

## COVID Continues to Grip India

(Sources: Article by Anju Ghangurde for Scrip, and an article from the Economic Times India)

Despite a critical second wave of the COVID-19 virus wreaking havoc in India, the country's pharma industry appears to be successfully stretching its resources amid a dip in personnel attendance and supply chain strains, including raw materials. Limited vaccine supplies, an increase in prices of active pharmaceutical ingredients (APIs) and an inevitable third wave could mean more troubles ahead.

COVID-19 has exposed the rifts in India's fragile healthcare system and is costing lives. It is also applying pressure on the resilience of the Indian population. The intensity of the second wave has amplified the inequities and evidence of a broken healthcare infrastructure within India, and they are not alone, as others with more advanced health systems shared struggles in coping with COVID before the arrival of a viable vaccine. The situation in India, however, is in large part a result of neglect of the health segment over the years, along with abysmally low public spending on healthcare in what is by and large a self-pay market.

India has one of the highest levels of out-of-pocket expenses in the world. Likewise, catastrophic health expenditures have plunged many into abject poverty. The current national public healthcare budget is only about 1.26% of GDP, and an under-resourced system cannot function optimally in normal times, let alone during a pandemic.

Somewhere along the way, India also severely underestimated its vaccine requirements for a significant portion of its population. There was a lack of a procurement and stockpiling strategy, and exigencies were not factored into the equation. Given the size of the population, demand will certainly outstrip supply for the foreseeable future.

India has temporarily cut back on exports of the AstraZeneca/Oxford University/Serum Institute of India vaccine amid the current surge. The vaccine shortage has put pressure on the Serum Institute to meet supply commitments to the COVAX program, which means that many African and other nations that depend on the Institute's manufacturing facility will have to find other strategies to access vaccine supplies elsewhere, likely through the end of the year.

The most glaring miscalculation by the Indian government appears to be the assumption that India has some level of control over the situation after having made it through the first wave reasonably well. While the ferocity of the second wave was not imagined, allowances to go ahead with potential "superspreader" events such as political rallies, religious events and festivals only accelerated and expanded the degree of severity for COVID's second wave.

With all that taken into consideration, the pharma industry's strategy is making headway. The local sector is holding up, but the fear is that this second wave will take over India's reputation as "pharmacy to the world". Pharma personnel is down 5-8%

(continued on page 2)

## In Brief...

- ◆ **AmerisourceBergen** reported its financial results for Q2 of its fiscal year 2021. Revenue increased year-over-year, up 3.7% to US\$49.2 billion. GAAP diluted earnings per share was US\$2.10 and adjusted diluted EPS (non—GAAP) increased 5.4% to US\$2.53 in the fiscal second quarter. The company is updating its outlook for fiscal year 2021. Adjusted diluted EPS guidance has been raised to a range of US\$8.45 to US\$8.60.

- ◆ **Cardinal Health** reported flat revenues in Q3 of 2021 amid pandemic headwinds. Third quarter revenues totaled US\$39.3 billion, in line with the same period last year. Earnings for the quarter decreased to US\$473 million. Pharma segment revenue was flat at US\$35.1 billion, reflecting sales growth from pharmaceutical distribution and specialty solutions customers.

- ◆ **McKesson Corporation** reported fiscal year 2021 Q4 revenues of US\$59.1 billion, an increase of 1% year-over-year, and full-year revenues of US\$238 billion, an increase of 3% from 2020. 4th quarter earnings per diluted share from continuing operations of US\$4.15 decreased US\$1.67 and Q4 adjusted earnings per diluted share was US\$5.05, an increase of 18%. Outlook for 2022 given by the company forecasts 9.5% to 13% growth in earnings per share.

- ◆ **Profarma Distribuidora** (Brazil) announced gross revenues for Q1 of 2021 of R\$41.7 billion (US\$7.97 billion), an increase of 7.4% from the prior year. The company's distribution segment enjoyed 9.0% growth. Net income was R\$8.9 million (US\$1.7 million), 1000% growth as compared to Q1 of 2020. Distribution net income grew 97.8% reaching R\$11.9 million (US\$2.27 million).

- ◆ **Pfizer** and **BioNTech** signed a memorandum of understanding with the **International Olympic Committee** to donate doses of the companies' COVID-19 vaccine to assist with the vaccination of athletes and their delegates participating in the Olympic and Paralympic Games in Tokyo,

(continued on page 2)

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**IFPW GENERAL**  
**MEMBERSHIP MEETING**  
**October 6-7, 2021**



TOKYO 2020

IFPW's General Membership Meeting will follow a **HYBRID FORMAT**  
(subject to change depending on Japan's COVID restrictions)  
A limited number of in-person seats will be available and all meeting sessions will be available **LIVE** and **ON-DEMAND** (for those who are unable to travel internationally.)

*Watch for updates and registration information in the coming weeks.  
For sponsorship information or general questions  
please contact Christina Tucker at [c.tucker@ifpw.com](mailto:c.tucker@ifpw.com)*

## India (cont.)...

across operations due to illness and associated fears of infections. Production is slightly down and currently sits at 75-80% of capacity, according to industry insiders. According to one industry expert, the amount of inventory and proactive efforts to stretch these supplies will ensure minimal impact on production.

However, one senior industry executive said that pockets of the pharma segment are already witnessing significant turbulence, including state-level lockdowns impacting activities within the supply chain. The hope is that this will calm down in the coming weeks and months.

Another result of the current conditions is the increase in API pricing. For instance, April prices of *amoxicillin*, *doxycycline*, *paracetamol* and *azithromycin* rose sharply according to data from February 2021. Some believe it is a product of supply and demand. There has been some stockpiling of APIs by customers since the first half of 2020, mostly in anticipation of supply disruptions due to the pandemic. Subsequently, any impacts to these supplies will take some time to show up going forward.

In spite of the many obstacles that are currently present, the industry within India is far more prepared than it was when the pandemic initially struck in 2020, and is making every effort to ensure that operations are running and employees are receiving the vaccine. It is not lost on the Indian pharma industry that much is riding on India and its ability to keep up supplies. In fact, it is estimated that 60% of the global production of all types of vaccines come from India's production facilities. Among these critical vaccines coming out of India include 40-70% of the WHO's demand of diphtheria, tetanus, pertussis, Baccilus Clamette-Guérin vaccines, and 90% of the WHO's demand for measles vaccines. It is not immediately clear if the "covidization" of resources has deprioritized such supplies.

The U.S. is also a large market for Indian generic supplies. One in every three pills consumed in the U.S. is made in India, according to some estimates, while approximately 25% of the medicines used in the U.K. also come from India. So a crisis of pharmaceutical supplies will be felt around the world.

Currently the world is rushing to aid India to assist with the second wave. Russia's Sputnik V vaccine has been approved for use in India (making it the third vaccine in India's arsenal) under an emergency use authorization, and countries are sending millions of doses of vaccines to gain control over the virus. The hope is that with a concerted and coordinated effort, the second wave of the COVID virus will be under control in the near future.

## IFPMA Expresses Concern for U.S. Support of Vaccine Patent Waivers

(Source: IFPMA Press Release)

The International Federation of Pharmaceutical Manufacturers and Associations expressed disappointment Wednesday at the United States' decision to support a global waiver on patent protections for COVID-19 vaccines.

"As we have consistently stated, a waiver is the simple but the wrong answer to what is a complex problem," the lobby group said in a statement, describing the U.S. move as "disappointing".

"Waiving patents of COVID-19 vaccines will not increase production nor provide practical solutions needed to battle this global health crisis," it continued.

Instead, IFPMA argued, governments should be focusing on eliminating trade barriers as well as "addressing bottlenecks in

supply chains and scarcity of raw materials and ingredients" for producing COVID-19 vaccines.

Proponents of doing away with IP rights, such as the governments of India and South Africa, say it could lead to more companies in more countries producing vaccines, providing broader access in poorer nations.

But pharmaceutical industry bodies have insisted that removing intellectual property protections or pressuring companies into technology-sharing, could actually slow down job production.

IFPMA chief Thomas Cueni told reporters last month that an IP waiver "wouldn't give us the tools to produce more doses of vaccines".

He added that around 275 manufacturing deals, including on technology transfer among staunch competitors, has helped the industry go from zero to one billion COVID-19 vaccine doses already produced, with the goal of 10 billion doses by the end of the year.

Other pharma industry figures have pointed to the unknown consequences of transferring technology to manufacturers who may not employ stringent quality and safety standards.

Stephane Bancel, head of vaccine-maker Moderna, has meanwhile argued that "if we have more players coming into the space, (they will be) taking more of the raw materials away from people (positioned) to make vaccines for this year".

## In Brief (cont.)...

which are scheduled to begin on July 23, 2021. The companies and the IOC will coordinate with national Olympic committees around the world to help address the local need for vaccine doses for national delegations' participation in the Games. Delivery of initial doses is expected to begin at the end of May. Separately the companies will seek authorization from Mexico, Switzerland, and the United Kingdom for use of its vaccine in children ages 12-15.

- ◆ Biotech company **Moderna** announced that it has received emergency use listing (EUL) by the **World Health Organization** for its COVID-19 vaccine. The EUL allows many countries around the world to expedite their own regulatory approval processes to import and administer a vaccine. It also enables UNICEF and the PAHO Revolving Fund to acquire the vaccine for distribution to countries in need.

- ◆ China's **Sinopharm Group Co., Ltd.** is expanding production capacity to 5 billion doses per year with accelerating overseas cooperation after one of its COVID-19 vaccines was included in the Emergency Use Listing with the World Health Organization. Sinopharm has produced more than 400 million doses of COVID-19 vaccines and more than 200 million doses have been supplied at home and abroad, according to company executives.

- ◆ Japan's top four wholesalers had disappointing earnings in their pharma wholesale business in FY2020 as COVID-19 pandemic raged and battles over pricing intensified, according to Jiho tally. Average operating margins fell far below 1%, which is recognized as a threshold for "reasonable profit rates" in the sector. **Alfresa Holdings, Medipal Holdings, Suzuken and Toho Holdings** posted combined sales of ¥7.6 trillion (US\$69.7 billion), down 3.2% year-over-year. Average operating profit was down 67.6%.

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