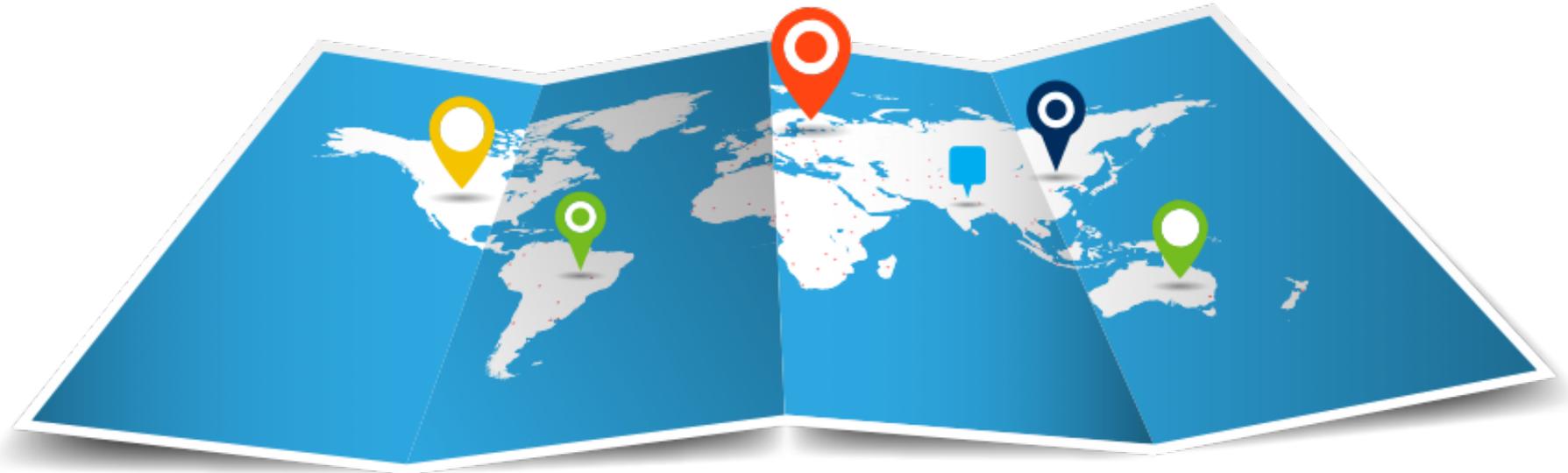




Your Generics & Biosimilars Industry

Generics and Biosimilars Industry Response to COVID-19



As the COVID-19 pandemic progresses, manufacturers of generic and biosimilar medicines are working around the clock to ensure America's patients have access to the medicines they need. Although the global pharmaceutical supply chain is straining under unrivaled stress and demand, the makers of 9 out of every 10 prescriptions filled in the U.S. are rising to the challenge.

AAM is proud of the resolve, initiative and generosity of its member companies.

In addition to working 24/7 to meet the surge in demand, our members are donating millions of doses of medicine and medical equipment, including PPE and ventilators, as well as working to ensure the health and safety of their own employees and local communities.

- **3M** is doubling its global output of N95 respirator face masks and getting them to health care providers on the front lines of the pandemic.
- **Accord's** UK arm is donating two million doses of hydroxychloroquine to Britain's National Health Service, for use in the world's largest trial.
- **Apotex** is producing hand sanitizer in support of front-line workers who are battling the COVID-19 virus in Canada, where the company is headquartered. An initial run of 500 one-liter bottles of sanitizer has been donated for distribution among local community

agencies and health care facilities in Ontario and an additional 1,200 liters of sanitizer will be produced and donated in the coming weeks. The manufacturer has donated nearly 300,000 doses of medicines COVID-19 patients need in the ICU setting to FEMA.

- **Amneal** is donating one million doses of potential COVID-19 treatment hydroxychloroquine sulfate to the Texas State Pharmacy, for direct distribution to hospitals, two million doses to New York and 400,000 to Louisiana.
- **Fresenius Kabi** is maximizing supply of essential drugs for the treatment of COVID-19 patients, especially medicines used for sedation and pain management, by dedicating all compatible manufacturing capacity to these vital drugs.
- **Lupin** is donating 10,000 N95 respirator face masks to hospitals and nursing homes in Florida, Maryland, New Jersey and New York. The company has been ramping up production of hydroxychloroquine and will donate to the National



Institutes of Health for research purposes, the Strategic National Stockpile for emergency use and to pandemic response efforts in Maryland.

- **Mallinckrodt Specialty Generics** is manufacturing and donating hand sanitizer to all opioid treatment programs (OTP) in support of its uninterrupted care of opioid use disorder patients during the COVID-19 pandemic. In addition, it is donating hand sanitizer to the state emergency management operations located in regions in which it operates manufacturing sites.
- **Sandoz** is donating up to 130 million doses of hydroxychloroquine sulfate to support ongoing clinical trials, of which 30 million doses were donated to the Strategic National Stockpile.
- **Sun Pharmaceutical** is donating 2.5 million doses of hydroxychloroquine sulfate.
- **Teva** is donating 10 million doses of hydroxychloroquine sulfate to hospitals nationwide.



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- **Zydus** is vertically integrated on hydroxychloroquine (HCQ) and has increased its API capacity from 3 metric tons to 30 metric tons, with the ability to further increase. The company supplies more than 35% of the patients within the U.S. who use HCQ as a daily therapy outside of COVID-19 and has obtained approval to export hydroxychloroquine to the U.S. to support its patients taking the product for lupus and rheumatoid arthritis, along with COVID-19 patients. Zydus can currently produce 35 million doses per month, and is working with the FDA to be able to increase this.

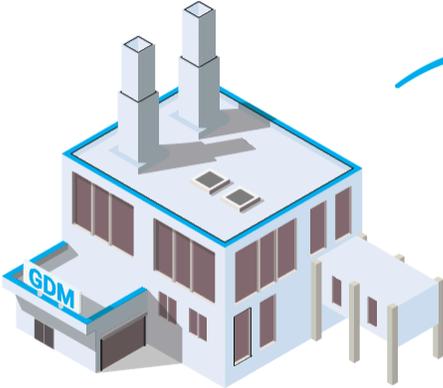


- AAM associate member **Direct Relief** is providing personal protective equipment and essential medical items to health workers and delivering protective masks, exam gloves and isolation gowns to health care organizations in areas with confirmed COVID-19 cases.
- AAM associate member **Dispensary of Hope** distributed 4.2 million doses of donated medication in February and 7.1 million doses in March to more than 200 non-profit clinics, community centers and pharmacies. With increased need across the U.S., the generics industry is answering the call: The organization received nearly 17 million doses of donated medicine in March, a record high for volume of donations.
- AAM associate member **Operation Smile** is donating gloves, masks and ventilators to hospitals in Virginia. Activity in mission countries includes CPAP helmets for non-invasive ventilation to a hospital in Italy and partnering with an Indian health foundation and local governments in Mumbai and Durgapur to distribute food and personal hygiene items to 700 families.



How Generics Reach Patients at the Pharmacy Counter

Generic Drug Manufacturers
Represented by the Association for Accessible Medicines



Using globally sourced ingredients, FDA-inspected facilities produce FDA-approved medicines.

Distributors/Wholesalers
Represented by the Healthcare Distributors Alliance



Finished medicines are purchased under contract, safely warehoused and organized to fulfill orders from downstream buyers including licensed pharmacies and health care providers. Ninety percent of these orders funnel through three distributors.



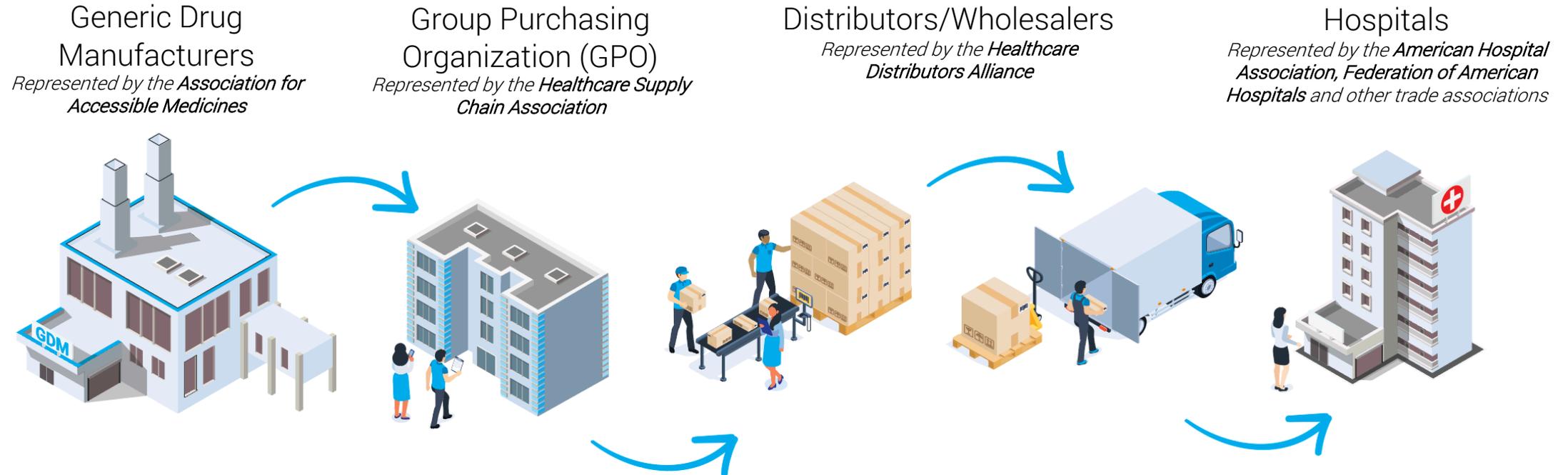
Orders are readied and transported to pharmacy buyers. With operations continuously running, primary distributors can take orders made by 8:00 p.m. and deliver them to their end destination as soon as the next morning.

Pharmacies
Represented by the National Association of Chain Drug Stores, National Community Pharmacists Association and other trade associations



Thousands of chain, community retail pharmacies, mail-order and specialty pharmacies receive medicines and dispense to patients as prescribed.

The Generic Supply Chain for Hospital-Administered Medicine



Using globally sourced ingredients, FDA-inspected facilities produce FDA-approved medicines.

GPOs contract for medicines directly from manufacturers to help health care providers — such as hospitals, hospital-owned nursing homes and home health agencies — realize savings and efficiencies by aggregating purchasing volume and using that leverage to negotiate discounts with manufacturers, distributors and other vendors.

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Hospital pharmacies dispense a large volume of medications per day to the wards and to intensive care units according to a patient's medication schedule. Hospital-based pharmacists have a professional society, the **American Society of Health-System Pharmacists**.

Generic Drug Supply Chain 101

Summary

Generic drugs in the United States form the backbone of affordable, accessible medicines for consumers, and are responsible for **90% of all prescriptions filled in the U.S., but only 22% of costs.**

This is made possible through fierce competition among the approximately 200 generic manufacturers for purchases by three dominant distributors/wholesalers (90% of all retail generic purchases), as well as group purchasing organizations (90% of all hospital generic purchases), pharmacies and other purchasers.



Generic Drug Supply Chain 101

Generic Drug Manufacturers



Generic manufacturers are responsible for developing products that meet FDA requirements for approval, as well as producing those products once approved. Generic drugs are required to have the same active ingredient, strength, dosage form and route of administration as the brand-name product. Generic drugs must also meet rigorous standards established by the FDA with respect to identity, strength and potency. Finally, generic drugs must have the same quality, purity and performance as their brand-name drug counterpart. This requires extensive investment in generic drug research and development, manufacturing facilities and equipment, continual maintenance of that equipment and, of course, compliance with quality systems and FDA good manufacturing practice regulations.

Most generic drugs are purchased by three distributor/wholesaler purchasing groups that collectively account for 90% of all generic drug purchasing. Due to the large number of manufacturers competing against one another on price, prices in the generic drug market can be volatile and are not controlled by a single entity. This volatility in price tends to be downward for the generic industry due to the additional competitors in the market and pricing pressure from others in the supply chain. Moreover, once a generic manufacturer sells a drug to a distributor, it plays no role in the further downstream pricing or distribution of the product across multiple entities prior to reaching a patient.

Generic Drug Supply Chain 101

Distributors/Wholesalers

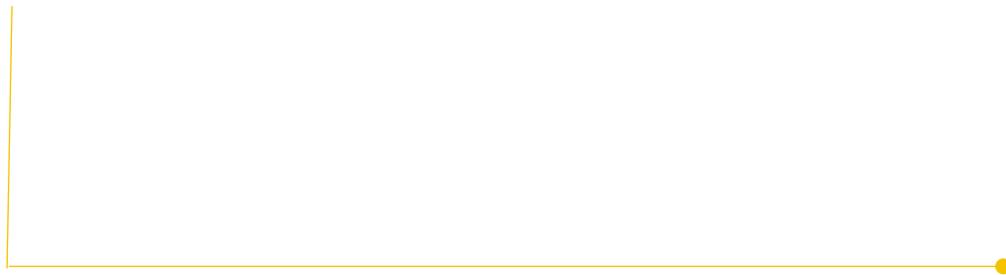
Distributors/wholesalers purchase prescription drugs in large quantities from manufacturers for storage in warehouses and distribution centers across the country. Those drugs are then sold to thousands of pharmacies. Distributors may also perform other functions for pharmacies, such as logistics and inventory management. Distributors negotiate discounts with manufacturers for the prompt payment of invoices. Distributors also generate revenue from sales to pharmacies and fees related to other services provided to customers. Like any other supply chain market, distributors can capitalize on price fluctuations – especially those in the generic market.



Generic Drug Supply Chain 101

Group Purchasing Organizations

A group purchasing organization (GPO) is an entity that helps health care providers – such as hospitals, nursing homes and home health agencies – realize savings and efficiencies by aggregating purchasing volume and using that leverage to negotiate discounts with manufacturers, distributors and other vendors.



Generic Drug Supply Chain 101

Pharmacies

Pharmacies are responsible for dispensing prescription drugs to individual patients. Generally this refers to a retail pharmacy located in the community, but pharmacies can also distribute prescription drugs via the mail, or can serve patients of hospitals, long-term care facilities and community clinics.



Generic Drug Supply Chain 101

Hospitals

Hospital pharmacies prepare and dispense medicines; counsel patients; consult with health care providers; and manage data.





Learn more at:
[accessiblemeds.org](https://www.accessiblemeds.org)



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