IFPW FOCUS
A Bi-Weekly Pharmaceutical Industry Newsletter
Vol 32 | No. 3
February 1, 2024

A More Sustainable Future for the Pharmaceutical Industry

(Source: An article by Scrip Intelligence)

Companies across all industries and regions are under pressure to focus on more environmentally sustainable operations. With alarming repercussions of increased global warming already in play, how to affect change is top of mind.

"Global climate change is appropriately in the news every day, and the pharmaceutical industry has played it role in creating negative environmental impacts," stated David Maier, Vice President and General Manager, Global Generics Market Unit at West Pharmaceutical Services, a leading supplier of packaging and services for injectable medicines. Studies have reaffirmed this stance, highlighting pharmaceuticals as a significant contributor to global warming.

As pharma companies look to adopt greener, more sustainable processes, old ways of working require change, presenting opportunities to innovate and optimize existing practices to affect lasting impact.

This includes initiating balance to achieve sustainable generics. Generics are known for their cost-effectiveness. Balancing sustainability initiatives with financial constraints can be difficult due to requirements of upfront investments that may not yield immediate returns. Regulatory compliance is also key, along with additional spending needed to ensure that eco-friendly processes and technologies adhere to these requirements.

Additionally, it is not enough to change just one aspect of the generics manufacturing process. The industry relies on the global supply chain for raw materials and active pharmaceutical ingredients (APIs). If one part fails to meet sustainability criteria, it can mitigate the positive steps taken in other areas.

These challenges require the industry to come together. Maier asserts that collaboration between vendors and customers is critical to improve sustainability and address emissions, energy, and water usage, along with waste reduction.

One challenging area for meeting ESG goals is packaging, in particular, glass vials used for single-use sterile injectable medicines, which result in significant waste. While it is clear that decisions need to be made regarding product design, eliminating single-use glass vials is not viable due to sterility and patient safety requirements for generic products. However, the industry is working towards the creation of greener alternatives. For instance, West Pharmaceuticals has partnered with Corning Incorporated to distribute Viridian™ Vials – an improved Type 1 borosilicate vial – that will provide both operational and environmental improvements over what is currently available on the market.

Creating operational efficiency and safeguarding product

(continued on page 2)

In Brief...

- Global wholesaler and distributor **Cencora** reported robust financial results for the first quarter of fiscal 2024, with revenue of US$72.3 billion, a 15% increase year-over-year. GAAP operating income came in at US$8232 million (adjusted to US$886 million), a 30% increase from the previous year. "Cencora had an exceptional start to our fiscal 2024 year, delivering strong results as we capitalize on the strength of the trends in our business, continue to prioritize customer centricity and enhance the services we provide, further differentiating the value we bring to our customers and stakeholders," said *Steven H. Collis*, Chairman, President, and Chief Executive Officer at Cencora.
- **Sigma Healthcare Limited (Sigma)** announced it has entered into a Merger Implementation Agreement (MIA) with **CW Group Holdings Limited (CWG)** to create a leading healthcare wholesaler, distributor, and retail pharmacy franchisor. In addition, Sigma has undertaken a fully underwritten pro-rata accelerated non-renounceable entitlement offer to raise gross proceeds of approximately AU$400 million (US$264.4 million) to provide increased working capital required to implement the CWG supply contract which commences on 1 July 2024, and for business growth initiatives. The combination of Sigma and CWG is considered a transformational and compelling transaction for both companies.

(continued on page 2)

U.S. FDA Aims to Initiate an Agencywide Overhaul in 2024

(Source: An article by Alexanda Pecci for PharmaVoice)

A proposed FDA reorganization might have food safety in mind first and foremost, but stakeholders across industries that fall under the FDA's reach will feel the effects of what associate commissioner for regulatory affairs Michael Rogers called "the largest reorganization in FDA's history."

The wide-ranging reorganization would replace the Office of Regulatory Affairs (ORA) with the FDA Office of Inspections and Investigations (OII). It would also touch "directly or indirectly, about 8,000 FDA employees," Rogers said on a webinar hosted by the Alliance for a Stronger FDA.

After its response to the 2022 infant formula crisis, which the agency's food safety director admitted was too slow, the FDA asked the Reagan-Udall Foundation, an independent industry watchdog, to conduct an operational review of its Human Foods Program.

The reorganization, which the FDA announced in December

(continued on page 2)

ESG (cont.)...

quality is critical to the longevity of sustainable practices. If changes result in increased expenditures and inefficient outcomes, companies will not embed these strategies into their operations. This is particularly the case for generics firms.

To keep on track, most companies now have clear sustainability plans or policies which govern their operations. Along with these policies, wider ESG priorities encompassing climate, reduction in operational waste, R&D dedicated to the environment, responsible supply chains, and attracting and retaining appropriate talent is all part of the overall picture.

"We must explore new processes and methods without diminishing the quality and efficacy of the products we make, and that our customers and patients rely on," Maier said.

FDA (cont.)

2023 and is undergoing federal review and approval, not only incorporated the review's findings as they related to the Human Foods Program but also included structural changes that would affect many FDA functions, said Principal Deputy Commissioner Dr. Janet Woodcock.

"Much of this was catalyzed by the Human Foods Program, but … this is a broader effort," Woodcock said. "We're trying to move toward [a] more enterprise-system, holistic look at how the FDA functions."

The proposed OII would oversee "the agency's field operations who carry out inspections, investigations, and import operations," according to the FDA. Ultimately, the goal is to put industries in more direct contact with inspectors to make communication more efficient.

Underneath the new office would be several specialized offices, including the Human and Animal Drug Inspectorate, Bioresearch Monitoring Inspectorate, Biologics Inspectorate and Medical Devices and Radiological Health Inspectorate.

"We think this will help ORA function better because they'll have more uniformity in how they're dealing with the various programs that they work with," Woodcock said.

In addition, the panelists said the new structure would be more streamlined and have greater budget transparency.

"This proposed organizational structure really makes FDA more efficient. It eliminates duplication of effort. It's a way to streamline decision making," Rogers said.

It will also change how regulated industries navigate the FDA.

"This will create new contacts for the regulated industry," Rogers saidelaborated. "We know that you all engage in regulatory meetings and discussions about responses to 483s and timelines associated with corrective actions."

Woodcock also mentioned that the FDA is trying to build a single, product-agnostic inspection platform. Although she didn't go into detail, she said the hope is that one day, "everybody will be online to the same platform."

"Eventually, as we get the platform running, I think there'll be even more efficiencies in bringing those programs together," she said.

Although the FDA reorganization is pending review, the agency hopes it will go into effect this year, the panelists said.

In Brief (cont.)

- Global pharmaceutical manufacturer **Johnson & Johnson (J&J)** reported 4th quarter and year-end results, with Q4 sales up 7.3% to US$21.4 billion, and 2023 full year reported sales growth of 6.5% to US$85.2 billion, including adjusted operational growth of 5.9%. "Johnson & Johnson's full year 2023 results reflect the breadth and competitiveness of our business and our relentless focus on delivering for our patients," said *Joaquin Duato*, Chairman and Chief Executive Officer. "We have entered 2024 from a position of strength, and I am confident in our ability to lead the next wave of health innovation."
- **Cardinal Health** announced that it has entered into a definitive agreement to acquire **Specialty Networks**, a technology-enabled multi-specialty group purchasing and practice enhancement organization for US$1.2B in cash. Specialty Networks creates clinical and economic value for independent specialty providers and partners across multiple specialty GPOs: UroGPO, Gastrologix and GastroGPO, and United Rheumatology. The acquisition of Specialty Networks demonstrates Cardinal Health's strategic prioritization of investing to accelerate growth in its Specialty business and provide leading-edge technologies, capabilities, and talent that address critical business and customer needs.
- **Sawai Group Holdings** (Japan) will exit the U.S. market with the sale of three of its U.S. subsidiaries to Taiwanese **CDMO Bora Pharmaceuticals**. The three units are the wholly owned subsidiary **Sawai America Holdings (SAH)**, **Sawai America LLC (SAL)**, and **Upsher-Smith Laboratories** (which is wholly owned by SAL). Sawai will sell their entire stake in these companies to Bora. **Sumitomo**, who also jointly holds SAL with Sawai Group Holdings, will also fully divest its interest.
- Senators on the U.S. Senate Health Committee are threatening to order CEOs from **Johnson & Johnson** and **Merck** to testify in the wake of the IRA legal fight (J&J and Merck are both plaintiffs.) Last summer many large pharma companies filed lawsuits questioning the constitutionality of the *U.S. Inflation Reduction Act (IRA)* price negotiation measures.
- **The Bayer Group** is introducing a new operating model called "dynamic shared ownership" worldwide, which will reduce hierarchies, eliminate bureaucracy, streamline structures, and accelerate decision-making processes. The goal of the new operating model is to make the company much more agile and significantly improve its operational performance. In a joint declaration, the Board of Management and employee representatives on the Supervisory Board have agreed on principles for the future of the company, including significant staff reductions expected during restructuring in Germany.

(Sources: Company Press Releases, Drug Store News, FiercePharma, FierceBiotech, Pharma Japan, Scrip Citeline, Yahoo! Finance, and World Pharma News)