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LESSONS LEARNED:

THE BIOPHARMACEUTICAL INDUSTRY'S RESPONSE TO COVID-19

Since the start of the pandemic, America's biopharmaceutical companies have worked around the clock to research, develop and manufacture treatments and vaccines to fight COVID-19. We've made unprecedented progress: three vaccines are currently available for protection against COVID-19 in the U.S., and manufacturers have delivered over 12 billion vaccines globally[i] with another 20 billion expected in 2022.[ii] During the pandemic, the U.S. Food and Drug Administration (FDA) provided emergency authorization for 13 products that target COVID-19 and its effects. These products include three vaccines and 10 drugs and non-vaccine biological treatments.

For more than two years, biopharmaceutical companies have been taking constant action to fight COVID-19. Here are some key lessons learned.

PARTNERSHIPS: A vital impact in responding to COVID-19

Given the magnitude of the threat posed by COVID-19, America's biopharmaceutical companies collaborated with hundreds of key health stakeholders at state, national and international levels. Together, we joined forces on everything from building production capacity to partnering with community organizations to address health disparities exacerbated by the pandemic. The result was multiple diagnostics, treatments and vaccines and an unprecedented ramping up of manufacturing to meet global demand. Enabled by intellectual property protections and voluntary licensing agreements, the industry has been able to boost capacity to keep pace with global demand, so vaccines and treatments make it to those in need as quickly as possible.

Even before the FDA authorized a COVID-19 vaccine, biopharmaceutical companies were scaling up manufacturing capacity, a decision that usually happens later in the drug development process. Understanding the need for continued manufacturing efficiency to produce vaccines, companies continue to identify and partner with other manufacturers with the appropriate expertise, technical capabilities and facilities to maximize the capacity across the health care ecosystem.[iii] These collaborations and agreements are created with specific considerations in mind and are highly technical, like mRNA-technologies, and are often focused on a single step or stage of the overall manufacturing process.

Lessons Learned

Public-private partnership and collaboration can be applied to areas beyond the COVID-19 pandemic to ensure a strong supply chain, create efficient manufacturing processes and limit production bottlenecks, all with the ultimate goal of ensuring patients have access to the lifechanging medicines they need when they need it.

CLINICAL TRIALS AND DIGITAL HEALTH: Making the future accessible

The pandemic posed many restrictions on in-person appointments, which prompted clinical trials to optimize telemedicine and remote monitoring technologies. It was necessary that during the pandemic, many clinical trials adapted to some form of decentralization using a "hybrid" approach with both remote and in-person consultations where possible. These approaches enabled researchers to continue to monitor patient safety and collect data on the medicine's efficacy, ultimately supporting the continuation of many clinical trials. And although much focus over the past couple of years was duly on coronavirus treatments and vaccines, biopharmaceutical companies maintained a steady drumbeat in drug development in other therapeutic areas.

To help navigate clinical trial barriers during COVID-19, the FDA issued timely and robust guidance for industry, investigators and institutional review boards regarding the conduct of clinical trials during the pandemic, which was revised as new information became available. Biopharmaceutical companies worked in unprecedented ways with patients, regulators and health care professionals regarding the conduct of clinical trials during the pandemic, resulting in lessons learned that can be implemented going forward.

Recent advances in information technology and data science have enhanced our ability to generate timely insights on the use, benefits and risks of medicines, including real world data (RWD). RWD, such as data collected from external data sources like registries, wearables, e-diaries and more, can help fill critical evidence gaps, leading to more efficient drug development programs and providing additional types of patient-centered information about the benefits and risks of new medicines. Real world evidence (RWE) provides information about the usage and potential benefits or risks of a drug or biologic that is generated by analyzing RWD. RWE can assess a broader range of outcomes in a wider range of patients, providing additional valuable information reflective of patients' perspectives and experiences.

While data-driven initiatives have proliferated throughout the regulatory lifecycle both within the United States and globally for many years, the COVID-19 pandemic has presented many opportunities for the biopharmaceutical industry to expedite initiatives and streamline processes in the digital and informatics space. The FDA has ongoing efforts to modernize and enhance its data and information technology (IT) infrastructure via the Technology Modernization Action Plan (TMAP) and the Data Modernization Action Plan (DMAP).

Based on member companies' experience during the COVID-19 pandemic, PhRMA has identified the following areas of FDA's technology infrastructure and processes that are critical to success in this new virtual environment:

- Shifting to a cloud-based submission architecture
- Supporting consistent virtual review and meeting capabilities, including a shift to all-digital submissions
- Facilitating more flexible, less formal, real-time communication methods between sponsors and the FDA
- Continuing to support rapid issuance of concise (e.g., bulleted) guidance on discrete topics

The initiatives included in the TMAP, such as master data management, will enable and support the fast sharing, with appropriate legal safeguards for confidential commercial information and trade secrets, of data between development partners and regulatory authorities.

Lessons Learned

These efforts have provided the foundation for potential long-term changes to the clinical trial process that could lead to a more streamlined and accessible approach to developing new medicines. There is now greater experience with and broader acceptance of telemedicine and digital health tools, making remote clinical trials possible. Further, the integration of cloud-based technologies as part of a comprehensive strategy for data modernization and regulatory processes is key to the FDA's ability to support a move to a more virtual environment. A properly designed cloud-based system will increase the scalability and performance of the submission and "ingestion" process, while allowing for streamlined analysis and review due to the co-location of all FDA data on hand and potentially reducing security risks.

It is critical to maintain momentum for the increased use of digital health technology tools in drug development. For instance, the Prescription Drug User Fee Act (PDUFA VII Goals Letter) includes proposals to advance the use of digital health technologies in decentralized clinical trials, as well as the use of RWD/RWE. The greater application of RWE in regulatory decision-making can ultimately lead to more timely access to innovative, safe and effective medicines for patients.

FUTURE PANDEMIC PREPAREDNESS: The importance of looking ahead

Based off our experience with COVID-19, PhRMA and 100 other organizations convened to develop recommendations to improve the nation's disaster preparedness and response.[iv] The recommendations include:

- Modernizing the health care supply chain through digitalization, automation and predictive analytics
- Improving supply chain resilience through targeted incentives
- Policy reforms to support rapid response including medical licensure portability, removing barriers to telehealth, and swift access to PPE and other protective equipment

PhRMA also supports efforts to ensure that we are ready for future wide-reaching health threats, such as a superbug caused by drug-resistant bacteria. Data shows the COVID-19 pandemic has been exacerbating antimicrobial resistance (AMR).[v] As more patients are hospitalized due to severe COVID-19 infections, often due to worsening respiratory symptoms requiring ventilation, an increasing number of patients have been acquiring secondary bacterial infections that require treatment with antibiotics — thereby worsening current levels of resistance.[vi] To address this crisis, our industry has proactively created the AMR Action Fund, which aims to bring two to four new antimicrobials to market by 2030, focusing on innovative medicines that address the highest priority public health needs. This industry-driven effort is key, along with the importance of driving comprehensive policy reforms like the PASTEUR ACT, which would incentivize companies to develop new antimicrobial medicines by awarding a partially delinked subscription contract to highly novel candidates.

Lessons Learned

PhRMA and our members are committed to bolstering pandemic preparedness and health care resiliency to make sure American patients are stronger, healthier and better prepared for the next public health emergency. This is integral to American national security, the health of the American public and future economic stability and growth.

Leveraging lessons learned to meet patient health needs now and in the future

As we continue to fight COVID-19, it is important to catalog which innovations have been deployed or expanded upon during the global pandemic and the operational, technological and regulatory considerations that pose unique challenges to biopharmaceutical companies. Additionally, it is important to evaluate the patient impact of these innovations to drive high quality, patient-centric clinical trials moving forward. Biopharmaceutical companies continue to work with stakeholders, including regulators, to assess the extent innovative approaches and durable learnings should be utilized routinely in medical product development in the future. The lessons we've learned over the past couple years will have positive implications lasting long beyond our fight with COVID-19.

Sources:

[i] UNICEF, COVID-19 Vaccine Market Dashboard.

[ii] Airfinity provided data on observed production through January 2022 and forecasted production capacity (as of February 16, 2022) through calendar year 2022 for all COVID-19 vaccines by assuming manufacturers continue to produce at, or scale up to, their announced capacities.

[iii] PhRMA, "Working Together to Fight COVID-19: Vaccine Manufacturing Collaborations," November 2021.

[iv] National Dialogue for Healthcare Innovation, "Framework for Private-Public Collaboration on Disaster Preparedness and Response," February 2021.

[v] German Medical Science, "Random effects meta-analysis of COVID-19/S. aureus partnership in co-infection," December 2020.

[vi] German Medical Science, "Random effects meta-analysis of COVID-19," November 2020.