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Building Resilience into Biotech Supply Chains

(Source: An article by Rachel Arthur for Outsourcing-Pharma.com based on the EY Report "Beyond Borders: EY Biotechnology Report 2022)

Biotech supply chains face an uncertain future from 2022 going forward, including a myriad of challenges ranging from future pandemic outbreaks to geopolitical tensions, as well as unforeseen threats. Communication and collaboration between policymakers and biotechs will be key to creating new resilient supply chain models, says a report from EY.

In the report, *"Beyond Borders: EY Biotechnology Report 2022"*, EY analysts note the pandemic has prompted greater government involvement in supply chains, and it expects this involvement to deepen in the future. Drug production – and the associated supply chains – could see a move away from the complex global networks to more localized ones.

What will this look like in the future? Future models are still evolving, and biotech companies and governments need to communicate to create the most resilient ones, say the analysts.

Increased Focus on Supply Chain Security. Despite great concern, the biotech industry largely met the challenges posed to the supply chain over the height of the pandemic, in contrast to other industries which experienced significant disruptions.

"While there were reported shortages of certain raw materials and consumables among biotechs (such as the sterile filters used in biological drug manufacturing), very few products have been unavailable during the crisis," notes the report. "In fact, within the U.S., issues have been reported for less than 1.5% of the more than 20,000 FDA-registered prescription drugs in 2020 and 2021."

However, the pandemic did increase the focus on the security of the supply chain, drawing more attention to the subject from policymakers.

"A year-long review of U.S. public health supply chains, published in February 2022, reaffirms the Biden administration's ongoing efforts to encourage domestic production and innovation, develop redundancies and ensure that diversification within the drug supply chains continue."

To effectively monitor its supply chains, the EU has imposed temporary vaccine export restrictions to secure supplies of vital medicines, assessed stockpiles and built regional capacity via its Health Emergency Preparedness and Response Authority (HERA).

From Local to Global and Back Again. The few decades have seen an increasingly globalized shift of biopharmaceutical supply chains. Driven by anxieties over the security of national drug supplies, a reversal may be underway – with increased localization of supply chains and greater emphasis on regional or national self-reliance.

"Other macro factors fueling this shift include the changing

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In Brief...

- **Cardinal Health** acquired **ScalaMed**, a HIPAA-compliant smart platform that transfers prescriptions to patients via a secure mobile app. ScalaMed pivots prescription management from provider to patient, allowing patients to send prescriptions written by their provider to any pharmacy for the first fill. The acquisition transfers ScalaMed's technology and assets to **Outcomes**, a Cardinal Health company.
- On July 25, 2022, **GSK** and consumer health unit **Haleon** will part ways. After the split, GSK aims to reach US$39 billion in revenue by 2031 and deliver annual sales growth of 5% in the next five years. The company is expected to accomplish this through M&A opportunities, according to a report by Reuters. It will also look at its *RSV* vaccine, which has been successful in its late stage testing, as well as its *Shingrix* vaccine.
- Japan's ethical drug sales climbed 6.2% in May over the same month in the prior year on a wholesaler shipment basis, according to a report by **Crecon Research & Consulting**. The growth was driven by a higher number of business days as well as a rebound in doctor visits and growth of COVID-19 drugs and specialty products.
- India has approved its first mRNA vaccine with **Gennova Biopharmapharmaceuticals Ltd's** *Gemcovac-19*, setting up competition with **Pfizer/BioNTech** and **Moderna**, and opening possible development of other drugs using mRNA technology. Clinical trials of an Omicron-target version of the *Gemcovac-19* are likely and Gennova will push for use of this iteration as a booster in India. Pediatric trials will also be conducted.

(Sources: Drug Store News, Pharma Japan, Press Releases & Scrip)

Generics Companies See a Bright Future in Biosimilars, Despite Challenges

(Source: An article by Nora Caley for Drug Store News)

Generic Drugs are more than just a cost-effective answer to expensive branded prescription drugs; they also give us insight into certain issues and challenges facing pharmaceutical companies. There is no question that the category of generics is complex and filled with barriers to success, it is also benefiting from exciting innovations, notably in the world of biosimilars.

One of the most notable trends today relates to pricing. While other categories are seeing price hikes due to inflationary pressures, generics are experiencing deflation due to several factors, including the influx of newly approved medicines, resulting in increased competition in an already crowded market.

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Building Resilience (cont.)...

globalization model wherein global trade agreements are declining in relevance in favor of increased regionalized trade and bilateral agreements. The pandemic may have accelerated this trend, but as the armed attack in Eastern Europe in 2022 emphasizes, COVID-19 will not be the last major crisis of the 21st century."

From Initiatives to Mandates: Potential Government Involvement. Biotech companies are already taking certain measures to build resilience into their supply chains: such as implementing multi-sourcing, leveraged local contract development and manufacturing companies (CDMOs), and establishing cross-registered manufacturing sites. Furthermore, EY suggests companies may begin collaborating more closely with nation-states to build strategic inventories or initiate public-private partnerships.

Policymakers may also seek to force greater localization of supply chains through measures such as R&D credits and incentives; export quotas; procurement mandates; or limitations on market access for companies without a local footprint. More radically, government could seek to impose localization of some or all stages of the biopharma supply chain.

"The degree of logistical challenges and investment needed to make this concept a reality would depend on the scope of the effort. It would be relatively simple for a biopharma to localize secondary product packaging. By contrast, localizing API manufacturing would a major challenge, both in terms of the scale of capital investment and the levels of technical and quality competency required."

"What would governments gain from localization? A localized supply chain would have a significant capability to respond to local conditions. However, it would entail building and maintaining infrastructure, services and talent at local sites. Separating operations from established centers of excellence in quality, process engineering, regulatory and IT operations, might negatively affect supply chain reliability. There may be political benefits from localization – for example, in the creation of jobs for a local workforce – but it is unclear if these incentives would justify the effort and expenditure."

One solution might be a move towards hybrid models, creating a much more interactive setup than previously seen and involving stakeholders from across the spectrum.

"Many approaches to building resiliency have been suggested, from hub-and-spoke manufacturing models to joint manufacturing or joint warehousing operations between companies, establishment of a joint procurement clearinghouse or the use of digital technology to build greater end-to-end transparency across the supply chain. Success in combining these approaches will depend on costs and opportunities generated for governments and companies…The biotech industry, policymakers and other stakeholder partners will therefore need to establish a dialogue for mutual education. In collaboration, they can adapt supply chain models to deliver the results prioritized by each partner in the future."

To access the full report, please visit *https://www.ey.com/en_us/life-sciences/beyond-borders*.

EY is a SILVER sponsor of the IFPW 2022 General Membership Meeting in Milan, Italy, October 18th-20th.

Generics (cont.)...

The industry is also dealing with more typical challenges of supply chain constraints, rising manufacturing costs and the emergence of buying groups. Industry executives say they are adapting by moving manufacturing and focusing on biosimilars.

While the U.S. Food and Drug Administration approved fewer generic drugs during the COVID-19 pandemic than in previous years, there were still plenty of approvals. According to annual reports from the Office of Generic Drugs (OGD), in 2019 the generic drug program approved, or tentatively approved, 1,014 generic drug applications (also known as Abbreviated New Drug Applications, or ANDAs) and 107 first generic drugs. In 2020, the OGD approved 948 ANDAs and 72 first generics. In 2021, the figures were 776 ANDAs and 93 first generics. The reports noted that first generics, which provide access to therapies where no previous competition existed, are particularly important to public health and the OGD prioritizes the review of first generic drug submissions for that reason.

Of course, increasing competition is presenting challenges for the industry. The rate of deflation, along with the number of competitors versus the available number of customers has promulgated a very competitive environment. Additionally, the supply of active pharmaceutical ingredients (APIs) and the supply of key starting materials has also been especially challenging.

The generics space has dozens of players, according to Andy Boyer, Executive Vice President and Chief Commercial Officer at Amneal Generics. Citing a Wall Street analyst's report, Boyer noted that the average generic product has six competitors. "Ongoing competition in the U.S. generics market continues to increase pressure for inline and pipeline product rationalization," Boyer said.

There has also been increased movement of manufacturing to lower-cost countries. Manufacturers are evaluating R&D investment in the United States versus the rest of the world and finding that the ROI in the U.S. for traditional products has little value, except for complex drug products.

Manufacturers agree that innovation will be the key to success in the current environment, with the key to success being "the first to market." It is evident that as the dynamics become more aggressive and competitive, being "late to the game" will present a missed opportunity.

The use of branded and generic drugs is increasing. According to "*U.S. Medicines Trends 2022 Report"* released in April by the IQVIA Institute for Human Data Science, prescription drug use reached a record 194 billion daily doses in 2021. Days of therapy from all types of prescription medicines grew by 3.3% in 2021, a rebound from 1.9% in 2020 when usage was disrupted by the pandemic. When people canceled or postponed certain healthcare appointments, new prescriptions for acute and chronic therapies decreased. COVID-related medicines accounted for part of the growth, and the non-COVID medicines market grew more slowly at 5%.

The IQVIA report also showed that generics make up 92% of prescriptions and account for 16% of invoice-level spending. At the same time, generics account for 65% of patients' out-of-pocket costs.

Manufacturers agree it is an exciting time to be in the generics, and especially in the biosimilars spaces.