IFPW FOCUS IFPW
Vol. 27, No. 14 International Federation of Pharmaceutical Wholesalers July 2, 2020

Gilead Sets Price for Remdesevir

(Source: An article by Mandy Jackson for Scrip Intelligence and a Press Release by Bloomberg)

The pricing of *remdesevir* has been highly anticipated since, to date, the drug shows the greatest promise in effectively treating COVID-19. Gilead Sciences revealed pricing in late June that is less than at least one model of fair costs for the antiviral. While donated supplies are beginning to dwindle in many countries, the U.S. Department of Health and Human Services (HHS) has struck a deal with Gilead which may mean that U.S. hospitals will be the first to receive *remdesevir*, at least for the next few months.

According to Gilead's CEO Daniel O'Day in a letter released June 29th, the pricing for *remdesevir* will be US$390 per vial for government payers in developed countries and US$520 for commercial payers in the U.S. This translates to a cost of US$2,340 for governments and US$3,120 for U.S. health plans for a six-vial five-day course of treatment. O'Day stated, "there is no playbook for how to price a new medicine in a pandemic," but noted that Gilead approached this with the aim of helping as many patients as possible, as quickly as possible and in the most responsible way. "The price will make sure that all patients around the world have access to this medicine," O'Day stated.

Results from a study of *remdesevir* conducted by the National Institute of Allergy and Infectious Diseases (NIAID) showed that hospitalized patients with COVID-19 that were treated with *remdesevir* were discharged four days earlier than those who received a placebo. This translated into a cost savings of US$12,000 per patient in the U.S.

While HHS will not receive a price cut for *remdesevir* in its agreement with Gilead, it will receive nearly all supplies of the product manufactured through September. This includes more than 500,000 course treatments that HHS will allocate to state and territorial health departments which will in turn distribute the drug to hospitals based on each facility's COVID-19 burden. Once supplies are less constrained, HHS will no longer manage allocation of *remdesevir*. Gilead expects *remdesevir* supplies to be more readily available by the end of September.

AmerisourceBergen will ship the HHS *remdesevir* drug supplies and no hospital will pay more than Gilead's wholesale acquisition cost for U.S. commercial payers. HHS notes that most Americans will not pay directly for *remdesevir* since it will be included in the overall cost of hospital care covered by Medicare and private insurers. The US$2,340 government price will be applicable only to the "Big Four" federal agencies – Veterans' Affairs, Indian Health Services, Department of Defense and the Coast Guard – and other government direct purchasers, such as the Federal Bureau of Prisons. Since Medicare and Medicaid are not direct purchasers of drugs administered in an in-patient setting, hospitals purchase at commercial prices and are reimbursed by the appropriate agency under set rates under bundled payment agreements for hospital services.

(continued on page 2)

In Brief...

- U.S.-based pharmaceutical manufacturer **Johnson & Johnson** announced that it will advance its schedule of starting human trials of its candidate COVID-19 vaccine to the second half of July from September and is working on simultaneous fronts to expand existing manufacturing capacity and establishing new units according to chief scientific officer *Paul Stoffels*. The company began developing a COVID-19 vaccine in January and is using the same technologies it used to make its experimental Ebola vaccine, which was provided to people in the Democratic Republic of Congo in late 2019. The technology involves combing genetic material from the coronavirus with a modified adenovirus that is known to cause common colds in humans. Separately, the company is in advanced talks to supply Europe with its COVID-19 vaccine once it is proven safe and effective. Currently AstraZeneca has already struck a deal with four European countries to supply a vaccine.
- **Bayer** announced its support of *"The Challenge Initiative"* with a payment of US$10 million. The initiative provides women and girls living in urban poverty in cities within Africa and Asia with family planning and reproductive health solutions. The Challenge Initiative is led by the **Bill and Melinda Gates Institute on Population and Reproductive Health** within the **Population, Family and Reproductive Health Department at the Johns Hopkins Bloomberg School of Public Health**.
- **Boehringer Ingelheim** named *Jean-Michel Boers* as U.S. country managing director, president and CEO, effective

(continued on page 3)

26 Japan Drug Makers Generate 56.4% Overseas in FY2019

(Source: Pharma Japan)

Combined sales of 26 major Japanese drug makers rose 15.6% to 11.3 trillion (US$104.9 billion) in FY2019, helping to offset sluggish revenue growth domestically, according to a Jiho tally. Takeda Pharmaceutical's Shire acquisition last year was influential on the overall tally, particularly the average offshore sales ratio, which rose as high as 56.4%.

Included are members of the Japan Pharmaceutical Manufacturers Association (JPMA) listed in the first section of the Tokyo Stock Exchange whose pharmaceutical businesses account for roughly 50% or more of their total sales. In FY2019, the number of companies decreased to 26 due to the delisting of Mitsubishi Tanabe Pharma, which became a wholly-owned subsidiary of Mitsubishi Chemical Holdings.

The Japanese pharma industry overall generated higher profits on high revenue. The 26 companies' total sales was up

(continued on page 3)

Gilead (cont.)...

The highly anticipated pricing of *remdesevir* has been the subject of much discussion as donated supplies began running low. The U.S. watchdog group, The Institute for Clinical and Economic Review (ICER) studied two different models to determine a fair price for COVID-19 treatments. According to ICER, a full course treatment of *remdesevir* priced at US$4,500 would be a reasonable price based on ICER's typical cost-effectiveness criteria for new medicines. On June 24th, ICER revised its assessment saying that US$1,010 to US$1,600 would allow Gilead to cover its R&D manufacturing costs and US$4,580 to US$5,080 would be a fair price based on the drug's cost effectiveness.

Gilead has also entered into agreements with several generics manufacturers to produce and sell *remdesevir* at local prices in more than 100 developing countries. The company has also penned non-exclusive licensing agreements with nine companies to manufacture and distribute generic versions in 127 developing countries. Several strategies to support access to *remdesevir* for countries not covered are being explored as well. Hetero and Cipla have already launched their generic versions of *remdesevir* under the name *Covifir* in India.

Gilead will study inhalable *remdesevir* in volunteers as early as August. Currently, *remdesevir* is not approved by the U.S. Food and Drug Administration, but the agency granted an emergency use authorization (EUA) to allow for use in the U.S. On June 26th, The European Medicines Agency's Committee for Medicinal Products for Human Use (CHMP) recommended on that the EU grant conditional marketing authorization for *remdesevir,* with a final decision by the European Commission expected any day. Early access was granted by the U.K. in May.

Pharma Sector in India is Challenged with Clearance of Imported APIs and Medical Devices

(Sources: Two articles from the Economic Times the Business Standard)

The strict customs scrutiny and non-clearance of imports from China is now challenging India's pharmaceutical sector, forcing industry representatives to reach out to the government seeking urgent clearance of goods at ports and airports.

The Pharmaceuticals Export Promotion Council (Pharmexcil) has said it is flooded with distress calls from its member companies over serious disruptions in manufacturing of products recently due to non-clearance of imported raw materials at various ports. A senior official of the ministry of commerce said most of the goods that must be cleared by the customs came from China.

In a letter written on January 27 to the Secretary, Department of Pharmaceuticals, Pharmexcil chairman Dinesh Dua said very critical key starting raw materials (KSMs), intermediates and active pharmaceutical ingredients (APIs) are not being cleared for reasons "not known to the industry at all." Even in the case of medical devices and diagnostics critical devices such as infrared thermometers and pulse ox meters, (which are specifically aimed at COVID-19 diagnosis), glucometers and strips are also held up. "We urgently appeal to you to kindly intervene in the matter on SOS and kindly instruct that clearances from customs are permitted and all these materials which are genuine in nature are allowed to be cleared and dispatched to ensure there is no disruption of manufacturing at all under any circumstances," Dua said.

During current distressed and challenging times of the global COVID-19 pandemic, the pharmaceutical industry of India has risen to meet the challenges and continues to ensure there are sufficient drug quantities in the country. He said the pharma exports grew by 27% in May 2020 over 2019 surpassing US$2 billion.

"With the above stated objectives, now man-made disruptions as stated above have created tremendous difficulties for the industry. We sincerely fear that if the same are not expedited on top priority in terms of clearances whatever great work has been done in the past through your good offices to help the industry to maintain the current 90-100% production and supply chain may get completely diluted," the pharma body head said.

Pharmexcil is yet another industry body which has recently reached out to the Indian government and raised concerns over the delay in customs clearance and its impact on the supply chain. Other industry organizations, including the Apparel Export Promotion Council and the India Cellular and Electronics Association have also contact government officials regarding early customs clearance of the imported goods needed for their manufacturing process.

Enter AI: How Technology is Changing the Pharmaceutical Industry for the Better

(Source: An article by Doug Zurawski for PharmD)

It is nearly impossible to discuss the future of any industry without mentioning machine learning and artificial intelligence (AI). Whether it is retail, manufacturing, or the health care industry at large, the discussion around the benefits continues. But for every conversation that focuses on the benefit of AI technology in health care, there is also a debate about the potential drawbacks, the most common being that AI is going to replace jobs.

AI is not replacing human involvement. Instead, it positions employees for success by freeing them up from what are often tedious, repetitive tasks to allow them to focus on patient safety, staff protection, and other clinical-oriented efforts. The pharmaceutical industry is already seeing the immense benefit of AI and machine learning technology. Pharma is currently facing challenges that affect providers, payers, and most importantly, patients. Some of the most widely discussed issues include drug shortages, drug recalls, and the opioid epidemic, all occurring while the industry deals with the challenges of the coronavirus disease 2019 (COVID-19) pandemic. Although these issues seem grim and overwhelming, AI is strategically positioned to help us better address all three areas.

Drug shortages typically occur due to as manufacturing issues or regulatory delays. They can also occur during widespread crisis situations, such as the COVID-19 pandemic, in which drugs like penicillin, aspirin, and ibuprofen are unable to be safely made and transported to the United States. AI is aiding in addressing drug shortages by examining mass amounts of data on current medications and their applications, and then actually predicting how they can be used in new ways to create effective treatments. This could address drug shortages by expanding the medications that are available and proven to treat a specific

(continued on page 3)

AI (cont.)...

disease. The automation of this task is a major relief to researchers in the pharma industry and assists in getting to life-sustaining—or even lifesaving—therapies more quickly. AI also shows promise concerning general insights into every facet of the supply chain. It can analyze trends in inventory management from manufacturer to patient use, which can help predict drug shortages before they happen.

Drug recalls occur when a medication in the supply chain is contaminated or compromised, making the output medication unsafe for prescribing. Drug recalls are another major challenge and can have very serious consequences for providers and patients. Medications are recalled for the protection of patients from contamination or adverse effects, but patients may need that medication to survive, leaving providers in very tough situations. Through the use of AI, we have the potential to pinpoint exactly where any contamination or defect originated in the supply chain, allowing teams to correct or work around the issue more efficiently than otherwise possibly using manual research-based processes. With AI-enabled item level visibility software solutions, the pharma supply chain can track every vial and syringe from manufacturer to patient, ensuring a recall is executed as quickly as possible and without creating cascading roadblocks to patient care.

The opioid epidemic is another ongoing, very serious topic of concern in the industry, fueled by years of insufficient oversight and a lapse in true medication intelligence. AI and machine learning tools provide a unique opportunity to combat this nationwide issue. The opioid epidemic is perhaps one of the most severe issues facing the pharma industry. More than 750,000 people have died from drug overdoses since 1999. This has become such a concern that higher education has taken steps to help prepare young pharmacists to navigate this aspect of their responsibilities. Universities and colleges are addressing the subject through seminars, community work and course content that teach students about medication management and how to handle drug diversion incidents. AI-powered technology provides increased insight into prescribing habits and visibility into the chain of custody of controlled substances. As AI is able to analyze huge data sets of provider behaviors, the technology can see abnormalities in the management of these medications.

Another important aspect in the use of AI gives pharmacists an opportunity to take an active role in patient care, which is extremely important as value-based care models continue to take center stage in the health care space. Pharmacists are highly trained in patient care and yet, they must act as de facto supply chain experts to keep their hospital stocked with the medications it needs. With AI, pharmacists can direct their energy toward patient care.

McKinsey estimates that machine learning and big data in the pharmacy and medical space could amount to a value of US$100 billion annually. Although some remain skeptical about the potential of AI, it is clear to see that the pharmaceutical industry is particularly poised to improve and thrive through its usage.

Japan (cont.)...

15.6% year-over-year with combined operating profits up 8.5% and net profits up 4.7%.

While the Shire buyout was a drag on profits, the overall revenue growth was attributable to the addition of Shire products to Takeda's sales.

Adversely, midsize companies with low overseas sales ratios continue to struggle overall. Fourteen of these companies saw combined sales fall 3.8% while operating profit fell 6.6%. Companies mainly operating in Japan were hard hit by ad-hoc drug re-pricing associated with the consumption tax hike in October of 2019.

FY2019 revenue showed Takeda was by far the largest drug maker in Japan, with Otsuka Holdings moving up to second to replace Astellas Pharma, which ranked third. Torii Pharmaceutical's sales dwindled following the return of its HIV franchise to Gilead Sciences, with its ranking falling from 20th to 23rd. The followng is a list of the top 26 companies.

Ranking	Company	Ranking	Company
1	Takeda	14	Tsumura
2	Otsuka Holdings	15	Nippon Shinyaku
3	Astellas	16	Kyorin Holdings
4	Daiichi Sankyo	17	Mochida
5	Eisai	18	Kaken
6	Chugai	19	Kissei
7	Sumitomo Dainippon	20	Zeria
8	Shionogi	21	ASKA
9	Kyowa Kirin	22	Fuso
10	Ono	23	Torii
11	Taisho Pharmacuetical	24	Nippon Chemiphar
12	Santen	25	Seikagaku
13	Hisamitsu	26	Wakamoto

In Brief (cont.)...

August 1, 2020. He will succeed *Wolfgang Baiker*, who is retiring after 31 years on July 31. Currently Boers serves as president of the company's U.S. commercial and medical organization.

- According to a newly released intelligence report, the United States is likely to see shortages of generic drugs if the COVID-19 outbreak continues. The report, prepared by the **Department of Homeland Security**, warns that the U.S. is already seeing shortages of more than 200 drugs and medical supplies due to strains on the supply chain cased by international shutdowns at the onset of the pandemic.
- On June 8th, the **U.S. Food and Drug Administration** issued temporary guidance to address concerns related to distribution of drug samples during the COVID-19 pandemic. Under an exercise of enforcement discretion, the FDA has declared it will not enforce certain requirement of the *Prescription Drug Marketing Act of 1987* and its implementing regulations during the pandemic with respect to the distribution of drug samples by mail or common carrier. Specifically, the FDA has expressed willingness to allow drug samples to be shipped directly to patients' homes and to allow for alternative forms of receipt and verification.

(Sources: ABC News, Company Press Releases, Drug Store News, Fierce Pharma, Lexology, and Supply Chain Brain)