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In Pharma's Competitive Environment, Companies Need to Think Beyond Clinical Trials

(Source: An article by Kelly Bilodeau for PharmaVoice)

As regulators and commercial payers demand more of pharma's profits, companies need to be proactive early to position drugs for a competitive market.

Convincing payers and doctors that breakthroughs and first-in-class therapies are worth the investment can be difficult, and many drugmakers are beginning to think about coverage and reimbursement strategy as early as phase 1 trials, according to a recent report from Norstella.

"A thoughtful market access strategy early in the development process is key to launch success in this world of personalized medicine, especially for competitive launches, where there are many different classes of treatment available," said Catherine Humphries, senior consultant in advisory services at MMIT, a Norstella company

Many companies find that making a successful case requires newer tools such as real-world data and AI analyses because clinical performance alone might not always be enough.

"Increasingly, payers are asking manufacturers to provide evidence of a brand's superiority beyond mere trial results," Humphries said.

Real-world patient data can highlight cost savings and improved outcomes, showing that patients who receive the drug need fewer emergency room visits or have better symptom control.

Pharma companies have lost some of their pricing power due to factors like Medicare's newfound drug negotiation position, which the industry has been challenging in U.S. courts. Pharmacy benefit managers have also been accused of inflating drug prices, drawing unwanted attention from the Federal Trade Commission.

In an increasingly competitive landscape, commercial payers can force drug discounts that leave drugmakers unable to compete. These add to existing financial stressors like rising R&D costs and shrinking patient pools as medicines become more targeted.

To thrive in this environment, pharma companies need an "agile brand strategy response" to navigate the growing number of payers, group purchasing organizations, integrated delivery networks, oncology pathways and healthcare providers, according to Humphries.

Evidence of a drug's value must be compelling enough to entice payers and doctors along with value analysis committees and health technology assessment organizations, which requires a more creative approach.

Companies can demonstrate additional value to insurers by becoming a critical resource and offering educational support for prescribers and patients. For example, the rise of biosimilars in

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In Brief...

- **McKesson Corporation** announced an agreement to acquire 80% of **PRISM Vision Holdings**, an ophthalmology and retina company. The acquisition comes less than a year after McKesson invested US$2.4 billion in a 70% stake in Florida Cancer Specialists. The acquisition gives McKesson access to PRISM's 1180+ providers, 91 office locations and 7 ASCs.
- **Cencora** has agreed to repurchase shares of its common stock from **Walgreens Boots Alliance** in the amount of approximately US$50 million in concurrence with Walgreens sale of Cencora shares. The concurrent share repurchase will be made under Cencora's share repurchase program and the repurchased shares will be held in treasury. Separately, Cencora has significantly expanded the number and type of medications available in its *Sure Supply Program*, a drug shortage mitigation initiative designed to provide health systems with reliable access to critical medications, including several oncology treatments.
- The **National Pharmaceutical Services Association (NPSA)** has welcomed a five-year agreement with the Australian Commonwealth Government that will enable ongoing timely and equitable distribution of PBS medicines to patients throughout Australia. The first *Pharmaceutical Wholesaler Agreement (1PWA)* is an agreement between the government and NPSA - the peak industry body representing full-line *Community Service Obligation (CSO)* medicine wholesalers. It addresses significant erosion of supply chain funding and means that Australians will continue to receive

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COFARES JOINS IFPW

IFPW welcomes COFARES as a member representing the European market and EMEA region.

COFARES, the leading pharmaceutical cooperative in Spain, distributes a full range of medicines and other healthcare products to pharmacies throughout the country. It distributes to over 13,000 member pharmacies (more than 55% of pharmacies in Spain) and holds 30% of the market share.

Founded in 1944, COFARES is the only Distributor with presence throughout the national Spanish territory.

Its mission is to promote healthcare for patients and consumers, bringing them closer to the pharmacy, making it a trusted health ally. They connect the pharmaceutical industry with its large network of pharmacies through technology and a proposal of logistical and commercial models, engaging patients/consumers with health products, services and solutions.

IFPW is pleased to have COFARES as its newest wholesaler/distributor member and looks forward to their active participation.

Pharma's Competitive *(cont'd.)*...

U.S. markets demonstrates the importance of that support.

Manufacturers of drugs for rare diseases and cancer subtypes are mining real-world data and lab test results to identify specialists who need education for challenging diagnoses.

AI can also help companies quickly assess the competitive landscape to determine other ways to make their product appealing to doctors and patients.

Companies are looking to new countries like Vietnam for manufacturing needs, but change comes at a cost.

The economy is on solid footing, interest rates are dropping, and the indications are favorable for pharma companies to offset patent expirations with new drugs. But amid these positive market dynamics lies an undeniable uncertainty-- tariffs and other economic levers promised by the new presidential administration could adversely affect the market.

The Trump administration has pledged to impose broad levies, with tariffs as high as 60% on Chinese goods and 20% to 25% on those from Canada and Mexico. The unresolved Biosecure Act could also deal a blow to China as the U.S. aims to strengthen national security by prohibiting companies that receive federal funds from making business deals with five key Chinese biotechs. The legislation has stalled in the Senate, but some experts expect it to ultimately gain approval, potentially reshaping supply chains through 2032, said Arda Ural, EY Americas industry markets leader for health sciences and wellness. "Companies would be wise to get ready", Ural said.

"We expect the president to continue to promote on-shoring, near-shoring and to use tariffs and other economic levers to implement his economic, national security and foreign policy priorities," Ural continued. "Agile companies will understand and be prepared for these externalities."

Tariff promises might not translate directly into policy, Ural said. Even so, many companies have begun shifting operations away from Chinese businesses, which make up 13% of global active pharmaceutical ingredient manufacturers. But these are capital-intensive, long-term strategic moves. Some are reshoring to the U.S. or looking to other countries such as Vietnam as China loses its appeal.

For branded pharmaceuticals, pivoting to avoid tariffs on APIs is inconvenient and costly but doable.

"This is not a situation where you need rare minerals — it's not like these products don't exist anywhere else in the world," Ural said. "It's just a matter of shifting the bases from China, which is a higher geopolitical risk, to more friendly manufacturing bases."

But companies making generic products, hamstrung by cost constraints, are less nimble, and tariffs could ultimately force increased prices for consumers. On all counts, moves to mitigate the effects of tariffs on the industry will likely bring short-term pain.

Those pivots, however, can potentially lead to longer-term benefits, positioning companies for the future.

U.S. economic indicators appear to be moving in the right direction to boost development, but there are additional uncertainties beyond tariffs. The industry has been uncharacteristically quick to adopt artificial intelligence, which has the potential to accelerate R&D and save money. This year, the industry is likely to get some answers on how well that investment will pay off.

It's not the only outstanding question.

"If there are new unknowns, they will probably come from the geopolitical side of the house," Ural said.

In Brief (cont.)

the uninterrupted medicine distribution service they have come to rely upon. NPSA Chair *Richard Vincent* said, "We are extremely pleased to have finalized this five-year agreement which secures medicine management and distribution and benefits all Australians. The 1PWA will enable available medicines, whether they be everyday tablets, high care specialized therapies or cold chain products to be carefully managed and distributed reliably to patients, no matter where they live."

- The **U.S. Food and Drug Administration** has approved the use of **Vertex Pharmaceutical's** *Jounavx* which has been shown to significantly reduce pain after surgery. The drug, a non-opioid, is being touted as "an important public health milestone in acute pain management".
- **Takeda** (Japan) has named *Julie Kim* as its next CEO, replacing the retiring *Christophe Weber* who will step down in June of 2026. The company called Kim's promotion part of a "multi-year succession process". Kim, 54, came to Takeda in 2019 with Takeda's US$62 billion acquisition of Shire. Since April of 2022, she has been president of Takeda's U.S. operations.
- **CVS** announced the launch of the CVS Health app. The company said the app's features will bring together all it offers to consumers, helping make health care more accessible, affordable and convenient. "As a company, we are super focused on improving the health care experience," said *Tilak Mandadi*, executive vice president at CVS Health. "The CVS Health app will make it easier for our customers to access and manage their health and care, save time and money, and make informed decisions about their health."
- For the first time, the volume-based generic drug use rate exceeded 80% in all 47 Japanese prefectures in September of 2024, according to a monthly report published by the **Japan Health Insurance Association**. To further spur generic use, the Japanese government has set goals of increasing the volume-based generic share to over 80% in all prefectures and the value share to over 65% by the end of FY2029.
- Two Chinese API manufacturers, **Nuowei Chemistry** and **Innovation Pharmaceuticals**, received reprimands from the U.S. Food and Drug Administration. Both involved production infractions, and the companies have been penalized with import alerts, according to warning letters which were posted on the FDA website. Nuowei received its write-up after an FDA inspection of its Xuancheng facility in September of 2024; infractions involved API purity, adherence to manufacturing standards and proper equipment maintenance. Innovation's reprimand followed a records request for its Chengdu plant by a U.S. regulator in April of 2024.

(Sources: Company Press Releases, Drug Store News, FiercePharma, Nephron Research, Pharma Japan, PharmaVoice and Scrip Citeline)