



Finding Solutions to Critical Drug Shortages

(Sources: An article by Zoe Becker for FiercePharma, an article by Jamie Smyth for The Financial Times and an article by CNN)

There is a crisis brewing that is affecting as many as a half million critically ill U.S. patients awaiting life-saving treatments. A severe shortage of cancer therapies is forcing thousands of these patients to miss treatments, according to several leading healthcare organizations, including the American Society of Clinical Oncology. Their chief medical officer, Julie Gralow, stated that hospitals are already rationing some drugs, and doctors are being forced to make difficult decisions about delaying chemotherapy treatment or resorting to substitute medications which may not be as effective.

Among the drugs in short supply are *cisplatin* and *carboplatin*, both platinum-based drugs used to treat a variety of cancers (*cisplatin* is used to treat testicular, bladder, cervical, ovarian, lung, gastric, breast, head and neck cancers.) A total of 301 drugs across all therapeutical areas were listed as “in shortage” at the end of March, including a total of 15 cancer therapy drugs. This is the highest number in nearly a decade, according to the American Society of Health System Pharmacists. The shortages can be found across 40 U.S. states.

Some newly developed oncology treatments, such as Novartis’s prostate cancer therapy *Pluvicto*, are also in short supply. The company temporarily had to stop taking on new patients in February was able to once again accept new patients in April.

Supply chain experts say generic drugs that require complex manufacturing processes to produce are the most vulnerable to these shortages. They make up 90% of all drugs sold in the U.S. but just 18% of all drug costs. Most of these current drug shortages include generics. According to some experts, the generics industry has become a “race to the bottom” on price that made quality control more difficult, particularly for complex medicines such as chemotherapy drugs.

When only a few companies supply a certain medicine, a single event can cause type of “perfect storm event” which is what is currently happening. With *cisplatin* and *carboplatin* specifically, the shortage started at one manufacturing facility in India run by Intas Pharmaceuticals after the FDA identified quality issues after an inspection. Once this occurred, the plant was shut down, rippling down through the entire supply chain.

The FDA has the ability to help mitigate cancer drug shortages, but those levers which it can pull are limited. The agency has offered assistance to the five manufacturers that produce *cisplatin* and is exploring “temporary importation” from other countries, including China, to mitigate the problem. As an example, Canadian-based manufacturer Apotex will oversee the

(continued on page 2)

In Brief...

- ◆ **Walgreens Boots Alliance (WBA)** announced the sale of shares of **AmerisourceBergen Corporation (ABC)** pursuant to variable prepaid forward transactions executed in reliance on Rule 144 for current proceeds valued at approximately US\$644 million. Proceeds from the sale will be primarily used for paydown of WBA debt and for general corporate purposes. There are no changes to WBA and ABC’s ongoing collaboration and long-term strategic partnership.

- ◆ Global conglomerate **Bayer** is launching a precision health unit as it ramps up its investment in consumer-facing digital health tools. The company will prioritize developing products that enable people to take great control of their own personal health through digital solutions that facilitate more informed choices based on personal insights and novel delivery mechanisms. Technology advancements have enabled a wave of new digital products such as diagnostics, apps and therapeutics to help consumers better manage their health.

- ◆ **Pfizer** has received **U.S. Food and Drug Administration’s (FDA)** approval of its RSV drug *Abrysvo* for use in adults 60 years of age and older. Both Pfizer and **GlaxoSmithKline** (who won approval of their RSV candidate earlier in May) plan to launch their offerings ahead of the upcoming RSV season, which typically starts in the late fall. Separately, Pfizer has reported Phase 3 data that suggests its hemophilia candidate, *marstacimab*, has shown great results with a 35% reduction in the annualized bleeding rate of patients with version A or B of the disease. Both Pfizer’s *marstacimab* and Novo Nordisk’s *concizumab* target the Kunitz-2 domain of tissue factor pathway inhibitor (TFPI), a natural anticoagulation protein.

- ◆ In the first lawsuit of its kind, **Merck & Co.** is suing the **U.S. Department of Health & Human Services** for violations of the First and Fifth Amendments to the U.S. Constitution. Under the *U.S. Inflation Reduction Act*, Medicare will begin negotiating prices for the drugs it spends the most on beginning in 2026. Because companies cannot walk away from these negotiations,

(continued on page 2)

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Drug Shortages (cont.)...

importation and distribution of cisplatin to the U.S. from China on a temporary basis.

Some companies have been reporting to the FDA that manufacturing costs have exceeded sales prices, forcing them out of certain markets. One potential solution could be a government contract with manufacturers to produce a “buffer stockpile” of essential oncology drugs.

Ultimately, the FDA says it cannot solve this problem on its own. It will take an investment by the industry to institute the appropriate measures to increase capacity. However, the FDA does not have the authority to force manufacturers to take the steps needed to build up their manufacturing capabilities.

Top Four Wholesalers in Japan see 30% Operating Profit Rise in FY2022

(Source: An article by Yuki Kato for Pharma Japan)

After weathering the period which was hardest hit by COVID-19, Japan’s Big 4 pharma wholesalers delivered growth in both combined sales and profits in FY2022 (ended March 2023), setting the stage for a further recovery going forward. This is excellent news for Japan’s wholesale industry, but there continues to be uncertainties over whether this trend will continue post-pandemic.

According to Jiho tally, total sales for the Big 4 came in at ¥8,147.8 billion (US\$58.3 billion), a 4% increase year-over-year in FY 2022, with an operating profit of ¥86.4 billion (US\$618.6 million). Three companies (excluding Toho Holdings) cleared the 1% mark in operating profit margins considered essential to stay in business.

By company, operating margins came in at 1.21% for Suzuken, 1.13% for Alfresa Holdings, 1.0% for Medipal Holdings and 0.78% for Toho Holdings, which works out at an average of 1.06%. This was up 0.18 points from the 0.88% seen in the first half of FY2022 (April-September 2022), signaling an improvement towards the latter part of the fiscal year.

The companies’ latest scorecard further illustrates an earnings recovery from FY2020 when their average operating margin sank to as low as 0.49% during the pandemic. However, this recovery trend may see a slowdown in the ongoing year through March of 2024. As Japan transitions into a post-pandemic phase with the severity reclassification of COVID-19, there remains uncertainties around future demand of COVID-19 drugs and test kits which have driven the earnings of these wholesalers in the recent years.

Suzuken President Shigeru Asano predicted that an anticipated decline in demand for COVID-related products could push down the company’s earnings. “We estimate a 60% decline for the distribution of government-purchased COVID-19 treatments. We also assume an 80% decline for PCR and other testing reagents (in our forecast),” he said.

Ryuji Arakawa, President of Alfresa Holdings, said the company is carefully monitoring the impact of the COVID-19 severity downgrade to “Class 5” and the ninth wave that might come later this year. “Since there are unpredictable factors, we made a very conservative sales forecast for this fiscal year, assuming minimal figures for COVID-19 vaccine delivery charges and for COVID-19 treatments. There will be more or less a

negative impact,” he elaborated.

Amid uncertainties over COVID-related demand, what is needed for wholesalers now would be thorough profit management for individual product transactions. As manufacturers’ rebates and allowances decrease year after year, wholesalers are now seeing weaker incentives for their business practice where they give deep discounts in some transactions as long as they can meet the gross target. With some regional distributors starting to end unprofitable trades, wholesalers should sharpen their commitment to profitability in each and every transaction to secure sustainable growth in the future.

In Brief (cont.)

some industry leaders have said that this setup is akin to “price controls.” If in violation of the Fifth Amendment, the government would be required to fairly compensate companies or individuals for property that is used for the public good. In addition, Merck says the Medicare pricing negotiation setup would force companies to sign contracts that they otherwise would not enter into, making it a violation of the First Amendment.

- ◆ **Celltrion** has received **U.S. FDA’s** approval for *Yuflyma (adalimumab-aaty)*, a high concentration and citrate-free formulation of the *Humira (adalimumab)* biosimilar. The FDA approved treating eight conditions – rheumatoid arthritis, juvenile idiopathic arthritis, psoriatic arthritis, ankylosing spondylitis, Crohn’s disease, ulcerative colitis, plaque psoriasis and hidradenitis suppurativa. “*Yuflyma* offers patients a high-concentration and citrate-free formulation of the *adalimumab* biosimilar, providing an alternative treatment option for patients, and represents a key treatment option in patient care and patient choice,” said *Tom Nusbickel*, Celltrion’s Chief Commercial Officer.

- ◆ According to the latest projections by **Bloomberg Intelligence**, newly branded anti-obesity drugs are set to bring in US\$44 billion in sales by the end of the decade. Nearly 70% of that figure will come from the U.S., with a slower ramp up in Europe. “We expect Novo Nordisk’s franchise [*Saxenda* and *Wegovy*] and Eli Lilly’s *Mounjaro (tirzepatide)* to dominate with shares of 54% and 46% respectively,” said *Michael Shah*, senior industry analyst at Bloomberg Intelligence, in the report. More drugs on the horizon could bump up those estimates.

- ◆ An evaluation of 14 studies (with 105,000 participants) of the highest quality conducted at the **German Cancer Research Center** has determined that Vitamin D intake could reduce cancer mortality in the population by 12% - provided the vitamin is taken daily. Vitamin D deficiency is widespread worldwide and is particularly common among cancer patients. Averaged over the year, the vitamin D blood levels of about 15% of the German adults are below the threshold for a pronounced vitamin D deficiency. In contrast, in a study of colorectal cancer patients, researched diagnosed vitamin D3 deficiency in 59% of participants, which was also associated with unfavorable prognosis.

(Sources: Company Press Releases, Drug Store News, FiercePharma, Reuters, and World Pharma News)