IFPW FOCUS
A Bi-Weekly Pharmaceutical Industry Newsletter
Celebrating Our 30th Year in Publication!
Vol 30 | No. 1
January 12, 2023

What Will the Pharma Industry Face in the Year Ahead?

(Source: An article by Natalie Dimambro for MedCity News)

Organizations across the life sciences industry have faced difficult challenges over the past several years – including a global pandemic, significant supply chain disruptions, geopolitical unrest, and an uncertain economic climate. As we move into 2023, there is hope that some of these challenges may be settling down, which will allow companies to look to the future, even in the face of some continued uncertainty.

Pharmaceutical companies continue to forge ahead with the goal of creating an end-to-end insights management. Insight generation and analysis still play a vital role in drug development. However, companies may lack the willingness to devote significant business resources to finding a solution to the overall problems that persist.

Even in this notoriously risk-averse industry, leaders are coming around to the idea that they can solve many of the challenges with technology. Pharma companies will begin putting both minds and money behind the push to put insights management into the spotlight as a strategic pillar of their business model.

One way they will accomplish this not insignificant goal is by using artificial intelligence (AI) to support – not replace – human talent who lack the time to manually sift through patient data, medical records, and other important sources of information. For pharmaceutical teams, 2023 will be the year of understanding that AI can be a necessary and useful partner rather than an intimidating threat.

Many teams do not understand that AI applications run the risk of missing out on key insights and the opportunities those can provide. This can have a particularly meaningful impact on applications such as precision medicine, where developing the most impactful treatment pathway often requires analyzing information about different aspects of the patient experience.

While much of this information is obtained from structured data from electronic medical records, there is also valuable information in the unstructured text of physician notes, referral forms and medical charts. Developing precision therapies also requires input from global experts who will not be easily or readily accessible.

Like many other industries, pharmaceutical and medical device companies are eager to return to in-person meetings and busy show floors. But as the industry returns to its more traditional in-person meetings and conferences, it is important to capture insights that may arise during these events, rather than leaving them behind once the conference is over.

How these important observations are collected and shared, and how will that information will make its way into the mix with data from other channels such as virtual meetings and social platforms? As organizations attempt to balance traditional and technology-enabled ways of working, technology will be a useful way to add consistency to the process.

(continued on page 2)

In Brief...

- **AmerisourceBergen** has completed its acquisition of **PharmaLex Holding GmbH**, a leading provider of specialized services for the life sciences industry. The deal is valued at €1.28 billion (US$1.35 billion). "The strategic acquisition of PharmaLex will expand our global platform of biopharma services, further advancing the strategy we detailed at our recent investor day. AmerisourceBergen is committed to building on our leadership in specialty services through a continued focus on innovation and partnerships."" said *Steven Collis*, Chairman, President and CEO.
- **McKesson Corporation** has launched *Atlas Specialty*, a new specialty-focused pharmacy services administrative organization to drive lower drug costs and total cost of care for providers and patients. Atlas enables health system pharmacies, medically integrated dispensary practices and specialty community pharmacies to care for patients with rare and complex diseases. Atlas members will benefit from access to negotiated specialty contracts, professional services aimed at optimizing financial and operational efficiencies, such as support with competitive reimbursements and reduced DIR fees, and data/insights to support better continuity of care which will assist in improved patient outcomes through greater treatment adherence.
- **Walgreens**, in partnership with **DoorDash** and **Uber**, announced free delivery of *Paxlovid*, a COVID-19 oral antiviral therapy, directly to the doorsteps of patients in needs. The company is offering same day delivery services to anyone living within 15 miles of participating Walgreens locations. This will provide the service to approximately 92% of the population. The initiative is aimed at increasing access to COVID-19 treatment, particularly to socially vulnerable and

(continued on page 2)

Meeting the Challenges of China's COVID-Zero" Policy Reversal

(Source: An article by Brian Yang for Scrip Intelligence)

Three years after the first SARS-CoV-2 infections were reported in Wuhan, China has begun to reverse its "COVID Zero" policies. But as Beijing relaxes its most restrictive rules, citizens remain concerned about ballooning infections. The vaccination rate among seniors and vaccine fatigue are also dimming hopes of a quick revitalization of the hard-hit economy and is lowering consumer confidence.

In its policy change, China has stopped requiring some nucleic acid testing - a key component of its "COVID Zero" policies. The capital of Beijing was among the many cities announcing on December 5th a halt to requiring negative test results to enter public places and take public transportation. But generally low vaccination rates, particularly in some populations areas, and other lingering concerns may complicate a rapid re-opening of the economy. Without herd immunity through vaccines and prior infections, the country also remains vulnerable to a spike

(continued on page 2)

Pharma Industry (cont.)

The question is what will it look like when put into practice? One possibility is that while teams will eagerly return to the traditional in-person medical/pharmaceutical congress, these events will use social listening to understand what topics are trending ahead of and during these meetings. This will add currency and weight to their real-time conversations. They might share same-day observations and work to achieve alignment on critical discussions before they head home. And once the event is over, the conversation can continue online with analysis tools to potentially shorten the time from insight to action by weeks or months.

Increasing the agility factor equips these life science organizations to have more choice in engaging truly global audiences. This will allow for more flexibility, a factor that cannot be overstated.

China's "COVID-Zero" (cont.)

in cases and rising death rates.

China has officially reported just 5,235 COVID-19 deaths, compared to over one million in the US and 690,074 in Brazil. "The infections will surely spike," Ke Wu, CEO of Wuhan-based vaccine company Bravo Vax Co Ltd, predicted. The lengthy lockdowns and economic slump have all hit the health sector hard.

Since the early days of the pandemic, the Chinese government has emphasized rapid vaccine development, turning to state-owned giant China National Biological Products Corp. and the smaller public firm Sinovac Biotech Ltd. to develop inactivated virus-based candidates. While the mature technology, around for decades, allows generally rapid development, China has the notable drawback of lower efficacy and protection rates. It is also harder and slower to make follow-on vaccines against virus variants.

With government backing, vaccines from the two companies sailed through clinical development and gained emergency approvals and aided by mass promotional efforts were successfully jabbed into arms over 2021. With many believing the two-dose shots would confer protection and enable somewhat normal lives, the reception was warm. In fact, China has one of the highest vaccination rates (90%) in those over the age of 18 globally.

In 2021, China approved the same vaccines for booster use, but promotion was underwhelming. Unlike many other countries, China has not required proof of full vaccination to enter public spaces or public transport, instead relying on negative results from mass testing. As a result, elderly individuals and children, in particular, were reluctant to get the shots, also due to the low reported infections under COVID Zero. While some schools required proof of vaccination, many parents were also concerned about potential adverse effects from vaccines.

To address the challenges of reopening amid this situation, experts say China must act quickly to get its vulnerable population boosted and offer better protection by promoting fourth shots to the general population. The other aspect is access to more effective mRNA vaccines; however, China's approval process has been ongoing for more than 18 months.

In July 2021, a Shanghai Fosun Pharmaceutical (Group) Co., Ltd. executive announced the pending approval of its mRNA shot, licensed from BioNTech SE, but there has been no word from the company since then on further progress. In the meantime, China is set to grant a green light soon to a domestically-developed mRNA vaccine from Walvax Biotechnology Co., Ltd., ABOGEN INC and Academy of Military Medical Science.

Experts urged a new roll-out of booster shots to the elderly, since they are more likely to have pre-conditions, higher severe cases, and death rates. These might include an adenovirus-based vaccine from Cansino Biologics Inc., also available in inhaled form, and Zhifei's recombinant protein-based vaccine.

In Brief (cont.)

underserved areas.

- **Pfizer** is focused on growing its inline business (excluding foreign exchange and COVID-19 revenues) at a compound annual growth rate of at least 6% through 2025, and continued growth through 2030, despite losses of exclusivity (LOEs) beginning in 2026. The company predicts new drugs from its internal pipeline, along with drugs gained through business development will more than offset what is expected to be a US$17 billion revenue loss from LOEs in the 2025-2030 period. Separately, the company announced major investment plans totaling US$2.4 billion in its Grange Castle, Dublin, Ireland faciity, and the other in site in Puurs, Belgium.
- *Robert Davis*, CEO of **Merck**, is urging the government of Japan to revisit drug pricing rule changes made over the past years and introduce mechanisms to support innovation in the 2024 reform. *Keytruda*, Merck's immune-oncology therapy, has been a major victim of Japan's drug re-pricing rules, with the two-time application of so-called "huge-seller" discounts for fast-growing blockbusters and multiple "spillover" price cuts. Separately, Davis also said that the Merck & Co. is already taking into consideration drug policies set forth in the *U.S. Inflation Reduction Act*, which are already affecting the company's R&D and business development decisions. "It's going to change how you think about strategically bringing assets forward," he stated.
- **Viatris** has closed its transaction with **Biocon Biologics**, creating what is expected to be a unique fully vertically integrated global biosimilars company. Upon completion of a transactions services agreement, Viatris will provide commercialization and other certain transition services for an expected two-year period intended to ensure business continuity for patients, customers and colleagues. After that period, Biocon will assume responsibility for commercial, regulatory and other related services.
- The U.S. "tripledemic" of influenza, RSV and COVID-19 is causing unit sales of OTC treatments to rise by as much as 69% according to **Catalina's** *Shopper Intelligence Platform*. Average prices rose 12% in November 2022. Children's OTC pain relief products are particularly vulnerable to scarcities, causing retailers such as **Walgreens** and **CVS Health** to institute product purchase limits.
- **Moderna** and **Merck's** success with an mRNA-based cancer vaccine in a Phase IIb trial has shown great promise. The companies reported that the study in post-surgical stage III/IV melanoma patients yielded a 44% lower risk of recurrence or death for a combination of Moderna's experimental mRNA personalized cancer vaccine and *Keytruda*, versus *Keytruda* monotherapy. There is also interest in studying the vaccine for other cancer types.

(Sources: Company Press Releases, Drug Store News, FiercePharma, Scrip Intelligence, World Pharma News and Yahoo News)