



SERVICE MEMBER SPOTLIGHT - HLA Key Take-aways From the 12th International Conference on Pharmaceutical Cold Chain Logistics in China

(Source: An HLA staff article)

The 12th International Conference on Pharmaceutical Cold Chain Logistics was successfully held in Xuzhou last month, hosted by the China Federation of Logistics and Purchasing (CFLP), co-hosted by Shanghai Pharmaceutical Co., Ltd. and Jiangsu Jingchuang Electric Co., Ltd., and organized by the Healthcare Logistics Association of CFLP, the Aviation Logistics Committee of CFLP, and Shanghai Pharmaceutical Logistics Center Co., Ltd.

A premier event on pharmaceutical cold chain logistics, the conference served as a one-stop platform bringing together all stakeholders - from policymakers to corporate executives to renowned research institutes and influential experts - where attendees exchanged insights, explored opportunities and collaborated on topics in the sector. Beyond keynote speeches and panel discussions, the conference featured concurrent seminars, networking sessions, several ceremonies, and a site tour. Below are some of the key takeaways from the conference:

Policies and Standards

China rolled out its first five-year plan focused on shoring up the growth of cold-chain logistics begun in 2021. Pharmaceutical-related focal points identified in the document included improving the network of cold chain logistics facilities for pharmaceutical products and ensuring the supply of pharmaceuticals in case of emergency, including vaccines. In 2022, China released its first national five-year plan on modern logistics to accelerate building a modern logistics system and promote high-quality development, highlighting the need to improve the pharmaceutical logistics socialized service system, and foster third-party pharmaceutical logistics enterprises.

By the end of 2022, the Healthcare Logistics Association of CFLP had taken the lead in formulating and revising 13

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In Brief...

◆ **AmerisourceBergen** has changed its name to **Cencora** and is now trading under the NYSE ticker symbol **COR**. The company's corporate venture fund, **AB Health Ventures**, has also been renamed **Cencora Ventures**. According to Reuters, **Walgreens Boots Alliance** holds roughly a 16% stake in Cencora.

◆ The **U.S. Food and Drug Administration (FDA)** has granted **Pfizer** approval for **Abrysvo**, a respiratory syncytial virus (RSV) vaccine and the first vaccine approved for use in pregnant women to lower respiratory tract disease and severe lower respiratory tract disease (LRTD) caused by RSV in infants from birth through six months of age. **Abrysvo** is approved for use at 32 through 36 weeks gestational age of pregnancy and is administered as a single dose injection in the muscle. The FDA previously approved **Abrysvo** in May for the prevention of LRTD caused by RSV in individuals 60 years of age and older.

◆ The **Centers for Medicare & Medicaid Services (CMS)** unveiled its list of 10 drugs up for the first price negotiation under the **U.S. Inflation Reduction Act (IRA)**. Included are **Johnson & Johnson's Imbruvica, Stelara and Xarelto, Bristol**
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Drug Shortages are a Hot Button Issue for FDA

(Source: An article by Karissa Waddick for PharmaVoice)

From diabetes medications to chemotherapies and antibiotics, drug shortages are wreaking havoc on the U.S. healthcare system, leaving patients, practitioners and even top regulators wondering how to solve this challenge?

"I did not come back to the FDA to spend all my time on supply chain issues but that's what happened" FDA Commissioner Robert Califf said at a public forum hosted by the Alliance for a Stronger FDA.

Fixing the shortage crisis has proved to be problematic, with some drugs absent from pharmacy shelves for months. In July the number of medications in low supply reached a 10-year peak, according to a report from the American Society of Health-System Pharmacists, with the leading causes being foreign manufacturing, lack of supply chain oversight and declining investment in the generics industry.

Califf is advocating for improvements in reshoring, improved manufacturing practices, financial incentives and regulatory or government intervention.

"The fundamental problem is that we essentially have two drug industries in the U.S., and we have an industry which is continuing to leave the U.S. because it's not viable to run the business."

Approximately 90-95% of generics and sterile injectibles are developed using APIs from China and India. As prices erode,
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HLA Conference (cont.)...

standards under the guidance of the Pharmaceutical Logistics Standardization Working Group of SAC covering facility and equipment validation, pharmaceutical logistics, cold chain logistics, refrigerated vehicles for pharmaceuticals, carrier audits, and other critical issues. Among them, the national standard of "Operation specifications for medicinal product cold chain logistics" was widely recognized by the government and industry enterprises after nearly ten years promotion.

Cold Chain Logistics Industry for the Pharmaceuticals

According to the Healthcare Logistics Association of CFLP, the cold chain logistics market for the pharmaceutical industry in China was valued at about RMB 545.9 billion (USD\$75 billion) in 2022, with year-over-year growth of 18.93%.

According to the Healthcare Logistics Association of CFLP, the cold storage capacity for pharmaceuticals reached 4 million cubic meters in 2022, with year-over-year growth of 10.44%, and the number of refrigerated vehicles for pharmaceuticals was 14,500 in 2022, with year-over-year growth of 13.54%. Qin Yuming, Secretary-General of the Healthcare Logistics Association of CFLP, noted that enterprises should plan and design based on their own actual development needs when investing in the construction of cold storage, and should be rational in their planning. In addition, digitization and sustainability are also important development directions for cold storage construction in the future.

Industry Development

With the implementation of centralized procurement and other policies, the average price of drugs has dropped significantly while the cost of cold chain logistics has not been able to decrease simultaneously. Subsequently, the allocated cost per unit ratio has increased. For large-scaled pharmaceutical commercial enterprises, cold chain logistics cost could be controlled through increased freight volume and value added services such as one-stop service products and integrated solutions.

As an important part of modern logistics, pharmaceutical cold chain logistics has made great contributions to ensure the safety of the whole process from storage, transportation and distribution of pharmaceutical products. Accelerating the improvement of the safety system and strengthening enterprises risk control, as well as emergency management processes are crucial for the high-quality development of pharmaceutical cold chain logistics. The quality and safety of pharmaceutical products throughout the process will be better ensured by strengthening the nation wide or industry standards, using new technologies to achieve data transparency in the full chain, and strengthening staff skill training and internal control inspections.

ESG

ESG is now more important than ever in reshaping the pharmaceutical supply chain sector. Mark Parrish, President of IFPW, shared his insights from a global perspective in the keynote speech delivered at the plenary session. IFPW has assumed a leadership role for pharmaceutical wholesalers activities in ESG and created a framework for members to use and address ESG. The pharmaceutical supply chain's contribution to ESG issues is multifaceted, e.g., pharmaceutical products accessibility, carbon footprint, and pay equity.

Industry Outlooks

Cui Zhongfu, Vice President & Secretary-General of CFLP, noted in his opening remarks that the modern pharmaceutical cold

chain logistics industry has entered a new stage of high-quality development, and these four trends are shaping the industry of the future: accelerating cold chain logistics infrastructure network building; improving the industrial regulation system; stimulating green and low-carbon development; and sustainably improving technical innovation.

The 13th edition of International Conference on Pharmaceutical Cold Chain Logistics will be held in China, with dates and location to be announced at a future date.

The Healthcare Logistics Association, IFPW's newest service member, invited IFPW president, Mark Parrish, to present at the 12th International Conference on Pharmaceutical Cold Chain Logistics. IFPW is grateful to HLA for the opportunity and looks forward to welcoming HLA members to IFPW meetings in the future.

Drug Shortages (cont.)

the investment outlook in generics has also declined.

Califf argues that a "modification in the market" is needed but acknowledged that "it's not the FDA's job to fix." This translates to the fact that the FDA has low visibility when it comes to the pharma supply chain.

While Congress and the European Union are working on policy to address the situation, there is not much hope for a short-term solution. Califf said the FDA is working to improve its site inspections and quality management framework to ensure companies are operating appropriately and reducing redundancies in their supply chain. As far as long-term solutions, he elaborates that eventually we're going to need to have a way for a government agency to delve in and do stress testing, and when there's an impending shortage, intervene."

In Brief (cont.)

Myers Squibb's Elequis, Merck & Co.'s Januvia, Novartis' Entresto, Eli Lilly's Jardiance, Astra Zeneca's Farxiga, Novo Nordisk's Fiasp and Amgen's Enbrel. Together the drug's accounted for more than US\$45 billion in Medicare Part D spending from June 2022 to May 2023. The companies will have a chance to submit data and information to CMS and the public by October 2, 2023. Meanwhile, legal challenges regarding the legality of the IRA will continue in court.

- ◆ **CVS Health's** new subsidiary, **Cordavis**, will work directly with manufacturers to commercialize and/or produce biosimilars. The subsidiary will build a portfolio of products aimed at improving access to biosimilars and affordability in the U.S. CVS pointed out that creating more competition should drive down product prices in the U.S. biosimilar market, which is projected to grow to more than US\$100 billion by 2029.

- ◆ A mutation of the SARS-CoV-2 virus has emerged. Named **Pirola**, the new strain has already spread across multiple continents and is causing concern that another "Omicron-like" event of the Pirola variant could cause another major global wave. Pirola is very different from the most current variants as the virus allows itself to attach more easily to receptors in the cells, and has 30 unique spike mutations. COVID infections are increasing internationally with 610,000 new infections per day in the U.S.

(Sources: Company Press Releases, FiercePharma, PharmaVoice, Seeking Alpha and Scrip Intelligence)