



Supply Chain Collaboration in Preparing for Drug Tracing Mandate

(Source: an article prepared by Greg Bylo and published by Pharmaceutical Executive)

As the US pharmaceutical industry prepares for the deadlines required by the U.S. Drug Supply Chain Security Act (DSCSA), it is facing new mandates in the “track and trace” space. One industry pilot study has demonstrated the value of a standards-based solution in prescription drug traceability as well as collaboration among trading partners.

Legislation is transforming the pharmaceutical supply chain to improve patient safety by requiring traceability of prescription drugs. Industry members are preparing to go live with the Drug Supply Chain Security Act serialization requirements for 2017, and are beginning to plan for the eventual implementation of the item-level traceability requirement that lies ahead.

Recently Johnson & Johnson Supply Chain (JJSC) and AmerisourceBergen Corporation (ABC) began collaborating on a pilot program testing a standards-based solution to meet the 2017 DSCSA mandate. The pilot results were published in a collaborative case study by GS1 US, the information standards organization, confirming actionable and repeatable results that offer valuable lessons for the entire industry.

With respect to the DSCSA, manufacturers, wholesalers, repackagers and pharmacies have been required to implement lot-level management since 2015. In phase two of DSCSA implementation, starting in November 2017, manufacturers and repackagers must serialize packages of drug products using a product identifier (GS1 Global Trade Item Number® [GTIN®] or FDA National Drug Code [NDC]), serial number, lot number and expiration date, and embed this information in a DataMatrix barcode.

Beginning in November 2019, wholesalers can only accept serialized products and must verify unique product identifiers; pharmacists must meet the same requirements by November 2020. Finally, by November 2023, they will be required to make available information that would allow supply-chain partners to trace the ownership back to the initial manufacturer or repackager.

Meeting the DSCSA compliance deadlines will require significant industry collaboration to implement a common, interoperable solution affording all stakeholders clear vision throughout the supply chain. The industry is already using the GS1 standard of GTINs for product identification to comply with the first phase of DSCSA requirements. Many companies are also leveraging Electronic Product Code Information Services (EPCIS) in preparation for serialization and item-level traceability, which allows trading partners to exchange and synchronize data with products' movement through the supply chain.

ABC, as a major participant operating throughout the supply chain, was eager to lead a unit-level traceability pilot with JJSC that involved serialization of individual products. “This pilot was

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♦ **Zuellig Pharma Malaysia** has been chosen by **Taiho Pharma Singapore Pte. Ltd.** as the sole distributor for *TAS-102* (trifluridine and tipiracil, aka “Lonsurf” in the Japanese, U.S. and European markets.) This prescription oral drug is used in colorectal cancer patients who have failed to respond to traditional chemotherapy. Taiho plans to file new drug application for *TAS-102* in Malaysia in 2017.

♦ U.S. wholesaler **Cardinal Health** has moved a step closer to its acquisition of medical device maker **Medtronic**. The deal, expected to be US\$6 billion, would streamline Medtronic's portfolio following the 2014 acquisition of Covidien. An agreement for the sale could be announced later this month, according to sources, who asked not to be identified since the negotiations are confidential.

♦ **Oriola-KD Corporation** (Finland) and **Kesko Corporation** have signed a joint venture agreement to build a new store chain aimed at comprehensive wellbeing. The first phase will include the building of 100 new store, as well as an online store, and will open in the Fall of 2017. Future expansion plans include pharmaceuticals if current legislation is amended. Both parties will have 50% ownership interest in the new company.

♦ In a recent presentation, **AmerisourceBergen's** Executive Vice President, *Peyton Howell*, emphasized the importance of pharmaceutical distributors in today's market, particularly for small pharmacy chains and independent drug stores. Large wholesalers are vital because of their ability to provide resources that allow community pharmacies to stay competitive, specifically in areas such as specialty pharma. Because of the

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Another “Patent Cliff” in 2019

(Source: an article prepared by Sukaina Virji and Lucie Ellis and published by Scrip)

2019 will be striking for the change the pharmaceutical sector will see to its top-selling drugs chart as a new wave of patent expiries hits. But the one thing that won't change is AbbVie Inc.'s *Humira's* (*adalimumab*) status as the world's best-selling drug – this position looks safe for years to come.

Humira has been in the top 10 of best-selling drugs by global revenue since 2009, when it entered the table in tenth position with sales US\$5.57 billion, climbing steadily to first place in 2012 with sales of US\$9.61 billion when Pfizer Inc.'s *Lipitor* (*atorvastatin*) went over the patent cliff.

In Datamonitor Healthcare's *Big Pharma Outlook 2025* report, lead analyst Ali Al-Bazergan forecasts that *Humira* will remain at the top until 2025, unaffected by the next patent expiry crunch in 2019. He expects *Humira* sales of more than US\$11 billion in 2025.

He also predicts that after 2015, 2019 will be the second

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an opportunity to not only help develop the industry solution, but also provide insights that may help our patients and customers use it and leverage it beyond compliance,” says Matt Sample, senior director for secure supply chain at ABC.

JJSC also seized the opportunity to participate. “Our collaboration with AmerisourceBergen highlights the importance of having a robust, well-implemented serialization platform—one that opens up a host of future supply chain and commercial capabilities, enabling the delivery of a reliable supply of high-quality products and other services to our customers,” says Mike Rose, vice president of supply chain visibility, JJSC.

ABC and JJSC are long-term members of the GS1 Healthcare US Initiative, the voluntary industry group implementing global standards to address patient safety and deliver supply chain efficiencies. The companies realize that using the common language of GS1 standards would make it easier to achieve interoperable traceability in compliance with DSCSA. The trading partners have also been active participants as subject matter experts in the Rx Secure Supply Chain workgroup, which developed the GS1 US Implementation Guideline: Applying GS1 Standards for DSCSA and Traceability.

For the trial, ABC and JJSC decided on a four-week pilot program in a live production setting. Beginning at the point of manufacture, a DataMatrix barcode was applied that contained a serialized GTIN, batch/lot number and expiration date to each lowest saleable unit. These units were packed into cases, and a logical relationship between the “children” and “parent” was established via aggregation. Product cases were then loaded onto a pallet or other logistics units, establishing yet another level of the aggregated hierarchy. At supply-chain points downstream, automated vision systems or manual barcode scanners read the DataMatrix barcode to capture the GTIN, serial number, batch/lot number and product expiration date. GS1 EPCIS was used to record business events associated with the serialized GTIN at various critical points along the supply chain, including commissioning, packing and shipping, followed by receiving and unpacking by the buyer.

Products were moved from manufacturing to distribution as in the past, with the addition of the serialized information. After the wholesaler placed an order and the truck departed, JJSC issued an EPCIS message containing the serialized GTINs and hierarchies contained in the shipment. This provided the ABC distribution center with the details of the specific products that were on their way.

When the shipment arrived, the EPCIS data allowed ABC to confirm receipt—without opening a single case—of every single item that had begun its journey at the manufacturing site. “Using EPCIS message standards provides for a more streamlined process, in that systems are established with similar data file expectations across the supply chain,” explains Jeffery Denton, senior director of ABC’s global secure supply chain. “Most failures experienced valid GLNs during past pilots are avoidable if manufacturers provide DSCSA-compliant EPCIS v1.1 files that include master data for material attributes as well as (global location numbers) and GTINs.” “We have a solid playbook on how to run a pilot with more than just one manufacturer and more than just one product. We have a good repeatable process for future pilots,” says Sample.

Patent Cliff (cont.)...

biggest year for patent expiry, resulting in US\$9.7 billion in sales deducted from company top lines. Key patent expiries include Roche's *Avastin* and *Lucentis*, and J&J's *Velcade*. According to Al-Bazergan, oncology will oust infectious disease in 2019 and account for the largest proportion of big pharma prescription sales by therapy area. However, a number of large product launches in the metabolic market will result in this market superseding infectious disease by 2023, owing to lucrative launches in diabetes and dyslipidemia. He believes the immunology and inflammation therapy area will remain stagnant as major biosimilar threats will be offset by new innovative product launches.

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influence of these wholesalers, biotech manufacturers can see the importance of community pharmacies as a vehicle to get their products to market. Howell said, “We share data that we collected about how well community pharmacies were already performing in caring for hepatitis C patients who were taking older products. That information opened everyone’s eyes as to how much specialized care is appropriate in the community pharmacy setting.” Ms. Howell gave her presentation at the *2017 NACDS Regional Chain Conference*.

- ◆ U.S. wholesaler **McKesson** announced the launch of a new whitepaper in conjunction with its sponsorship of the *CBI Conference*. In the whitepaper, McKesson discusses how brands can combat nonadherence effectively through the integration of behavioral coaching into comprehensive support programs designed around the patient. “The convergence of drug prices and patients’ rising financial obligations increases the likelihood of medication nonadherence by patients. Fortunately, there are effective tools to mitigate the risk of financially motivated primary fill abandonment,” stated *Reagan Tully*, VP of product strategy for **McKesson Specialty Health**. Tully led the conference session “*Formulary Breakthroughs – Moving Beyond Co-Pay Programs to Encourage Collaboration and Improve Patient Outcomes*.” In separate news, **McKesson Canada** will take over all outstanding shares of **Uniprix** (Canada), pending shareholder and Competition Bureau of Canada approval. Uniprix generates annual sales of over US\$1.6 billion and its banners - Uniprix, Uniprix Santé and Uniprix Clinique - extend across 375 pharmacies in Quebec.

- ◆ **Walgreens** and **Prime Therapeutics** have closed their deal to form a combined central specialty pharmacy and mail services company, the companies announced on April 3, 2017. The new company, **AllianceRx Walgreens Prime** will be based in Orlando, Florida and will be led by *Joel Wright*, a 25-year veteran of Walgreens. *Guillermo Sollberger* will serve as Chief Operating Officer, and *Alex Katen* will take on the role of Chief Financial Officer. The AllianceRx Walgreens Prime brand will be rolled out in the coming months throughout the marketplace.

(Chain Drug Review, CNBC, Press Releases, & Drug Store News)