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Japan's Pharmaceutical Industry is Slowly Recovering from Covid-19

(Source: Various articles released by Pharma Japan)

Japan is slowly getting into motion after its state of emergency over the novel coronavirus pandemic were lifted. Tokyo's metropolitan government has eased its business suspension request in three steps, and the city has entered the first stage. Museums, libraries, and indoor sporting facilities may reopen while restaurants can now remain open with later hours and offer alcohol until 10 pm. Likewise, department stores have reopened with workers wearing masks and face guards. Sanitation guidelines have also been put in place. Other prefectures have issued similar guidelines and seem to be off to a slow start.

The effects on Japan's pharmaceutical industry are very evident in both manufacturing and distribution. The Japanese ethical drug market in January-March 2020 eked out 0.2% growth year on year to \(\frac{2}{2}\).49 trillion (US\(\frac{2}{2}\).86 billion) on an NHI price basis amid the Covid-19 crisis, according to data released by IQVIA on May 26, 2020.

Among drugs in the top 10 list, sales jumped for Daiichi Sankyo's anticoagulant *Lixiana*, up 20.6%. Other drugs included were Takeda's peptic ulcer treatment *Takecab*, AstraZeneca's cancer drug *Tagrisso* and Otsuka's heart failure medication *Samsca*. AbbVie's hepatitis C combination therapy *Maviret*, Bayer Yakuhin's anticoagulant *Xarelto* and Shionogi's anti-flu drug *Xofluza* disappeared from the top-10 list.

Fifteen Japanese drug makers are forecasting an average negative growth of 3.6% in Japanese ethical drug sales in FY2020 and are bracing for sharp declines stemming from price cuts and generic inroads. The effects of Covid-19 on the pharmaceutical market are uncertain at best at this point.

The largest loser by projected revenue decline in Japan is Taisho Pharmaceutical Holdings, which expects to suffer negative growth of a hefty 20.9%, attributable to a 46.7% cut in sales of the osteoporosis treatment *Edirol (eldecalcitol)* as well as sharp falls in off-patent original medicines. The guidance means that the company's Japan ethical drug sales would dwindle by half in five years from 107.2 billion yen in 2015.

Astellas Pharma, meanwhile, is expected to face a 17.3% decline, or nearly 60 billion yen, after the company saw the termination of co-promotion pacts for the COPD treatment *Symbicort* in the previous fiscal year. Its anti-flammatory analgesic *Celeco (celecoxib)* will also face competition from generics now on the market.

These and other forecasts do not factor in the impact of Covid-19. There are also concerns that remote promotions might affect the adoption of new drugs by medical institutions and hospital avoidance might result in the contraction of the market.

Japan's top four drug wholesalers achieved higher operatingprofit rates for their pharmaceutical wholesale business in FY2019 compared to the previous year with an average rate of 1.45%,

In Brief...

- U.S. pharmaceutical manufacturer, Merck & Co., has launched an alliance with non-profit research organization IAVI to develop a vaccine using recombinant vesicular stomatitis virus technology that Merck used to develop its Ebola vaccine. The company has also signed an agreement with the U.S. Biomedical Advanced Research and Development Authority (BARDA) to provide initial funding support for its work with IAVI. Finally, Merck has partnered with U.S.-based Ridgeback Bio to develop a novel antiviral candidate, as limitations of Gilead's remdesivir have recently been highlighted. Merck & Co. is among the top five vaccine manufacturers in the world.
- Walgreens President *Richard Ashworth* has left his position to take over as President and CEO of **Tivity Health**, a provider of fitness, nutrition and social engagement solutions, effective June 1. He will also sit on the company's board of directors. Ashworth has held various positions within the Walgreens organization since 1992. Throughout the Covid-19 pandemic, he has served as the public face of the company.
- CVS Pharmacy will begin offering autonomous delivery to its customers beginning in June, as part of an area pilot program in Houston, Texas. The first-of-its-kind partnership between Nuro, an autonomous delivery company, and CVS will utilize Nuro's fleet to deliver prescriptions and essentials across three zip codes in the Houston area. Orders can be placed on CVS.com or via the CVS pharmacy app. Orders will then be delivered curbside to the customer's address within three hours. Customers will need to confirm their identity to unlock their delivery.
- The percentage of infants in Japan receiving vaccinations through public vaccination programs plummeted due to the impact of stay-at-home requests during the Covd-19 outbreak.

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India's Drug Market Shows Resilience

(Source: An article written by Staff for The Economist)

Nothing could have prepared Indian drug manufacturer, Cipla for the ramifications of the Covid-19 pandemic. Production at Cipla's 30 plants fell by 70% nearly overnight in March as India's government ordered a lockdown that made it hard for its 23,000 employees to work. Critical inputs, from packaging to active ingredients, became scarce. The price of some sourced from China quickly increased by as much as five-fold.

Today, Cipla's output is still lower than pre-crisis levels. Operations in hard-hit Mumbai remain curtailed. However, a factory in the north-eastern state of Sikkim is fully staffed. The firm ferries employees to work in sanitized buses with socially distanced spacing between riders. Basic supplies are available again, and the premium charged by Chinese sellers has narrowed

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Japan (cont.)...

according to Jiho. Likewise, all four achieved operating profit rates of over 1%, which is seen as the threshold for "reasonable profit rates" in their wholesale business. The NHI price revision associated with last October's consumption tax hike and the Covid-19 pandemic had a limited impact. Sales of anti-cancer agents and specialty products remained strong. Combined, the four companies' drug wholesale business sales were up 2.7% over the previous year with operating profits up 12.0%. Sales rankings remained unchanged year-over-year in terms of total sales. However, Suzuken ranked second in terms of ethical drug sales, replacing Medipal Holdings.

Due to the Covid-19 outbreak, wholesalers have not set clear forecasts for FY2020 ending March of 2021. Medipal, Suzuken and Toho have all said that their forecasts are "pending". Only Alfresa has announced its forecast, but it does not factor in the impact of Covid-19, saying it is impossible to make that prediction.

India (cont.)...

to 10-20%.

This is good news—and not just for Cipla or India, which has largely avoided drug shortages thanks to in-country pharma firms. Their revenues amounted to US\$40 billion in 2019, half of it from exports. They produce one-tenth of all pharmaceuticals by volume, including 50% of the world's vaccines, 40% of generics sold in America and a quarter of all medicine bought in Britain. Visitors from Africa leave India with suitcases stuffed with inexpensive pills that sometimes are not even available in their own countries.

India's pharmaceutical industry was not in great shape prior to the pandemic. Revenue at big firms is expected to grow by 5% this year, down from 18% in 2016, shortly after their share prices peaked as Western countries brought about fierce competition in the generics market. Today, competition continues to erode the already-slim margins that these firms earn on generics. Prices of drugs sold by Indian firms declined by 8% in 2018 and 5% in 2019, according to McKinsey & Co. Concerns about the quality and efficacy of Indian-produced drugs led America's Food and Drug Administration to issue "import alerts", which block products' distribution, for 15 Indian firms in 2019 and 2020.

Fears of rising costs and depressed sales, as patients and hospitals everywhere deal with limited access to non-Covid treatments, have added to the existing concerns. Yet the coronavirus may be an inflection point for the industry, if it demonstrates that it can produce huge volumes of coronavirus drugs with speed and efficiency. Evidence show that this is indeed possible.

Indian firms, including Cipla, are manufacturing *favipiravir*, an anti-viral drug developed by the pharmaceutical unit of Japan's Fujifilm, which has shown promise in treating Covid-19. Last month, the Serum Institute of India, the world's biggest vaccine manufacturer, broke with standard practice and announced it was producing 40m-50m doses of a vaccine developed by researchers at Oxford University before human efficacy trials have even started. On May 5th the Indian press reported that Gilead, the manufacturer *remdesivir*, has received emergency approval in the U.S. for treating Covid-19 infections. Gilead is also in advanced negotiations with four domestic firms—Cipla, Dr Reddy's Laboratories, Jubilant Life Sciences and Strides Pharmaceuticals—

to produce remdesivir.

More partnerships are expected as the merits of co-operation become evident. So it seems investors—who also predict collaboration might prove lucrative. Stock share prices point to this as Indian drugmakers' share prices are seeing increases. An index of these larger manufacturers is up by 43% since the lockdown began in mid-March amid a stockmarket meltdown in India.

In Brief (cont.)...

A survey, conducted by a nonprofit organization that promotes educational activities to protect children from preventable diseases, estimates that vaccine rates have fallen from 95% to approximately 70% in April. The organization pointed out that vaccinations were not included in non-urgent, non-essential activities included in stay-at-home orders.

- Gilead Sciences' remdesivir is likely to be under consideration for addition to the top-secret US Strategic National Stockpile (SNS), and individual states' Covid-19 could become endemic and so there will be stockpiles, in the event donated doses run out and Covid-19 cases outstrip supply. Gilead's donation of 1.5 million individual remdesivir doses equates to more than 140,000 treatment courses, according to a company press release. However, because it is challenging to forecast what the Covid-19 pandemic could look like within the next year, stockpiling at a national and state level could be a way to prevent shortages and if full approval comes through, could involve price discounts as Gilead starts selling the drug.
- Governments and other research funders may be missing an opportunity to help speed the development of coronavirus vaccines and treatments by not insisting that drug makers share intellectual property, research data, and other information, some watchdog groups and patient advocates say. As billions of dollars are given for pharmaceutical companies' research into coronavirus medicines, the **World Health Organization** has encouraged funders to include clauses in their contracts requiring equitable distribution of Covid-19 medicines and publication of trial data. It's joined advocates who say a failure to be proactive on property and data rights shifts the power to the drug industry.

(Sources: Drug Store News, Fierce Pharma, GlobalData, IP Law News and Scrip)



On June 4th, GAVI will host its virtual Global Vaccine Summit 13:00-16:30 GMT/13:00-16:30 GMT/ 14:00-17:30 CET /08:00-11:30 EST

Follow the event live as the world comes together to make #VaccinesWork for everyone, everywhere.

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