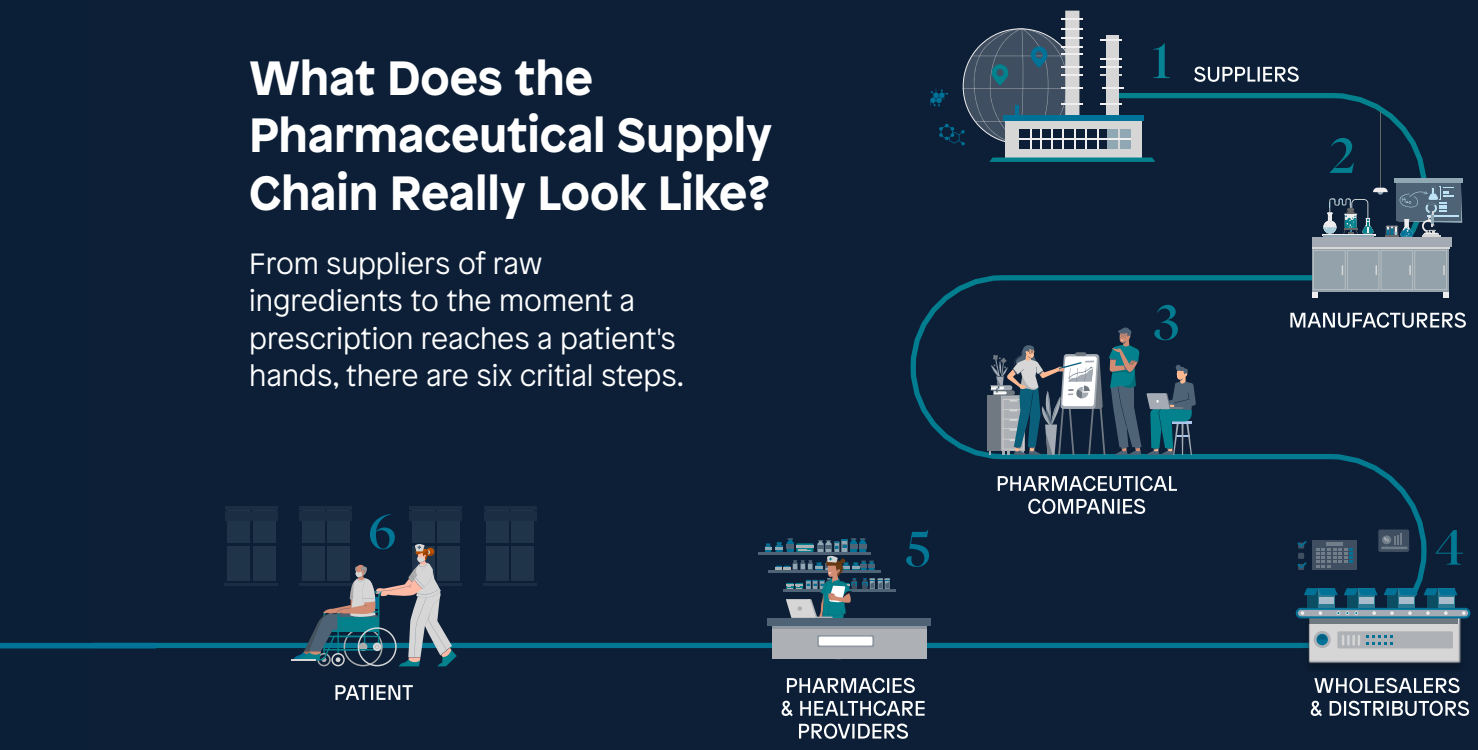
The complex path a drug takes from raw ingredient suppliers, across international borders, to a patient's medicine cabinet has implications for security, health costs, and patient safety. The first step to addressing the issues within the supply chain is knowing how it is structured. That is why West Health developed this cheat sheet that describes each part of the chain in 300 words or less. Explore West Health's broader work on prescription drug affordability and access at https://westhealthmosaic.com/categories/prescription-drug-affordability.

What Does the Pharmaceutical Supply Chain Really Look Like?

From suppliers of raw ingredients to the moment a prescription reaches a patient's hands, there are six critial steps.



Suppliers

Suppliers provide the ingredients needed to manufacture prescription drugs. Starting materials for drugs are commonly sourced from specialized chemical manufacturers. In many cases, these suppliers serve not just pharmaceutical companies, but a wide range of other industries, such as cosmetics and automotive manufacturers.[1]

Many suppliers of starting materials are in China, which dominates the market for chemicals, especially those that entail dangerous manufacturing or toxic byproducts. China has become an important source of the starting materials for drugs such as antidepressants and antibiotics.

The United States is particularly reliant on China for ingredients used in generic drugs,[2] which account for roughly 90 percent of prescription drugs dispensed in the U.S.[3] China also is a key supplier of materials used for other types of drugs, including amino acids used in the production of biologic drugs.[4] European countries, meanwhile, are prominent in the supply of more specialized starting materials.[5]

Manufacturers

Manufacturers transform ingredients (or products of cell cultures, in the case of biologics and some small molecule drugs) into pharmaceutical products.[6] The first step of drug manufacturing is to turn these starting materials into active pharmaceutical ingredients (API), the compounds responsible for a drug's therapeutic effects. It is common for makers of API to sell them to other companies, which then use them to manufacture the finished drug taken by patients.[7]

As of 2021, "about half of FDA-registered finished dosage form manufacturing facilities and most API manufacturing facilities were located outside the United States," according to a government analysis of U.S. drug shortages, which noted how this dynamic "increases supply chain complexity and limits the United States' ability to respond to supply chain disruptions."[8] Indeed, India and the European Union (EU) are the two largest sources of API used in the U.S.[9] India is responsible for most of the API for generic drugs, which account for 90 percent of drugs dispensed to Americans.[10]

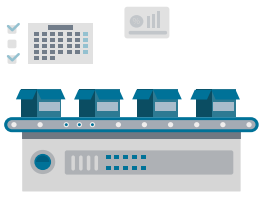
APIs must be formulated with additional ingredients before being used by patients. These inactive ingredients have no standalone therapeutic effect. Rather, they ensure that the APIs have the expected therapeutic effect when taken by or administered to the patient.

Pharmaceutical Companies

Pharmaceutical companies are responsible for bringing prescription drugs to market. In this role, they interact with federal regulatory agencies, including FDA and CMS, to gain marketing authorization for the drug and ensure its coverage.

In many cases, pharmaceutical companies are also responsible for manufacturing, especially in the case of branded drugs. However, many pharmaceutical companies outsource production to contract manufacturing organizations (CMOs).[11]

Pharmaceutical companies arrange for finished and packaged forms of their drugs to be distributed into the U.S. supply chain by contracting with wholesale distributors or specialty distributors.



Wholesale Distributor and Specialty Distributor

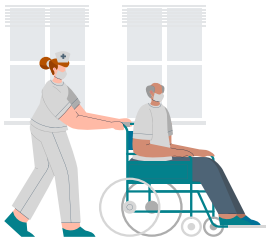
Wholesale distributor and specialty distributor act as intermediaries, facilitating the flow of medications from pharmaceutical manufacturers to pharmacies and healthcare providers. They serve as clearinghouses that purchase drugs from manufacturers; handle logistics from the factory to the point of sale; and provide services such as ordering, account management, and inventory management.

Many medicines administered by providers require specific storage, handling and safety requirements, and are therefore distributed by "specialty" distributors to ensure quality and oversight.[12] Specialty distributors can also provide cold-chain management for temperature-sensitive biologics, waste management programs for cytotoxic drugs, inventory management systems, and clinical support services.[13] Three companies—Cencora (formerly AmerisourceBergen), McKesson and Cardinal Health—control most of the wholesale distribution market,[14] and dominate the specialty distribution channel.[15]

Pharmacies & Healthcare Providers

Pharmacies buy medications from wholesale distributors and dispense them to the patient upon receiving a prescription. Pharmacies negotiate reimbursement rates with pharmaceutical benefit managers or health plans, and receive payment for dispensing drugs to their members. There are three broad categories of pharmacies: retail (i.e., chains and independent pharmacies with a storefront); online/mail order pharmacies; and specialty pharmacies that handle drugs requiring more sensitive handling. CVS, Evernorth (formerly Express Scripts), Walgreens, and UnitedHealth Optum account for a significant share of these markets.[16]

Healthcare Providers—including hospitals, health systems, and physician practices—purchase drugs from wholesalers and specialty distributors. Drugs given to patients by healthcare providers are usually administered on the premises by clinicians. Healthcare providers make decisions about which drugs to purchase and keep in stock based on their clinical characteristics, the patients they serve, and the contractual terms offered by wholesalers as well as pharmaceutical companies.



Patients

Patients are the last stop in the prescription drug supply chain and pay for their drugs in two primary ways. (1) Patients with insurance pay their pharmacy a co-pay or co-insurance that is set by their health plan for the drugs they buy at the pharmacy or receive in clinic, in addition to a monthly premium paid to the health plan. (2) Patients without insurance may pay the list price of a drug or use patient assistance programs to gain access to drugs they could not otherwise afford.[17]

Americans pay three times more for brand-name prescription drugs than other industrialized nations,[18] and patients are not happy about it. West Health-Gallup polling shows **four out of five Americans** are concerned about prescription drug costs,[19] while **one in three older adults** worry about being able to pay for prescription drugs.[20] Studies have shown that high costs force many older adults to forgo medications due to costs,[21] and some patients even ration lifesaving diabetes and obesity medication.[22]

Why it Matters

One of the most effective ways to improve access of and affordability to prescription drugs is to allow generic competition to enter the market. Studies have shown that generic drugs bring down prices by 80 percent by the time four have entered the market.[23]

While generic drugs account for about 90 percent of prescription drugs dispensed to Americans today,[24] the international nature of generic manufacturing presents challenges and barriers. These issues include drug shortages, supply chain disruptions and trade policy.

- **Shortages:** Generic drugs are highly susceptible to shortages. In recent years, the duration of shortages has increased even as their frequency have decreased.[25] Shortages present problems for patients when time-sensitive treatments like cancer medication are not readily available. The shortages have prompted calls to improve supply chain monitoring, resilience and preparedness.[26]
- **Supply Disruptions:** Disruption due to quality concerns and regulatory violations can create or worsen drug shortages. Consolidation within the supply chain has increased the risk of widespread disruptions when a single supplier is taken offline.[27] For example, contamination at a single manufacturer in 2018 affected blood pressure medication purchasing in dozens of countries including the U.S.[28]
- **Trade**: The international nature of the drug supply chain makes it susceptible to changing trade policy. Tariffs levied on the pharmaceutical supply chain has the potential to affect U.S. drug prices, depending on the countries affected and types of imports subject to new tariffs.[29]

Like other aspects of prescription drug policy, it is important to know how changes to one part of the supply chain may affect other parts, including, most importantly, the patient. As policymakers consider issues ranging from trade policy to on-shoring pharmaceutical manufacturing, West Health is providing resources that can help make sense of these complex relationships.

Learn more with West Health

West Health has supported research by Brookings Institution Fellow Marta Wosinska that further explores the pharmaceutical supply chain on a range of issues including:

Trade Policy and U.S. Prescription Drugs

Oversight of the Pharmaceutical Supply Chain

The Economic Impact of Generic Shortages

The Role of China and Other Nations in the Pharmaceutical Supply Chain

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