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LOGISTICS REPORT

Drugmakers Race to Build Covid-19 Vaccine Supply Chains

Supply shortages, specialized handling and tight transportation capacity will make it harder to distribute hundreds of millions of vaccine doses

By Elaine Chen

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Pharmaceutical companies that are racing to develop vaccines for the coronavirus are already working behind the scenes to build the supply chains needed to deliver their drugs to billions of people as rapidly as possible.

To serve global demand once a vaccine is approved, a complicated and high-stakes supply chain would kick into gear on a scale that the drug industry has rarely seen. The preparations involve lining up raw materials and factory capacity to manufacture a vaccine in large volumes, and the equipment needed to transport many millions of doses at once through distribution channels that will be subject to tight security and temperature controls.

The magnitude and speed of the effort creates the potential for lapses at each step that could cost invaluable doses.

Vaccines likely would be sent to hospitals, pharmacies, and central vaccination points, in the same way that medical teams have set up in parking lots, schools and other sites to provide testing for the virus that has, by Johns Hopkins University's latest count, infected over 16 million people world-wide and killed over 661,000.

“We’ve never had to do something at this scale before,” said Remo Colarusso, vice president of supply chain at Janssen Pharmaceutical Companies, a company owned by Johnson & Johnson that says it is on the verge of clinical trials for a potential vaccine.

U.S. government is getting involved, allocating \$10 billion for Operation Warp Speed, an initiative that aims to speed up vaccine development with the objective of distributing 300 million doses of coronavirus vaccine by January 2021. By comparison, drugmakers supplied 174.5 million doses of the flu vaccine between last September and February in the U.S., according to the Centers for Disease Control and Prevention.

Lawmakers are considering plans to bolster the vaccine effort with an additional \$25 billion. “Once a vaccine has been successfully developed, how do you get all the production you need, and how do you get it out? That is a role we obviously will be playing a part in,” Senate Majority Leader Mitch McConnell (R., Ky.) said in July ahead of negotiations in Congress for the next round of coronavirus aid.

The planning comes as developers in several countries are reporting progress.

Three vaccine initiatives—University of Oxford researchers and AstraZeneca PLC; Pfizer Inc. and its German partner BioNTech SE; and China’s CanSino Biologics—all said last week their shots generated immune responses and appeared generally safe to use. Earlier this week, there were 25 potential vaccines in clinical evaluation and 139 in preclinical evaluation, according to the WHO.

Shoring up manufacturing, distribution channels

Some of the companies involved are building this supply chain for the first time.

Moderna Inc., the 10-year-old Cambridge, Mass.-based company earlier this week said it had started final-stage testing of a vaccine, had never sold a product on the market. Neither has Novavax Inc., a Gaithersburg, Md.-based drug developer that was awarded the biggest federal grant for vaccine manufacturing to date.

“Just because Novavax has yet to bring a product to market, doesn’t mean that we don’t have a team of people that does have experience and ability to do that,” said John Trizzino, executive vice president, chief business officer and chief financial officer at Novavax, which hired a manufacturing chief in June. Moderna didn’t respond to requests for comment.

Experienced drugmakers say they are moving to shore up their existing processes for making and shipping pharmaceuticals.

“Just every day, [we are] trying to do things that we normally do in a year, do them in months. Things that normally take months, do them in days,” said Pamela Siwik, vice president of a division in global supply at Pfizer Inc., which is developing vaccine candidates with BioNTech.

Pharmaceutical companies at the start will need to produce enough of what is known as the drug substance, the primary vaccine ingredient.



Inside a research lab of Johnson & Johnson subsidiary Janssen Pharmaceutical in Beerse, Belgium.

PHOTO: VIRGINIA MAYO/ASSOCIATED PRESS

J&J is developing a vaccine that uses an inactivated cold virus to deliver a part of the drug. To manufacture it, the company plans to use the same type of bioreactor that it used for making an Ebola vaccine, which this month won critical regulatory approval in Europe, but at 90 times the scale, Mr. Colarusso said.

Other companies, including Moderna and Pfizer, are developing a novel type of vaccine that delivers mRNA, a type of genetic material. Making this drug substance in bulk would require smaller equipment than other methods, Ms. Siwik said. But formulating the drug substance requires a unique process, so Pfizer is designing new machinery with its vendors and modifying its plants to install equipment needed for the work, she added.

J&J has struck deals with U.S. contract drug manufacturers Emergent BioSolutions Inc. and Catalent Inc. and plans to expand manufacturing in Europe and Asia. The company

will make a drug at sites around the world simultaneously for the first time, Mr. Colarusso said.

Once they have produced the final liquid vaccine, the pharmaceutical companies will need to fill vials with it, adding another hurdle to distribution.

The Expected Journey of Covid-19 Vaccine From Lab to Doctor's Office

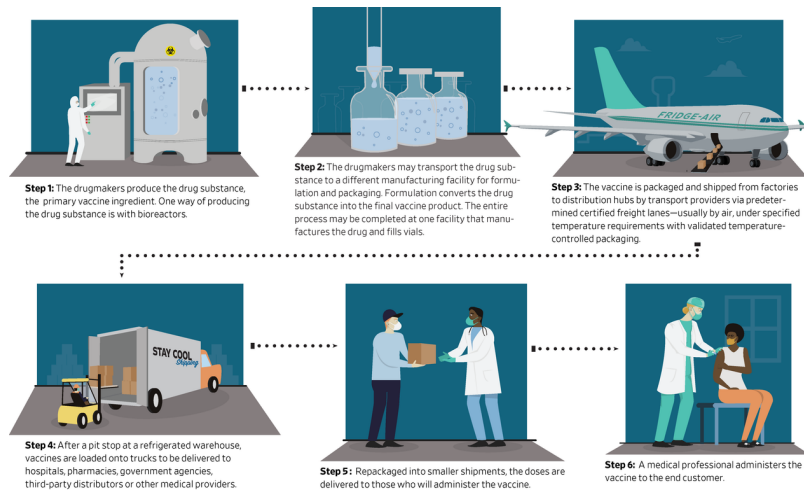


PHOTO: ILLUSTRATION BY THOMAS LECHLEITER/THE WALL STREET JOURNAL

Medical glass has been in short supply since before the pandemic, when China began to require containers for long-term storage of pharmaceutical products, and that shortage has worsened. In June, the U.S. awarded glass products manufacturer Corning Inc. \$204 million to expand manufacturing capacity and produce vials for coronavirus vaccines.

J&J alone has bought 250 million vials, WSJ has reported previously. Pfizer went to its suppliers early to secure the containers, Ms. Siwik said.

After drugmakers fill the vials, they will turn to logistics providers experienced in handling pharmaceuticals to ship them to distributors or directly to medical providers.

Shipping capacity in question

Logistics operators could be another speed bump. They have struggled at times during the pandemic amid upheaval in demand—particularly for consumer products and medical gear—that has left companies scrambling to find warehousing and transportation space. Airfreight capacity, which will be crucial for moving a vaccine in the early days of distribution, has been hit particularly hard because thousands of passenger flights—which carry goods as well—have been grounded since the pandemic began.



A vial with a potential Covid-19 vaccine at Novavax laboratory in Rockville, Md.

PHOTO: AGENCE FRANCE-PRESSE/GETTY IMAGE

“The logistics industry doesn’t have enough of anything—air capacity, ground handling personnel, specialized equipment—to handle this,” said Neel Jones Shah, executive vice president and global head of airfreight at Flexport, a freight-forwarding company.

“No one company can own the end-to-end vaccine supply chain. Collaboration will be critical,” Mr. Shah said.

Throughout transportation, pharmaceutical companies and logistics providers will need to ensure doses are kept in a very tight temperature range to prevent the vaccine from becoming ineffective. That requires the use of specialized refrigerated containers and handling procedures at all times.

The drugmakers also need contingency plans in place in case all the preparations fall through.

“There’s storms, the plane doesn’t get off the ground, the truck gets involved in an accident,” said Mark Capofari, a supply-chain management lecturer at Penn State Lehigh Valley. “What plans do we have in place to get that product to put it back into cold storage?”

Drug makers will even need to be on guard against criminal groups that target high-value pharmaceutical goods, said William McLaury, an associate professor of supply-chain management at Rutgers Business School.

Finally, companies will have to be ready to adjust any part of the manufacturing and distribution process as scientists track responses to a vaccine—a process that will be as

closely watched as the development of the drug itself, Mr. McLaury said.

“The supply chain is going to have to be on its toes,” he said.

Write to Elaine Chen at Elaine.Chen@wsj.com

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