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Pharmaceutical Distributors Seek Two-Year Delay in DSCSA Tracking Rules

(Source: An Article by Joanne S. Eglovitch for Regulatory News)

Pharmaceutical distributors are calling for the U.S. Food and Drug Administration (FDA) to grant a two-year delay in enforcing the pharmaceutical tracing provisions in the Drug Supply Chain Security Act (DSCSA), citing that the industry still does not have the necessary track and trace systems in place for compliance. The Healthcare Distribution Alliance (HDA) has proposed a phased implementation approach to minimize potential disruptions to the supply chains and any possible resulting drug shortages.

Scott Mooney, Vice President of Distribution Operations for McKesson Corporation, gave details for HDA's request and why the group is calling for the enforcement delay during a July 27th HDA webinar.

Under the current timeline, DSCSA requires manufacturers, wholesalers, distributors and dispensers to exchange serialized product information starting November 27, 2023. This marks the culmination of the law's implementation.

"There are a lot of changes coming up this November, and industry has been working very hard to get ready for these changes," said Mooney. "But as of today, we are now four months from the "go live" date. This is the date when everything has to happen all at once in the supply chain. The manufacturer has to send serialized data to the distributor and the distributor has to send the serialized data to the dispenser."

Yet while a "great number of suppliers" are making these connections, he said that "for some reason we are not seeing the data flow in quite yet."

According to Mooney, only 35% of manufacturers are currently sending this serialized data to distributors, causing "significant concern" that most products will not be serialized in time to meet the November 27th deadline. This will force products into quarantine, potentially leading to supply chain disruptions.

Due to the situation outlined by Mooney, HDA requested an extension in a June 2nd letter to the FDA. The letter states that instead it favors a phased approach to implementation, and that "simply extending the compliance date without a rational phase-in just moves the date on which the problems and issues become apparent once again."

During the first phase, which would run from November 27, 2023 to November 26, 2024, manufacturers would "ramp up and stabilize their provision of package-level data" to wholesaler distributors with each prescription drug transaction or obtain an exemption from the FDA.

In second phase proposed (from November 27, 2024 to May 26, 2025), manufacturers must comply with all DSCSA requirements and provide package level data to wholesale distributors or obtain an exemption from the FDA. Wholesale

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In Brief...

- **Walgreens Boots Alliance (WBA)** announced the departure of *James Kehoe*, Executive Vice President and Global Chief Financial Officer. Mr. Kehoe will leave WBA in mid-August to pursue an opportunity in the technology sector. *Manmohan Mahajan*, Senior Vice President, Global Controller, has been named Interim Global Chief Financial Officer while the company conducts a search to fill the role with a leader who not only brings deep financial acumen to WBA, but also healthcare experience.
- **Good Neighbor Pharmacy (GNP)**, a national independent pharmacy network offered through **AmerisourceBergen**, today announced that it has been ranked *"First in Customer Satisfaction with Chain Drug Store Pharmacies"* in the **J.D. Power 2023 U.S. Pharmacy Study**[SM]. This is the 12th time that Good Neighbor Pharmacy has earned this recognition in the last 14 years and the network's seventh consecutive win. The J.D. Power 2023 U.S. Pharmacy Study was conducted using a methodology consisting of the evaluation of seven factors that represent distinct parts of the customer experience.
- Pharma manufacturer **Pfizer** and the **U.S. Food and Drug Administration** are working together to ease shortage concerns after a tornado hit Pfizer's North Carolina injectables plant. The site, which plays a critical role in the U.S. healthcare system, will be closed due to the damage which occurred at the warehouse facility, home to raw materials, packaging supplies and finished medicines awaiting release by quality assurance, according to Pfizer. The company said it is working to move products to other nearby sites for storage and to identify sources to replace damaged raw materials and supplies. Pfizer is also informing hospitals that dozens of its products could

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The EU's Step Up Actions to Prevent Shortages of Antibiotics This Winter

(Source: A Press Release from the European Medicines Agency)

The European Commission, the Heads of Medicines Agencies (HMA) and the European Medicines Agency issued recommendations for actions to avoid shortages of key antibiotics used to treat respiratory infections for European patients in the upcoming winter season. These recommendations, which have been developed through the Executive Steering Group on Shortages and Safety of Medicinal Products (MSSG), complement the process of develoeping an EU list of critical medicines. In close cooperation with the EU Member States, the Commission will take operational follow-up actions, including, if necessary, possible joint procurements.

If the demand in the coming winter season is similar to an average level of consumption in previous years, the data

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Pharma Distributors (cont.)...

distributors would "ramp up and stabilize their provision of package level data to dispensers with each prescription drug transaction and would also continue to provide lot-level data to dispensers so that prescription drugs continue to move in the supply chain to patients."

During the third proposed phase, from May 27, 2025 to November 26, 2025, manufacturers and wholesale distributors "must comply with all DSCSA requirements and provide package-level data to their customers (including dispensers) with each prescription drug transaction."

Tish Pahl, an attorney at Olsson Frank Weeda Matz PC, told the group that the phased approach "gives time for trading partners to stabilize the data exchange and to…work on the data accuracy issues that we know are there and to recognize that inaccurate data would otherwise result in product stoppage. The phased approach is designed to keep the good product flowing to patients while also at the same time working on that data quality."

You can find more information on HDA's Traceability Webinar series by visiting their website *https://hda.org/events/2023-traceability-webinar-series/sessions/*.

The EU's Step Up Actions (cont.)...

collected suggests that supply to the EU of oral formulations of key first- and second-line antibiotics for respiratory infections will match demand in the next winter season. EMA and the European Health Emergency Preparedness and Response Authority (HERA) will continue to work with marketing authorization holders to strengthen measures to increase the supply of some intravenous (IV) antibiotics.

To be better prepared for the winter season, the EMA's MSSG agreed on the following recommendations for proactive actions:

1. *Increase the production of key antibiotics.* To avoid shortages in the upcoming autumn and winter season, EMA and HERA are recommending continued engagement with marketing authorization holders to step up measures to increase production. Early action ahead of the autumn and winter season should give manufacturers enough time to ensure they have sufficient manufacturing capacity to meet the demands.

2. *Monitoring of the supply and demand.* EMA and the Commission, together with the Member States will continue to monitor the demand and supplies in cooperation with companies. Given that the measures taken are designed to ensure sufficient supply, all stakeholders are reminded to order medicines as they normally would, with no need to stockpile medicines. Stockpiling medicines can put further strain on supplies and cause or worsen shortages.

3. *Public awareness and prudent use.* Antibiotics should be used prudently to maintain their efficacy and avoid antimicrobial resistance. Medical professionals have key role to play, and antibiotics should only be prescribed to treat bacterial infections. They are not suitable for the treatment of viral infections such as cold and flu, where they are not effective. Citizen awareness-raising initiatives and campaigns are also recommended.

Next Steps

In line with the European Council conclusions of June 2023, the EMA and the Commission through the HERA will continue to closely monitor demand and supply, and interact with marketing authorization holders throughout the rest of the year for early detection of any unexpected shortfalls of supplies and take necessary measures. A dedicated HERA Board meeting with representatives of Member States' Ministries of Health, the Commission and the industry were also held on July 20th to discuss the matter further and agree on possible additional steps.

In Brief (cont.)

face "continued or new supply disruptions in the near-term" due to the storm damage.

- Chinese makers of COVID-19 vaccines are shifting their development focus to multi-valent shots that targets the Omicron XBB.1.5 sublineage, which had become the most prevalent in China by mid-2023. Chengdu-based **WestVac Biopharma** and its partner **West China Medical Center of Sichuan University** plan to investigate *WSK-V101C* (a bivalent recombinant protein vaccine) in a Phase II clinical study. *WSK-V101C* contains spike proteins for the XBB.1.5 sublineage of SARS-CoV-2 and the original strain as a heterologous booster vaccine, according to data from Citeline's Trialtrove database.
- **Biogen** announced that it will acquire **Reata Pharmaceuticals**, the maker of an approved therapy for a rare neurological condition, in a deal worth US$7.3 billion. Reata won its first approval in February 2023 for a drug *(Skyclarys)* that treats Friedreich's ataxia and is the first treatment to be authorized by the **U.S. Food and Drug Administration** for the condition which causes progressive damage to the brain, nervous system and muscles. Separately Biogen also announced a new US$1.0 billion cost savings program that will result in 1,000 job cuts. US$300 million of the savings will be reinvested in new drug launches and R&D.
- **Astellas Pharma** (Japan) has filed a lawsuit against the U.S. government over the *U.S. Inflation Reduction Act (IRA)* becoming the first Japanese pharma company to challenge the constitutionality of its provisions on drug price negotiations under Medicare. This marks the third lawsuit filed by a drug maker, with Astellas treading in the footsteps of **Merck** and **Bristol Myers Squibb**. The **Pharmaceutical Research and Manufacturers of America (PhRMA)** and other industry organizations have also brought forth lawsuits declaring the IRA unconstitutional.
- **Novo Nordisk** has launched its blockbuster weight loss drug *Wegovy* in Germany, its first big European market, with the hope that Germans will pay hundreds of euros out of pocket for a drug that public health insurance plans are thus far barred from covering. The drugs, shown to help patients reduce body weight by as much as 15% when used along with exercise and lifestyle changes, is already available in the United States, and very small markets in Norway and Denmark. Doctors in Germany expect high demand for the weekly injection with many patients prepared to take on the cost which starts at 170 euros (US$190.00) a month.

(Sources: Company Press Releases, Drug Store News, FiercePharma, Pharma Japan, Reuters and Scrip Intelligence)