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Pharmaceuticals Outlook for 2022

(Source: An article published in PharmaTimes Magazine, Dec. 2021)

The pharma industry has been pivotal during the pandemic and this focus looks set to continue into 2022. The coronavirus pandemic has not only boosted many pharmaceutical companies' revenues but has also bolstered their reputations. The value of pharma innovation is solidified after COVID-19 vaccines were developed at record speed and pharma manufacturing and supply chains have so far delivered 7.5 billion vaccine doses while keeping supplies of most other medicines on track.

Despite outcry from emerging markets over the uneven distribution of vaccines, the patent system seems to have survived intact. Even so, there will be challenges ahead. However, market growth will not be one of them. Overall, pharmaceutical sales in the 60 biggest markets worldwide are expected to increase by 4.6% in US-dollar terms to about US$1.5 trillion. That is about half the growth rate seen in 2021, but still faster than that seen in most of the previous decade. It is not surprising that many pharma companies, having upgraded their 2021 earnings forecasts, are issuing tentative but bullish forecasts for 2022.

COVID will continue to be a major driver for several companies. Pfizer expects earnings from its *Comirnaty* vaccine to be around U$29 billion in 2022, only slightly down from the expected earnings of US$36 billion last year. Add in revenues from its new COVID treatment, and prospects are good. Even AstraZeneca will finally start charging commercial rates for its COVID vaccine in 2022.

Vaccine supply problems should also ease in 2022. UNICEF, which is monitoring COVID vaccine supply deals as part of its COVAX program, reckons that global production capacity will jump from 8.5 billion doses in 2021 to over 40 billion doses next. Some of that extra capacity will come from India, where the export ban for vaccines has finally been lifted despite the lingering caseload. India already has deals in place to produce 2.8 billion doses.

More groundbreaking, though, will be expansion of vaccine production in Africa. From late 2022, the Pasteur Institute of Dakar in Senegal will start producing 25 million doses of coronavirus vaccines a month, with international backing. Vaccine capacity will also rise in Egypt, South Africa and Morocco as existing plants expand.

Other medicines will see some supply-chain problems – albeit not as extreme as in other markets. The disruption suffered in 2020 - when many countries were scrambling for medtech supplies - has died down, but the pharmaceuticals industry is still suffering from the rapid rise in shipping and delivery costs, particularly in Asian shipping routes.

Coronavirus cases and power cuts are also causing occasional production stoppages in China, affecting supplies of active pharmaceutical ingredients as well as inputs such as magnesium

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- **Walgreens** is offering **Pfizer, Moderna** and **Johnson & Johnson** COVID-19 vaccine boosters to individuals 18 years and older at all its locations. News of the initiative follows the **U.S. Food and Drug Administration's (FDA)** decision to expand the Emergency Use Authorization for Pfizer and Moderna vaccine boosters. It also follows the Centers for Disease Control and Prevention's guidance for issuing boosters to individuals aged 18 and older, according to the company. Appointments for vaccine boosters can be made online through the Walgreens app or by telephone. Currently boosters are approved for individuals as young as 16 years of age, and approval by the FDA for those as young as 12 is expected in the coming weeks.
- With the **FDA** granting emergency use authorization (EUA) to **Pfizer's** oral COVID-19 therapy *Paxlovid*, the company is devising ways to increase awareness of the new treatment option and ensure patients can gain quick access to the new therapy. The EUA was granted on December 22nd and covers use in patients 12 years of age and older weighing at least 40kg for the treatment of mild-to-moderate COVID-19 in patients at high risk of progression to severe disease, including hospitalization or death. Treatment should be initiated as soon as possible after positive COVID test results and within 5 days of symptom onset.
- Pharma manufacturer **Shionogi** announced that its oral COVID-19 treatment *S-217622* showed high antiviral activity against the Omicron variant of COVID-19 in

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Latest Chinese Drug Coverage Comes At A Steep Cost with Price Cuts & Caveats

(Source: An article by Dexter Yan for Scrip Intelligence, Dec. 2021)

November negotiations in China over the prices of 67 new drugs have resulted in record price cuts, averaging around 62% overall and 65% for anti-tumor products. But the sting is alleviated by the prospect of substantial volume increases. And while pharmaceutical firms in China are getting faster insurance coverage for newly approved drug, it comes with the cost of steep price reductions.

A total of 22 novel products developed by Chinese biotechs were included in the latest annual update of the country's national reimbursement drug list (NRDL) after rounds of price concession discussions organized by the National Healthcare Security Administration (NHSA) in November, according to official results published by the NHSA. Inclusion in the NRDL will enable the drugs to enter the Chinese public hospital market

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(used to make aluminium foil packaging). The effect is likely to last into 2022, and will push the EU and US, among others, to move ahead with the reshoring initiatives they started last year, when supply-chain disruption underlined their reliance on China. New regulations will also hold risks. The EU, for example, plans

Pharmaceutical Sales in 2022	US$ billion
North America	493.7
Western Europe	332.6
Central and Eastern Europe	92.5
Asia & Australasia	445.5
Latin America	76.7
Middle East & Africa	19.6
World Total	1460.5

a full overhaul of its regulatory framework for pharmaceuticals, encompassing everything from incentivizing innovation to securing supplies and ensuring equal access.

The pharmaceutical industry is likely to be most concerned about the European Commission's efforts to boost market competition, with the aim of promoting generics and bringing down prices. A promise to overhaul the R&D incentives on offer, such as extended marketing exclusivity, will also ring alarm bells, although the results are unlikely to involve drastic cutbacks. As always, the Commission will need to tread carefully between innovation and affordability. Other countries are also pursuing new regulations.

In 2022 Japan will implement the final stage of its rules requiring barcodes on pharma packaging – the kind of small-sounding reform that can be surprisingly difficult to implement. In China, meanwhile, drugmakers are still feeling their way forward as the National Health Commission tries to centralize and streamline drug procurement processes, including instructions designed to ensure "more rational drug use".

China is progressively improving the environment for innovation, with firmer patenting rules, the emergence of bioclusters, and faster approval processes. Chinese biotech companies are growing rapidly, aided by both public and private funding.

Not only is global R&D spending in good shape, but the pandemic has accelerated several pathways to innovation. One is the access to and use of digital data to drive research. Pharma companies may not want to repeat the cooperative data sharing that helped them to develop COVID vaccines, but the data analytics tools are still there and being used.

The sudden move from site-based clinical trials to virtual trials during lockdowns, though painful at the time, has opened up new ways of getting such trials done quickly. The same has happened for diagnostics, with the rapid roll-out of home testing kits. Liquid biopsies, an innovation that predated the pandemic, are now helping clinicians to catch up with missed non-COVID investigations. And mRNA and lipid nanoparticles, the innovation behind some of the vaccines, may have new uses for other treatments. The pandemic was an ill wind for the world, but it has blown the pharma industry some good.

Latest Chinese (cont.)...

beginning January 1, 2022 when the newly negotiated prices will be implemented nationwide.

To qualify for inclusion and pricing negotiations, originators had to have secured regulatory nods for their products by the end of June. In the first half of 2021, a total of 21 innovative medicines – mostly developed by domestic companies – won approval in China. The figure exceeded the 20 approved in the same period of 2020.

Those with a national "major new drug" designation fared better in the brutal price negotiations. A total of 46 domestically developed products have obtained the designation since 2018 and garnered comparatively higher premiums during the price negotiations with the NHSA.

Meanwhile, the overall price reduction for the 67 new drugs included in the NRDL this year was higher at 61.7% and was 64.9% for the listed oncology medications on average. This was deeper than the 50.6% and 60.7% for all drugs in 2019 and 2020, respectively.

While inclusion comes at the cost of such price cuts, Chinese firms will generally benefit from the NRDL listing as they lay a solid groundwork for future commercialization efforts.

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nonclinical preliminary testing, as also observed against other existing strains of the virus. *S-217622* is an antiviral agent that selectively blocks the 3CL protease, an enzyme necessary for viral replication. The drug is currently being investigated in Phase II/III studies in Japan, with the company preparing to launch an overseas trial as well.

- Among 19 of the largest U.S. and European biopharmaceutial companies, **Bristol Myers Squibb**, **Amgen** and **Pfizer** will face exposure of a large portion of their 2025 revenues to generic or biosimilar competition due to patent cliffs, according to **SVB Leerink**. By contrast, **Vertex**, **Sanofi** and **Novo Nordisk** are expected to have the smallest erosion in revenue due to patent cliffs.
- The Biden administration announced the purchase of a half-billion at-home rapid COVID-19 tests and a plan to distribute them free to Americans who request them through a website. The 500 million new tests will be made available next month and will reach Americans through the mail. The administration is still working to determine how many tests each household may request. Also starting next month, private insurance will cover at-home testing so that individual can get reimbursed for those orders and additional plans will be put in place to provide tests to those who don't have insurance.
- Thirteen Indian pharmaceutical companies, including **Torrent Pharmaceuticals**, **Cipla Pharmaceuticals**, **Sun Pharma**, **Dr Reddy's**, **Natco Pharma**, **Mylan**, **Hetero**, and **Optimus Pharma** will manufacture *Molnupiravir*, developed by US-based biotech company **Ridgeback Biotherapeutics** in collaboration with US Pharmaceutial manufacturer **Merck & Co**. With the **Drugs Controller General of India (DCGI)** emergency use authorization for the generic version of Merck and Ridgeback's oral COVID-19 antiviral medicine *Molnupiravir*, these companies are gearing up to launch the oral anti-COVID drug with the aim of strengthening the COVID-19 battle in the country. According to findings from an interim analysis of the Phase 3 MOVE-OUT trial, the drug reduced hospitalisation or death by approximately 50% in non-hospitalized adult patients with mild-to-moderate COVID-19.

(Sources: Company Press Releases, Drug Store News, FierceBiotech, FiercePharma, Medical Dialogues, Pharma Japan, and World Pharma News)