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Pharma Gears Up for Supply Chain Overhaul

by Beth Stackpole

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Side effects from Baxter Healthcare's heparin blood-thinning drug made headlines in January. A month later, the big story involved problems with fentanyl patches. Last year, the spotlight was on GlaxoSmithKline's Avandia diabetes medication, Novartis' Zelnorm irritable bowel syndrome drug, and a multitude of antidepressants. A slew of pharmaceutical makers have faced the pain of orchestrating a product recall due to industry or U.S. Food and Drug Administration concerns about contamination, defects, or linkages to adverse patient reactions.

But beyond the complex tactical and public relations cleanup associated with drug recalls, the recent spate of high-profile events points up a larger, more strategic challenge confronting the pharmaceutical industry: the lack of end-to-end visibility in the supply chain, which leads to the inability to easily track product down to the consumer level. Without the ability to track and trace a specific batch of pills or medicinal liquid to a specific pharmacy or healthcare provider, it's nearly impossible to keep a recall from impacting the entire product line.

"While other industries, like consumer packaged goods and automotive, have been able to use or identify the supply chain as a strategic weapon in their organizations to create joint value with different trading partners, the supply chain has historically been a stepchild within life sciences," says Hussain Mooraj, research director of healthcare and life sciences at AMR Research Inc. "When faced with a recall situation, companies first have to figure out where all their product is, and that's a bear of a job because of the fragmented nature of the healthcare value chain."

This laissez-faire attitude toward supply chain best practices will very likely change soon. Pending regulations in California and Florida are putting pressure on pharmaceutical makers to revamp their supply chain practices as part of a mounting effort to curtail drug counterfeiting. The initiatives, known as electronic pedigree (e-pedigree), require manufacturers to track individual units of pills and other medications from the time they leave the factory floor to when they actually land in an individual patient's prescription package.

The high-profile California e-pedigree program, which had been set to go into effect by January 2009, was extended by two years in March. The extension is intended to give the industry more time to develop track-and-trace standards and to help pharmaceutical makers better absorb the multimillion-dollar investments in hardware and software that will be required to comply with what observers expect will be a nationwide mandate over time.

Addressing e-pedigree compliance and the larger supply chain visibility issue will be no easy task. Cost is a huge factor, with companies looking at investments in additional enterprise software, along with new scanners and other equipment associated with bar codes or radio frequency identification (RFID) technology. The latter technologies are essential for storing and accessing critical details about the product, including where it was manufactured, what its ingredients are, and where the ingredients originated.

Given the global nature of the pharmaceutical supply chain, it's not enough for companies to invest in the technology for their own manufacturing facilities; they also need to ensure that their networks of suppliers make the investment and participate in the process. "It's expensive to put the infrastructure in place to support all this traceability," says Jim Sabogal, vice

president of the global industry business unit for life sciences at SAP AG.

Beyond the cost factor, the existing technology has limitations. On the hardware side, an ongoing debate over the merits of bar code vs. RFID technology is slowing down the process of creating industry track-and-trace standards. On the software side, most enterprise software platforms, including popular ERP packages, lack the ability to serialize and track pharmaceutical product information at the lowest level — for example, an individual pill or bottle instead of tracking at the lot or pallet level.

"When every bottle has a unique serial number with its life history, you're talking about tracking more fine-grained information and doing it at an item level," says Peter Spellman, senior vice president of sales and software-as-a-service at SupplyScape, a provider of e-pedigree applications. "Existing SCM and ERP systems are not designed to work that way."

SAP and other enterprise software providers, including CDC Software/Ross Enterprise, are working with customers to address those capabilities. For example, SAP's Auto-ID Infrastructure uses RFID technology to facilitate the capture of serialized data from devices at local sites while providing business context to turn that data into meaningful business events. SAP's Object Event Repository serves as the centralized system of record for tracking the serialized objects.

In addition to the ERP providers, best-of-breed companies, such as SupplyScape and Acsis Inc., are providing vertical capabilities in the areas of e-pedigree and pharmaceutical-specific track-and-trace functionality.

"If you set up a production run in a manufacturing facility today, you have an eight-hour shift making the same product and you put the same identifier on any of the products that are produced that day," says Stuart McCutcheon, CEO of Acsis, which offers the PharmaTrak serialized distribution application, which works with SAP. "We take serialization to the next level where you have visibility to each pallet of product, each case, each individual item. Pharmaceutical makers don't currently have systems in place with that kind of granularity that would allow them to do that."

Facilitating Drug Recalls

Once those systems are in place, however, companies can expect to see real business value from these compliance-driven initiatives, particularly with regard to their ability to handle product recalls.

Just ask US Oncology, a distributor of oncology drugs, which was one of the first to roll out SupplyScape's e-pedigree software, in mid-2006. When one of its pharmaceutical manufacturers issued a recall that year, US Oncology was able to tap into the e-pedigree database and within minutes knew the exact location of all of the affected shipments so that it could expedite the recall process.

"The whole thing took 15 or 20 minutes instead of weeks or even months," says Rolando de Cardenas, US Oncology's vice president and general manager of Oncology RX.

Sharp Corp., a contract pharmaceutical packager, views its ability to handle serialization and the e-pedigree directives coming out of California and other states as a key competitive differentiator. Therefore, it sees an investment to create track-and-trace capabilities as worthwhile. Sharp is partnering with Systech International, which delivers packaging execution systems for the pharmaceutical industry, and its ERP provider QAD, on its e-pedigree and serialization solution. "We see this as a technology-enabler for our business and an opportunity for us to establish ourselves as a top-tier contract packager," says Rick Siebert, Sharp's vice president of project management and business development.

Yet, Siebert doesn't downplay the money and effort it will take to gear up Sharp's technology infrastructure. "This means we have to revitalize our entire manufacturing process to have the hardware capabilities and software to individually mark the lowest unit of sale," he says, citing new 2D bar coders, RFID tags and readers, printers, and cameras among the investments Sharp

will have to make to equip its 50 packaging suites. "To equip one packaging suite to do e-pedigree and serialization is about a \$400,000 to \$500,000 investment, which is very significant for a company our size," he says.

In the end, however, it's the consumer who should benefit from the e-pedigree and serialization efforts and the pharmaceutical industry's focus on supply chain best practices. "To be able to have supply chain visibility to trace a product down to a consumer level ultimately lets a company react [to a recall] within hours," says Phil Friedman, vice president, consumer goods, and the head of QAD's life sciences vertical division. "What you want to be able to do is be super-responsive and protect the brand at the same time."

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