CAUSES AND RESPONSES TO DRUG SHORTAGES

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What's causing drug shortages in the United States?

Medications are composed of a complex blend of active and inactive ingredients. A typical tablet is primarily made up of inactive ingredients that are designed to hold the dosage form together and make the administration of active ingredients easy and consistent. The active pharmaceutical ingredient, or API, is the "active drug" component of a tablet or capsule.

Today, most API manufacturers are located in China, India, and Italy (combined up to approximately 80%). The use of these three countries as the primary sources for worldwide API supply impacts both brand and generic pharmaceutical manufacturers, as pharmaceutical manufacturers have grown to increasingly rely on a few concentrated sources for outsourced API.

As COVID-19 has spread around the world, it has reduced industrial production. Manufacturing processes have been curtailed as workers are ordered to stay at home to limit the opportunities for disease spread through direct person-to-person contact. This reduced production is why drug supply in the U.S. may be negatively impacted.

How can somebody find out if a drug they're taking is likely to be in short supply soon so they can stock up on it before it runs out?

The short answer is you can't. Because the legal obligation to report existing or pending drug shortages to the Food and Drug Administration (FDA) lies on pharmaceutical manufacturers, the FDA is forced to be reactive, not proactive, when reporting manufacturer shortages to the public. The FDA's public database is only as reliable as the self-reported information provided to it by the manufacturers. While manufacturers are legally required to report drug supply disruptions to FDA, they are not required to provide detailed information on their supply chain.

For these reasons, we are unable to determine the specific names of any drugs potentially looming to be in short supply. However, the fact that up to 80% of the world's API is currently manufactured in China, India, and Italy sets up the possibility that certain drugs may end up in short supply at some point over the next several months. We have provided links to the FDA's and American Society of Hospital Pharmacist's drug shortage tracking websites at the end of this article.

Drug hoarding is also a problem that could accelerate drugs becoming in short supply, not due to insufficient supply but due to increased demand. While many pharmacy benefit managers (PBMs) and carriers have relaxed their refill frequency rules to facilitate unencumbered access due to social distancing and other restrictive requirements, nobody is encouraging hoarding, which will only make limited supply scenarios even worse. Efforts to minimize hoarding and panic-buying through communication and awareness are critical to ensure viability of the entire drug supply.

You may hear specific news related to chloroquine and hydroxychloroquine shortages. These drugs have historically been used to treat conditions such as malaria, lupus and rheumatoid arthritis. However, small studies in other countries have indicated these drugs may be beneficial in treating patients with COVID-19. Based on that information, the FDA has issued emergency use orders to allow hospitalized adult and adolescent patients to receive these medications through a national drug supply donated free of charge from manufacturers. This helps prevent shortages in the commercial supply while full-blown clinical trials are underway to fully assess the drugs' safety and efficacy in treating COVID-19.

Some patients are obtaining these drugs in an outpatient setting from their physicians despite the absence of FDA approval for use in treating COVID-19 in the ambulatory setting. The majority of PBMs have instituted quantity limits on these medications to ensure current patients can continue to access these drugs. Some state boards of pharmacy are also requiring the diagnosis to be specified on prescriptions being written for patients new to these therapies. Unfortunately, despite these efforts, both chloroquine and hydroxychloroquine are currently listed as being in shortage by both of the tracking resources linked at the bottom of this article. The FDA is closely monitoring supplies of these drugs in the face of increased demand.

What should I do if I find that the drugs I take are unavailable due to a shortage?

The best answer to that question is to reach out to your physician and ask what suitable substitutes may be appropriate for you in your unique clinical circumstances. Also, don't wait until you are almost out of your prescription(s) before attempting to get a refill. If you normally submit refills a week before running out, consider expanding that window to two weeks to allow time for making any changes that might be required.

Finally, while it is impossible to predict how, or even if, any future drug shortages may impact various contractual performance guarantees with PBMs/carriers (such as generic dispensing rates, rebates, etc.), rest assured Excelsior is vigorously advocating on behalf of clients during this time of unprecedented challenge.

Drug shortage tracking resources:

FDA: https://www.accessdata.fda.gov/scripts/drugshortages/default.cfm

American Society of Hospital Pharmacists: https://www.ashp.org/Drug-Shortages/Current-Shortages

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