



# COVID-19: Impact on Global Pharmaceutical and Medical Product Supply Chain Constrains U.S. Production

Pharmaceutical and medical product supply chains are struggling on a global scale to keep pace with the rapid spread of the COVID-19 virus. Below is a snapshot of the impact of the global medical supply chain on U.S. medical supply production, a summary of the actions taken by the Chinese government and the U.S. FDA to address this crisis, and the “new norm” that may materialize in the coming months.

## Pharmaceutical Impact

The disruptive effects of the coronavirus COVID-19 have placed enormous strain on the global supply of medical products, increasing the risk of shortages. Although production across various industries and regions in China has been gradually resuming since late February, U.S. pharmaceutical and medical device manufacturers, which heavily source directly and indirectly from China, are now exposed to high risks in supply shortages over the next one to two months. These risks are due primarily to limited operational capacity in China and how resumption of production will be prioritized.

In the United States, approximately [72 percent of active pharmaceutical ingredients \(APIs\)](#) that supply the domestic market are foreign-sourced. Production in China (which [manufactures 13 percent](#) of U.S. medical products), for instance, has been significantly curtailed as the country strives to contain the outbreak.

India (the [source of 18 percent](#) of U.S. pharmaceutical imports) is also constrained. Furthermore, the country has restricted the exportation of 26 pharmaceutical ingredients and the medicines manufactured from them, which add up to 10 percent of its total pharmaceutical exports. (Currently, there is only one drug shortage that has been attributed to the outbreak. While the FDA will not name the drug, it states that alternative medications are available.) Most recently India has banned the export of the established malaria drug hydroxychloroquine, which is being tested in the United States as a potential promising treatment for COVID-19.

These two countries also lead in the exportation of generic drugs, which account for about 90% of the medicines taken by Americans. India supplies about 40% of over-the-counter and generic prescription drugs to the United States and depends, in turn, on China for about 80% of APIs and chemical intermediates essential for production. China also

ranks first among countries that export medical devices to the United States by import line, making the supply of medical products in the U.S. vulnerable when suppliers' production in China is disrupted unexpectedly.

Typically, manufacturers in China operate at lower capacity in the beginning of every calendar year, as manufacturing facilities are usually shut down for about one week in celebration of Chinese New Year. To control the spread of COVID-19 that sickened tens of thousands of people, China's State Council announced on January 27, 2020, that the Spring Festival holiday would be extended to February 2 across the country. Most local governments posted additional requirements that non-essential enterprises were not allowed to re-open earlier than February 9, 2020.

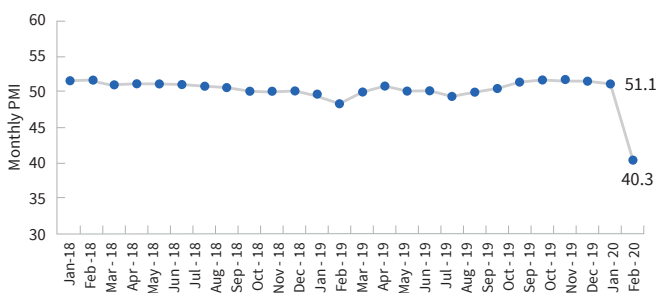
Since late February, when positive signs started emerging in its efforts to fight against the COVID-19 outbreak, China has been gradually resuming manufacturing activities with

an approach that prioritizes regions based on their health risks and industries based on their perceived level of importance.

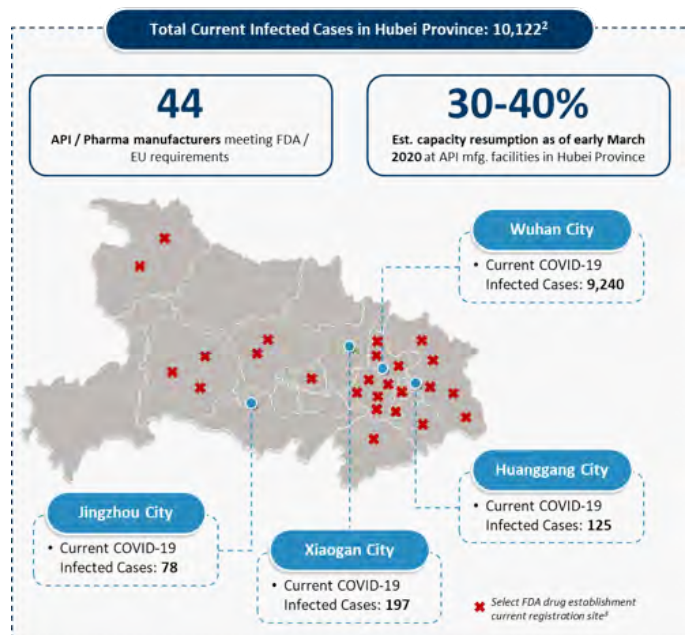
**58.98%**  
**Average capacity utilization at Top 500 manufacturing enterprises in China** surveyed between February 18 and 20, 2020<sup>1</sup>

<sup>1</sup> Primarily due to the COVID-19 outbreak and extended Spring Festival holiday, the Caixin China General Manufacturing PMI plunged to 40.3 in February, the lowest level since the survey began in April 2004

**Monthly General Manufacturing Purchasing Managers Index (PMI)**



Local authorities are ordered to take region-specific approaches reflecting local health risks when advancing the resumption of work and production. Non-essential enterprises are required to go through administrative processes to first obtain re-opening permits. Additionally, enterprises are facing labor shortages as their returning migrant workers are subject to a two-week quarantine, making it challenging to resume operations at full capacity in a short period. Enterprises that produce antiviral drugs or APIs have been reallocating their capacities based on market needs and supply to the Chinese market.



<sup>2</sup> In Hubei province, where COVID-19 emerged, there are 44 companies that are FDA-approved and/or meet EU standards and manufacture APIs or supply chemical ingredients to API manufacturers. Most of these companies have been shut down since January 24, 2020. As of March 19, 2020, there are still over 10,000 confirmed COVID-19 cases in Hubei province. API manufacturers resuming their production are estimated to be operating at 30%-40% of capacity, and products still need to go through inspection and quarantine processes before they are transported to customers.

It will take some time before manufacturers in China can resume their full operational capacity. To prevent and mitigate potential supply shortages, U.S. pharmaceutical and medical device manufacturers need to evaluate and plan for sourcing alternatives.

### Clinical Trial Impact

Clinical trials are also being affected. Approximately 20 percent of studies are conducted in China. According to the U.S. clinical trials database *ClinicalTrials.gov*, close to 500 trials are conducted at sites in the city of Wuhan — the very location where the virus originated.

Beyond site issues, other delays in current and planned trials are likely to occur as the pandemic spreads. Stoppages resulting from reduced patient enrollment, patients dropping out of trials, or non-compliance with study protocols are expected. The FDA may work with companies to address these issues in order to support the availability of new medical products.



The short- and long-term effects of COVID-19 on supply chains, clinical trials, and the overall business of pharmaceutical and medical device companies are still materializing. Government bodies are moving quickly to blunt the impact on public health.

### The FDA in Action

The U.S. Food & Drug Administration has long been the protector of public health, with significant responsibilities concerning the development and production of medicines and medical products.

The FDA has taken unprecedented action in these challenging times. The agency has issued three Emergency Use Authorizations (EUAs) to expedite the review and authorization of diagnostic testing kits and make them available for cases involving COVID-19. As of this article, 30 labs have notified the FDA that they intend to develop COVID-19 tests under the EUA mandate.

Other significant FDA actions include:

- Exercising enforcement discretion to allow other laboratories to develop COVID-19 tests.
- Working closely with manufacturers to expedite the initiation of clinical trials of COVID-19 vaccines as well

as subsequent review and approval. FDA Commissioner Dr. Stephen Hahn has stated that he expects a COVID-19 vaccine would be available for approval in approximately 12 months.

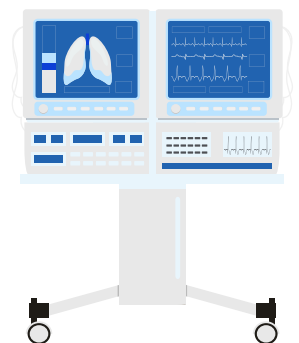
- Evaluating approved, currently available drugs, such as chloroquine (approved for malaria) and Actemra (approved for rheumatoid arthritis), to treat COVID-19.
- Actively reaching out to pharmaceutical manufacturers to identify potential drug shortages. (Manufacturers of critical drugs are required to report potential or actual drug shortages to the FDA; other reporting is voluntary.)
- Continue working with manufacturers in the coming months to mitigate supply chain risks and avoid shortages of medical device protective gear (masks, gowns, gloves, etc.).

The FDA has also been working through the disruption of inspections of drug and medical supply firms in China that followed the U.S. State Department’s travel advisory for that country. Roughly 100 scheduled inspections in February and March have been placed on hold. Consequently, FDA has stated that it will use, where appropriate, the agency’s authority to request records from firms “in advance or in lieu of” drug surveillance inspections in China. The FDA will also likely implement alternatives to on-site inspections internationally, enabling the agency to prioritize and concentrate resources, and travel only as needed.

We note also that the FDA continues to monitor marketing materials to protect the public from false and misleading information. To date, the agency has issued eight Warning Letters to companies promoting their products as treatment for or prevention of COVID-19.

### A “New Norm”?

The federal government has recently taken bold steps to address the pandemic and supply shortages. Most recently, President Trump stated that he would invoke the Defense Production Act (DPA), which empowers the government to direct factories to produce



more products crucial to national security. In this case, that would include medical products such as protective gear, ventilators, and perhaps even drugs. The global shortage of ventilators has become a growing concern as the number of reported infections increases across the United States and the world.

Automotive companies Ford and General Motors have had discussions with the U.S. government regarding the feasibility of manufacturing medical equipment, including ventilators. Tesla has been in discussions with Medtronic regarding assembling ventilators. The UK government is also addressing this shortage by enlisting Rolls-Royce and Dyson. Ford announced that it is partnering with GE Healthcare to produce ventilators for the United States, and with McLaren Automotive and Airbus in the United Kingdom. General Motors is working with Ventec Life Systems to significantly scale up their production, leveraging GM's supply chain to source the parts necessary to build ventilators. GM is also evaluating whether it can manufacture the ventilators at any of its U.S.-based facilities.

The quality standards and complexities of the regulatory and compliance frameworks for medical devices are different than automotive. These challenges are not insurmountable, but they require time and collaboration with regulatory agencies to address.

To mitigate the heavy reliance on China for medicines, several bipartisan Congressional bills, including the “Pharmaceutical Independent Long-Term Readiness Reform Act,” are awaiting further action.

Other ideas include creating incentives to move drug manufacturing to Puerto Rico and Mexico, which is a complex process. Challenges include sustaining product availability, starting up and qualifying manufacturing lines, and the qualification and certification of new facilities. There are also numerous regulatory requirements that must be satisfied to ensure product quality.

In the coming weeks and months, life sciences companies will take the lessons learned from this crisis, as the industry has with other events in the past, and work to improve their agility and resiliency. The impact on clinical trials and the drug approval pipeline will also come into focus and underscores the need for the same energy, collaboration and commitment by industry and governments to minimize disruption and provide patients with new medicines and treatments.



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