NCSL COVID-19 WEBINAR SERIES

COVID-19 THERAPIES AND VACCINES

APRIL 17, 2020
The National Conference of State Legislatures is the country’s most trusted bipartisan organization serving legislators and staff. We promote policy innovation, create opportunities for lawmakers to share knowledge and ensure state legislatures have a strong, cohesive voice in the federal system. We do this because we believe in the importance of the legislative institution and know when states are strong, our nation is strong.
COVID-19 WEBPAGE

Information on state policies and responses related to continuity of government, education, fiscal, elections, criminal justice and more.

Go to www.ncsl.org
▪ FDA update on development of COVID-19 therapies and vaccines
▪ Pharmaceutical industry response
▪ Generics and biosimilars industry response
- Coronavirus Treatment Acceleration Program (CTAP): working on therapies as well as clinical trial conduct, drug shortages, hand sanitizers, fraudulent activity, drug imports and stakeholder engagement, among others

- With CTAP, triaged requests from developers and scientists that are working develop or evaluate new therapies

- This includes ultra-rapid interactive input, prioritizing products on their scientific merits

- CTAP support includes redeployed medical and regulatory staff, redeployed medical, operations and policy staff, all helping to streamline processes for developers and scientists as well as health care providers and researchers
FDA has been working with companies to identify potential new treatments with 284 clinical trials underway, along with 10 therapeutic agents in active trials and another 15 in planning stages.

For vaccine development, the FDA has been able to help accelerate development timelines to enter into clinical trials in humans as quickly as possible.

Last month, the FDA and European Medicines Agency jointly chaired the first global regulators meeting to discuss strategies to facilitate the development of a SARS-CoV-2 vaccines.
Resources:


FDA UPDATE ON THERAPIES, VACCINES AND OTHER RELEVANT ACTIONS

Anand Shah
Deputy Commissioner for Medical and Scientific Affairs
Office of the Commissioner
U.S. Food and Drug Administration
NCSL Briefing:
Biopharmaceutical Industry Efforts to Combat COVID-19

April 17, 2020
How Industry is Working to Combat COVID-19

Developing Treatments and Vaccines

Partnerships

Monetary & In-Kind Support

Supply Chain Integrity
Armed with experience garnered from previous outbreaks and a vast storehouse of knowledge about infectious diseases like influenza, malaria and HIV, researchers are working to develop and deliver diagnostics, treatments and vaccines to save lives and restore the rhythms of daily life for billions of people.
As of April 8, 2020, of the more than 300 global clinical trials for COVID-19 treatments and vaccines, more than 40 of these trials are taking place in the United States.
Timeline for a COVID-19 Vaccine

- It will take a minimum of 18-24 months for potential FDA approval of a COVID-19 vaccine – this is significantly less time than it took previously without compromising safety
  - In 2003, it took 20 months from sequencing SARS to the first human study of a vaccine
  - Today, less than 4 months from sequencing COVID-19 to the first human study of a vaccine

- Some approaches offer speed – knowing the virus’s genetic sequence, companies can synthesize and scale up production of a RNA vaccine in a matter of weeks

- Some approaches can boost the impact of a potential vaccine – adjuvants can boost the immune response and minimize amount of vaccine needed

- There is a high failure rate – Only 5-10% will succeed, meaning we need lots of shots on goal
### Ensuring Continuity in the Drug Supply Chain

<table>
<thead>
<tr>
<th>Companies</th>
<th>FDA</th>
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<tr>
<td>• Companies report substantial data on potential shortages to FDA and they work closely with the agency to prevent and mitigate shortages</td>
<td>• FDA is working with individual companies to facilitate ramping up manufacturing to address surges in demand and expediting approvals of changes in the drug supply chain</td>
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<td>• Companies have robust inventory management systems that include:</td>
<td>• FDA is working closely with companies to expedite development and availability of COVID-19 treatments and vaccines, including helping companies to leverage scientific and clinical trial data from the United States and other countries</td>
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<tr>
<td>- Data on anticipated demand reflecting historical demand and supply data</td>
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<td>- Risk management plans that address additional or alternate manufacturing sites, inventory reserves, and/or a range of global external suppliers</td>
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<td>- Logistics planning to ensure continuity in shipping of supplies</td>
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Resources for You and Your Communities
What is MAT?

950+
Public and private programs

The Medicine Assistance Tool (MAT) is a web platform designed to help patients, caregivers and health care providers learn more about some of the resources available to assist in accessing and affording medicines.
How can MAT help patients learn more about their medicine costs?

PhRMA member companies are committed to helping patients make more informed health care decisions by providing more transparency about medicine costs. Through MAT.org, we share links to member company websites that include:

- List price of a medicine
- Average estimated or typical patient out-of-pocket costs
- Other context about potential cost of the medicine

*Each member company has individually and independently determined the content of any cost information provided on their websites.*
PhRMA has joined forces with Healthcare Ready to facilitate the financial support and in-kind donations of personal protective equipment, medicines, and critical medical supplies.

Examples of requests Healthcare Ready can support include:

• Personal protective equipment
• Medical supplies
• Assistance in helping a constituent fill their prescription

These requests can be made by contacting alerts@healthcareready.org.
Healthcare Ready programs for constituents

Healthcare Ready Resources

RX OPEN: Provides access to open and closed pharmacies in a disaster-stricken area.

RX ON THE RUN: Personalized wallet card to document prescriptions and other important medical information.

COVID-19 Resource Hub: Resources for individuals and patients including state-level insurance emergency orders on prescription refills and telehealth coverage policies for COVID-19, and relevant pandemic business continuity resources.


#MYM #COVID-19
Resources and Information Available at PhRMA.org/Coronavirus

- Full list of member company efforts to combat COVID-19
- Factsheet on the pipeline for new vaccine and treatments
- Open letter from PhRMA CEO and Chairman
- Links to blog posts on *The Catalyst*
- Infographic on how the industry is fighting COVID-19
# PhRMA’s Team in Your States (East to West)

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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.

- **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.

• **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.

• 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.

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

- 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.

- 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-Administerated Medicine

Generic Drug Manufacturers
Represented by the Association for Accessible Medicines

Group Purchasing Organization (GPO)
Represented by the Healthcare Supply Chain Association

Distributors/Wholesalers
Represented by the Healthcare Distributors Alliance

Hospitals
Represented by the American Hospital Association, Federation of American Hospitals and other trade associations

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

GPOs contract for medicines directly from manufacturers to help healthcare 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.

Finished medicines are purchased under contract 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.

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.
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

@accessiblemeds
Questions and Answers

Please type your questions into the chat box in the lower left-hand corner of your screen.
COVID-19 WEBPAGE

Go to:

www.ncsl.org or