

## COVID-19 is Changing How Pharma Operates and Responds to Challenges

(Sources: An article by the Scrip Team for Scrip Intelligence and an article by Josep Borrell for Project Syndicate)

In times of crisis, it is human nature to look inward. While understandable, this reaction can be self-defeating. Going it alone all but guarantees that the fight will last longer and the toll on populations and economies will be much higher. It is a “war” that will be won through cross border coordination. Beyond international coordination between governments, cooperation among scientists, economists, and policymakers also needs to be scaled up. There is an urgent need for global leadership to work together.

There are four major priorities for global cooperation. First, resources should be pooled to produce new treatments and a vaccine, which should be regarded as a global public good. Second, work to limit the economic damage by coordinating fiscal and monetary-stimulus measures and protecting the global trade in goods. Third, plan to re-open borders in a coordinated way whenever health authorities give the green light. Lastly, institute means of cooperation to fight disinformation campaigns. The outcome of the G20’s recent virtual summit points to these priorities. To that end, global and multilateral initiatives will need to be sustained and fully implemented in the days and weeks ahead.

As countries mobilize resources against a common enemy, it has already become clear that the COVID-19 pandemic is reshaping the world. These changes will be determined by the choices made given the challenging climate. Drug and personal protective equipment shortages are front and center, particularly ventilators which are in short supply. Healthcare services company Vizient (which services more than half of US hospitals and health systems) reviewed its member purchase data and orders from 1-24 March and compared that to a baseline period of 2-25 January. In several key areas, the data show demand has clearly been outstripping supply.

The COVID-19 pandemic has also meant a 51% increase in demand for sedatives and anesthetics in March – including *dexmedetomidine*, *etomidate*, *ketamine*, *lorazepam*, *midazolam* and *propofol* – while the fill rate dropped to 63%. Analgesic purchases – including *hydromorphone*, *fentanyl* and *morphine* – were up 67% with a 73% fill rate, and there was a 39% increase in demand for neuromuscular blockers – including *cisatracurium*, *rocuronium*, *succinylcholine chloride* and *vecuronium* – with a 70% fill rate.

Further compounding the challenge of these shortages are restrictions on active ingredients for widely used medications as well as a 21-day manufacturing lockdown that has been imposed in India to stem the spread of COVID-19. Both industry and the Indian government are actively engaged and working together to ensure that worldwide disruption to the pharma supply are kept to a minimum.

Additionally, in response to drug shortages, the pharmaceutical industry is calling upon the US Food and Drug Administration to approve new lines of manufacturing for these critical drugs and

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## In Brief...

- ◆ **Walgreens Boots Alliance** reported overall sales for its second quarter 2020 of US\$35.8 billion, up 3.7% year over year. WBA’s pharmaceutical wholesale division reported sales of US\$6.1 billion for the quarter, up 5.7% year-over-year, including an adverse currency impact of 2.3%. The company stated that it would be closely assessing and managing their forecasts, taking into consideration the current COVID-19 global pandemic.

- ◆ **McKesson, Cardinal Health, Henry Schein and Medline** are collaborating as part of an emergency COVID-19 relief effort led by the **U.S. Federal Emergency Management Agency (FEMA)** and **HHS**. The four companies will work with other medical supply distributors and logistics firms on *Project Airbridge*, a joint effort to rapidly manufacture, source and distribute personal protective equipment and COVID-19 treatments. The initiative is meant to improve access to gloves, masks and gowns, which are in short supply due to the pandemic. After an expedited review process meant to ensure the collaboration is within the bounds of antitrust law, the U.S. Department of Justice announced on April 4 it will not challenge the joint effort.

- ◆ U.S. pharma manufacturer **Mylan** announced that it will voluntarily waive its exclusive rights in the U.S. to distribute its generic version of *Kaletra* in 100mg/25mg and 200mg/50mg tablets to help increase the available supply of the product should it prove to be effective in the treatment of coronavirus.

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## Finding a Solution to Drug Shortages

(Source: An article by Shabbir Dahod for STAT)

Every quarter since 2014, roughly 150 to 300 drugs have been in short supply in the U.S. The drug shortages list has included injectable painkillers, anesthetics, antibiotics, cancer drugs, medications for mental illness, and much more.

Drug shortages can have profound adverse consequences not only in the U.S., but on a global scale: economic, clinical and, humanistic. For specialty drug manufacturers these shortages have a direct impact on patients’ well-being and health outcomes.

The U.S. FDA proposed a handful of solutions to get the industry on the right track, including:

- Offering education to supply-chain stakeholders and legislation around the impact of drug shortages on patients and the factors contributing to them.
- Developing a rating system for product quality to incentivize drug manufacturers to focus on quality management for their facilities.
- Creating sustainable private-sector contracts to ensure a reliable supply of medically important drugs.

While these are all solid foundational solutions to a much larger problem, better supply-and-demand forecasting among all parties along the pharmaceutical supply chain is an important

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provide accessibility for compounders to produce any essential medications.

There is also an effort to stem shortages in healthcare workers. Several leading US-based big pharma companies have announced a medical service volunteer program “to enable employees who are licensed medical professionals to aid in the fight against COVID-19 while maintaining their base pay.” An announcement on 1 April from Pfizer Inc., Merck & Co. Inc. and Eli Lilly & Co. states that “together, these three major biopharmaceutical companies employ thousands of doctors, nurses, pharmacists, medical laboratory technicians and other medical professionals whose services are in high demand during the COVID-19 pandemic.” All three companies are allowing licensed medical professionals to volunteer, while Lilly is also using its medical professional employees to open a free drive-through COVID-19 testing facility at its Indianapolis headquarters. “The testing facility serves active front-line health care workers and first responders,” the firm noted. “Lilly scientists are using the company’s specialized research laboratories to analyze the tests, as well as samples taken in Indiana health care facilities, including nursing homes and emergency rooms, in partnership with the Indiana State Department of Health.”

The COVID-19 pandemic is even prompting major pharmaceutical companies to hold their annual shareholder meetings online only, in virtual formats. The latest to announce that approach include Baxter International Inc., Sanofi and Johnson & Johnson. Baxter and J&J shareholders have been told that although they will not be able to attend the meetings in person, voting on resolutions and the submission of questions will be possible online during the AGM by eligible stakeholders. Sanofi has told its shareholders it would not be possible for them to ask questions nor to submit draft amendments or new resolutions during their virtual AGM and that they are instead invited to exercise their right to vote prior to the general meeting through the provided internet platform.

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first step for easing the negative outcomes associated with drug shortages.

Pharmaceutical companies have traditionally predicted the demand for drugs based on multiple sources of data, including previous information related to sales data, supplier input, and historic transaction volumes. There is often a lag time for collecting this information, leading to outdated and inaccurate forecasts into medicine availability and whereabouts in the supply chain.

To more accurately forecast demand, companies must gain greater visibility into where their drugs are in the supply chain — all the way down to the patient. Instead of predicting units of medication sold during a quarter and comparing that forecast against actual sales during the period, what if pharmaceutical companies could gain real-time knowledge of drug consumption at hospitals, pharmacies, and clinics?

That type of end-to-end visibility would be a boon for companies and patients, but it would require more collaboration throughout the entire supply chain and a means of sharing information without compromising privacy or confidentiality.

These more precise supply-and-demand forecasts could save pharmaceutical companies hundreds of millions of dollars a year

by not having excess drugs on hand and avoiding costs related to expedited shipments.

Due in part to track-and-trace requirements resulting from the Drug Supply Chain Security Act (DSCSA), more data about drugs in the pharmaceutical supply chain now exists than ever before. But even with the data generated from DSCSA’s serialization requirements, the life-science supply chain is still several steps away from gaining true end-to-end visibility into product movement — and fighting drug shortages.

To accomplish this, drug manufacturers need to leverage advanced technologies, like artificial intelligence, to share data signals with upstream suppliers of raw pharmaceutical materials and downstream partners like distributors and health care systems. That would allow supply chain leaders to proactively make fast, real-time decisions on inventory and medicine availability.

Identifying the root causes of drug shortages and devising workable solutions for them will require a multi-stakeholder effort with more accountability and greater agility than seen in the past. To improve patients’ access to essential drugs, all entities in the pharmaceutical supply chain must work toward increased collaboration, data sharing, and transparency.

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This will allow other generic applicants to be eligible for U.S. Food and Drug Administration approval of their medicines for patients in the U.S.

- ◆ The **World Health Organization** said there are signs of some stabilization in Europe’s coronavirus outbreak as the hardest-hit country in the region, Italy, reported the smallest number of new cases in almost two weeks. *Mike Ryan*, head of health emergencies at the WHO, said Monday that’s “our fervent hope” Italy and Spain are approaching a peak, and that European lockdowns which started several weeks ago will start to bear fruit. New cases now reflect exposure to the disease about two weeks earlier, he said.

- ◆ On March 30, 2020, **The Japan Pharmaceutical Manufacturers Association (JPMA)** and the **Federation of Pharmaceutical Manufacturers’ Associations of Japan (FPMAJ)** were leaning on the government to prepare an emergency package totaling roughly 100 billion yen (US\$919.8 million) to help the industry develop treatments and vaccines against the novel coronavirus and secure APIs for antibiotics. The request has been submitted to the **Ministry of Health, Labor and Welfare (MHLW)**.

- ◆ **Aurobindo** and **Novartis AG** have terminated their 2018 deal under which Aurobindo would take over Sandoz’s U.S. generic oral solids and dermatology businesses. The decision was made in light of the fact **U.S. Federal Trade Commission** clearance for the transaction was not anticipated to happen under established timelines.

- ◆ **Johnson & Johnson**, one of the leading companies developing a vaccine for COVID-19, has estimated that it will likely cost as little as “ten dollars or ten euros a dose”. Availability of the vaccine for millions of patients is anticipated in late 2021. J&J is collaborating with the U.S. government agency **BARDA (Biomedical Advanced Research and Development Agency)**.

(Sources: *ACS Reveiw, Drug Store News, Pharma Japan, and Scrip Pharma Intelligence*)